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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 001-38319

QUANTERIX CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**20-8957988**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
900 Middlesex Turnpike, Billerica, MA	**01821**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(617) 301-9400**

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value per share	QTRX	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☐
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2022), the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the last reported sales price for the registrant's common stock, par value $0.001 per share, on The Nasdaq Global Market on such date, was approximately $558 million.

As of February 28, 2023, the registrant had 37,248,605 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2023 Annual Meeting of Stockholders, which the registrant intends to file with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements (within the meaning of the U.S. Private Securities Litigation Reform Act of 1995) that involve risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, forward-looking statements can be identified by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the implementation of our business model and strategic plans for our business, products and services, especially following the restructuring and strategic realignment we commenced in the third quarter of 2022;
- the potential size of the markets and fields addressable by our Simoa technology platforms;
- the commercialization and adoption of our existing products and services and the success of our new product and service offerings;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and our needs for additional financing;
- the ability of our Simoa technology's sensitivity to improve existing diagnostics and to enable the development of new diagnostic tests and tools;
- the potential of our Simoa technology in the field of screening/diagnostic tests linked to therapeutic drugs and adoption by healthcare professionals;
- the impact of our Simoa technology on proteomic research;
- our ability to implement and realize the intended benefits of our restructuring and assay improvement program;
- our ability to retain and expand our customer base and achieve sufficient market acceptance of our products;
- the ability of our contract manufacturers to reliably and consistently manufacture and supply our Simoa HD-X instrument and our Simoa SR-X instrument;
- the usefulness of the data generated by our Simoa technology in the life science research and diagnostics fields; and
- our financial performance.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those further described in "Part I, Item 1A, Risk Factors" and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report on Form 10-K may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Readers should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report on Form 10-K to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

Readers should read this Annual Report on Form 10-K and the documents that we reference herein and have filed with the Securities and Exchange Commission (SEC) as exhibits to this Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the markets in which we operate and intend to operate that are subject to a high degree of uncertainty. We caution not to give undue weight to such projections, assumptions and estimates.

Service Marks, Trademarks and Trade Names

Unless the context otherwise requires, the terms “Quanterix,” the “Company,” “we,” “us” and “our” in this Annual Report on Form 10-K refer to Quanterix Corporation and its subsidiaries. “Quanterix,” “Simoa,” “Simoa HD-X,” “Simoa HD-1,” “SR-X,” “SP-X”, “HD-X”, “NF-light” and our logo are our trademarks. All other service marks, trademarks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

PART I

Item 1. BUSINESS

Overview

We are a life sciences company that has developed next-generation, ultra-sensitive digital immunoassay platforms that advance life sciences research and diagnostics. Our platforms are based on our proprietary digital "Simoa" detection technology. Our Simoa bead-based and planar array platforms enable customers to reliably detect protein biomarkers in extremely low concentrations in blood, serum and other fluids that, in many cases, are undetectable using conventional, analog immunoassay technologies, and also allow researchers to define and validate the function of novel protein biomarkers that are only present in very low concentrations. These capabilities provide our customers with insight into the role of protein biomarkers in human health that has not been possible with other existing technologies and enable researchers to unlock unique insights into the continuum between health and disease. We believe this greater insight will enable the development of novel therapies and diagnostics and facilitate a paradigm shift in healthcare from an emphasis on treatment to a focus on earlier detection, monitoring, prognosis and, ultimately, prevention.

We believe that our Simoa platforms are among the most sensitive commercially available multiplex protein detection platforms and significantly advance enzyme-linked immunosorbent assay (ELISA) technology, which has been the industry standard for protein detection for over 45 years. Proteins are complex molecules that are required for the structure, function and regulation of the body's tissues and organs, and are the functional units that carry out specific tasks in every cell. The human body contains approximately 20,000 genes, each of which can produce multiple proteins. It is estimated that these 20,000 genes can produce over 100,000 different proteins, of which 10,000 – 15,000 are estimated to be secreted in blood. Proteins are considered to be the best analytes – providing the most real-time picture of disease, and researchers and clinicians rely extensively on protein biomarkers for use as research and clinical tools. However, normal physiological levels of many proteins are not detectable in easily accessible blood samples using conventional, analog immunoassay technologies, and many of these technologies can only detect proteins once they have reached levels that reflect more advanced disease or injury. For many other low abundance proteins, these technologies cannot detect proteins even at disease- or injury-elevated levels. We believe that Simoa's sensitivity offers a new way to monitor healthy individuals and detect proteins associated with nascent disease or injury early in the disease cascade, which holds the key to intervention before disease or injury has advanced to the point where more significant clinical signs and symptoms have appeared.

Our Simoa platforms have achieved significant scientific validation and commercial adoption. Simoa technology has been cited in over 2,000 scientific publications in areas of high unmet medical need and research interest such as neurology, oncology, cardiology, infectious disease and inflammation. Our growing customer base is comprised of over 1,300 customers across our end markets.

Restructuring and Strategic Re-Alignment

Following a strategic review and assessment of our operations and cost structure, in the third quarter of 2022 we announced a plan of restructuring and strategic re-alignment (the Restructuring Plan). As part of this plan, we began an assay redevelopment program with the ultimate objective of improving our ability to manufacture and deliver high-quality assays at scale. The Restructuring Plan aligns our investments to best serve the needs of customers, focuses innovation efforts on key platforms and provides the foundation for our entry into translational pharma and clinical markets, which we believe will be required to access new growth categories. The Restructuring Plan included the elimination of 119 positions and other cost-saving measures. The workforce reduction was substantially completed by the end of the third quarter of 2022.

Our Products and Services

Our proprietary Simoa technology is based on traditional ELISA technology, which has been the most widely used method of detection of proteins for over 45 years. Given our target customers' familiarity with the core ELISA

technology, we believe this offers us a significant competitive advantage. Our Simoa bead-based platform differs, however, from conventional ELISA in its ability to trap single molecules in tiny microwells, 40 trillionths of a milliliter, that are 2.5 billion times smaller than traditional ELISA wells, allowing for an analysis and digital readout of each individual molecule, which is not possible with conventional ELISA technology. Leveraging our proprietary sophisticated Simoa image analysis and data analysis algorithms, we have also developed a planar array technology to provide sensitivity similar to that found in our Simoa bead-based platform. We currently offer the following three Simoa instruments, which we believe are among the most sensitive multiplex protein detection platforms commercially available today:

- **HD-X:** We commercially launched our HD-X instrument in the second half of 2019. The HD-X is an upgraded version of the Simoa HD-1 (our first Simoa instrument, which was launched in January 2014) that was designed to deliver significant productivity and operational efficiency improvements, as well as greater user flexibility. The HD-X is based on our bead-based technology, and assays run on the HD-X are fully automated.

- **SR-X:** We commercially launched our SR-X instrument in December 2017. The SR-X utilizes the same Simoa bead-based technology and assay kits as the HD-X in a compact benchtop form with a lower price point, more flexible assay preparation, and a wider range of potential applications.

- **SP-X:** We commercially launched our SP-X instrument in April 2019. The SP-X is based on our Simoa planar array technology, which allows for significantly greater multiplexing capabilities, and is, we believe, ideal for oncology and immunology applications.

The current menu of approximately 36 analyte-specific single-plex and multi-plex bead-based assay kits includes assays for biomarkers in the areas of neurology, infectious disease, immunology, oncology and cardiology for both human and mouse samples. The current menu of Simoa planar array reagent kits includes approximately 115 biomarkers ranging from 1-10 analytes per assay in the areas of immunology and oncology research. In addition, both the bead-based platform and the planar array platform allow ease and flexibility in assay design, enabling our customers to develop their own in-house assays, called “homebrew” assays.

We also provide contract research services for customers through our CLIA-certified Accelerator Laboratory. The Accelerator Laboratory provides customers with access to Simoa technology and supports multiple projects and services, including sample testing, homebrew assay development and custom assay development. To date, we have completed over 1,900 projects for more than 400 customers from all over the world using our Simoa platforms. We have recently begun offering laboratory developed tests (LDTs) through the Accelerator Laboratory. LDTs are diagnostic tests that are developed, validated and performed by a single laboratory. In July 2022, we launched an LDT to quantitatively measure phospho-Tau 181 (pTau-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.

In August 2019, we acquired UmanDiagnostics AB (Uman), a company located in Umeå, Sweden, that commercializes proprietary NfL antibodies and NfL ELISA kits. Uman’s NfL antibodies are widely recognized by researchers and biopharmaceutical and diagnostics companies world-wide as the premier solution for the detection of NfL to advance the development of therapeutics and diagnostics for certain neurodegenerative conditions. Since we commercially launched the first assay that could reliably measure NfL in blood using Uman’s antibodies and our Simoa technology in 2017, NfL has seen dramatic growth as a neurological biomarker. The Uman acquisition secured the NfL antibody supply critical to our industry-leading ultrasensitive Simoa NfL assays and services and provides us with additional revenue via the sale of the NfL antibodies and NfL ELISA kits.

We sell our instruments, consumables and services to the life science, pharmaceutical and diagnostics industries through a direct sales force and support organizations in North America and Europe and through distributors or sales agents in select markets. In addition, we sell Uman’s NfL antibodies and NfL ELISA kits directly and in conjunction with a distributor worldwide. We have an extensive base of customers in world class academic and governmental

research institutions, as well as pharmaceutical, biotechnology and contract research companies, using our technology to gather information to better understand human health.

Our Competitive Strengths

We believe that our competitive strengths include the following:

- ***Proprietary ultra-sensitive Simoa digital immunoassay technology platforms.*** We believe our Simoa platforms are among the most sensitive, commercially available protein detection platforms, and can detect and quantify proteins of clinical interest that are undetectable using conventional, analog immunoassay technologies. This sensitivity allows researchers to measure critical protein biomarkers at earlier stages in the progression of a disease or injury, which we believe will enable the development of novel therapies and diagnostics and facilitate a paradigm shift in healthcare from an emphasis on treatment to a focus on earlier detection, monitoring, prognosis and, ultimately, prevention. The sensitivity of our Simoa technology also allows researchers to gather biomarker information from smaller samples that can be collected less invasively than samples required by other assay technologies.

- ***Technology platforms that leverage and improve upon industry standard ELISA technology.*** Simoa uses the basic principles of conventional bead-based ELISA immunoassay technology, which has been the most widely used method of detection of proteins for over 45 years. Adding digital capability to this industry standard platform has resulted in expanded capabilities and improved performance. Given our target customers' familiarity with the core ELISA technology, our Simoa platforms are easily integrated with existing customer workflows including data analysis.

- ***Deep and expanding scientific validation and customer base.*** Our Simoa technology has been cited in over 2,000 publications to date, including *JAMA Neurology* and *Nature*, and is becoming a vital tool in cutting edge life sciences research. We have established relationships with key opinion leaders, and our growing base of over 1,300 customers includes some of the world's leading academic and government research institutions and many of the world's largest biopharmaceutical companies.

- ***Leading position in market solidified by robust customization capabilities, assay design flexibility and automation of our HD-X instrument.*** Our technical capabilities and expertise allow our customers to design high-quality, customized assays utilizing our Simoa platforms. The needs of our customers vary widely, and the flexibility of the Simoa detection technology utilized across both our bead-based and planar array platforms allows us to provide innovative, low cost solutions for customers in multiple markets across various applications. In addition, the HD-X instrument provides fully automated analysis from sample introduction to analytical results, and our proprietary approach to ELISA digitization enables rapid digital data acquisition and assay results. This automation and speed provides customers high research and development productivity through greater throughput and lab efficiency.

- ***Business model that leverages growing installed base of instruments.*** Our installed instrument base increased to 876 instruments as of December 31, 2022. The integration of our technology into our customers' projects provides ongoing sales of assays and consumables, and as we continue to grow our installed instrument base, optimize workflows and expand our assay menu, we expect to increase our revenues derived from consumables.

- ***Our highly experienced senior management team.*** We are led by a dedicated and highly experienced senior management team with significant industry experience.

Our Strategy

Our goal is to enable new research into biomarkers to allow greater insight into their role in human health in ways that have not been possible with any other current research and diagnostic technology. We believe this greater

insight will facilitate a paradigm shift in healthcare from an emphasis on treatment to a focus on earlier detection, monitoring, prognosis and, ultimately, prevention.

Our strategy to achieve this includes:

- ***Focus on the highly attractive, expanding market for protein detection and analysis.*** Our focus on the detection of protein biomarkers is driven by a growing understanding of the essential role and impact of proteins on human health. While genomic research provides valuable information about the role of genes in health and disease, proteins are both more prevalent than nucleic acids and, we believe, more relevant to a precise understanding of the nuanced continuum between health and disease. Protein measurement goes beyond genetic predisposition, indicating the impact of a range of influences on health, including environmental factors and lifestyle, providing deeper and more relevant insight into what is happening in a person's body in real time. Our technology provides a unique bridge between understanding the human genotype and phenotype, which we believe addresses a large unmet need in life science research, translational medicine and diagnostic and drug development.

- ***Continue to drive adoption of our Simoa technology in the life science research/pharma market.*** We believe our Simoa technology has the potential to significantly expand the life science research market because of its unrivaled sensitivity, in particular by enabling researchers to perform studies on protein biomarkers that they were previously unable to perform. We also believe that our Simoa technology is uniquely positioned for use by pharmaceutical companies in drug trials as biomarkers are being increasingly used as an adjunct to help increase the potential of regulatory approval. We have focused initially on these markets because we believe there is reduced regulatory and reimbursement risk for us in these markets.

- ***Expand our presence in the diagnostics market.*** We believe Simoa technology has the capability to enable the development of a new category of less-invasive diagnostic tests and tools based on blood, serum, saliva and other fluids that could replace current invasive, expensive and inconvenient diagnostic methods, including spinal tap, diagnostic imaging and biopsy. In July 2022, we launched an LDT to quantitatively measure pTau-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.

- ***Leverage the growing importance of neurological biomarkers to advance the development of therapeutics and diagnostics for neurodegenerative conditions.*** The importance of neurological biomarkers, such as NfL, pTau-181 and pTau-217, has increased significantly in recent years, and our ultra-sensitive Simoa platforms have allowed research of neurological disorders, previously limited primarily to cerebrospinal fluid (CSF), to expand significantly. Neuro biomarkers, such as NfL, pTau-217 and pTau-181, have shown increasing relevance in neurological research and drug development. In 2021, Eli Lilly and Company (Lilly) presented new data from its Phase 2 TRAILBLAZER-ALZ study of its Alzheimer's disease drug candidate donanemab, which employed our ultra-sensitive Simoa technology to measure plasma pTau-217, using antibodies developed by Lilly. Lilly reported a significant reduction in blood levels of phosphorylated Tau protein after treatment with donanemab, and that a reduction in plasma pTau-217 levels correlated with the slowing of cognitive decline. In November 2022, Eisai Co., Ltd. and Biogen Corporation presented results from the Phase 3 clinical trial (Clarity AD) of lecanemab, an investigational drug aimed at slowing the progression of cognitive decline caused by Alzheimer's disease. Target engagement and activity of the drug in downstream processes was explored with a panel of fluid biomarkers, including plasma pTau-181, glial fibrillary acidic protein (GFAP) and NfL using Quanterix's ultrasensitive Simoa assay kits We believe that the use of biomarkers in clinical trials for neurological conditions is becoming increasingly important. With Simoa's sensitivity and its ability to detect many neurological biomarkers in blood and plasma that cannot be detected by many other technologies, we believe that we are uniquely positioned to take advantage of this opportunity.

- ***Expand further into indications beyond neurology.*** Because the blood-brain barrier severely restricts the movement of proteins and other substances into blood circulation, we believe that our ultra-sensitive Simoa platforms are particularly well suited for neurology indications. We also believe, however, that the ability of our Simoa technology to detect and quantify low abundance proteins is a distinct advantage in detecting disease earlier in other indications, including oncology, cardiology, infectious disease and inflammation, and there are nearly 700 scientific publications using our Simoa technologies in these non-neurology indications. We intend to expand further into these markets, with a particular focus on oncology.

Industry Background

We intend to pursue the application of our Simoa technology to the life science research/pharma and diagnostics markets. Our initial commercial strategy has targeted the large and growing life science research/pharma markets, and we believe that the diagnostics market represents a significant commercial opportunity for Simoa. Based on industry estimates, we believe the aggregate commercial opportunity across these markets is approximately $75 billion.

Proteins are versatile macromolecules and serve critical functions in nearly all biological processes. They are complex molecules that organisms require for the structure, function and regulation of the body's tissues and organs. For example, proteins provide immune protection, generate movement, transmit nerve impulses and control cell growth and differentiation. Understanding an organism's proteome, the complete set of proteins and their expression levels, can provide a powerful and unique window into its health, a window that other types of research, such as genomics, cannot provide.

The human body contains approximately 20,000 genes. One of the core functions of genes, which are comprised of DNA, is to regulate protein production—which ones are produced, the volume of each, and for how long—influenced by both biological and environmental factors. These 20,000 genes help govern the expression of over 100,000 proteins, of which 10,000 – 15,000 are estimated to be secreted in blood, the majority of which cannot be consistently detected in healthy individuals using conventional immunoassay technologies. Accordingly, the study of much of the proteome has not been practical given the limited level of sensitivity of existing technologies.

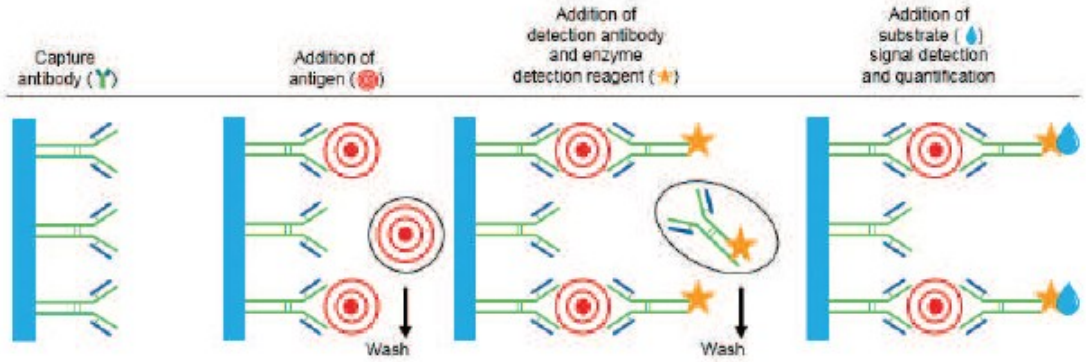
Much like the sequencing of the human genome with the Human Genome Project and the development of both polymerase chain reaction (PCR) and next generation sequencing technologies to detect nucleic acids, both of which accelerated biomedical genomic research, we believe the ability to study more of the proteome enabled by our more sensitive protein detection technology will have a profound impact on proteomic research. With our ultra-sensitive Simoa detection technology, researchers can assess the symptoms of disease or injury and compare them to the presence and levels of relevant proteins that are not detectable using conventional technologies, leading to a better understanding of how proteins individually and/or collectively impact and influence important biological processes and the health and well-being of individuals. We believe this research into understanding the individual characteristics and functioning of proteins will be central to earlier detection, monitoring, prognosis and, ultimately, prevention by providing researchers with the ability to assess the impact of particular proteins on the progress of disease and injury from the time of early onset of symptoms.

Existing Technologies and Their Limitations

Protein Analysis

ELISA has been the most widely used method of sensitive detection of proteins for over 45 years. In simple terms, in ELISA, an unknown amount of antigen (e.g., protein, peptide, antibody, hormone) is affixed to a solid surface, usually a polystyrene multiwell plate, either directly, or indirectly through use of a conjugated secondary or "capture" antibody (sandwich ELISA). A specific "detection" antibody is applied over the surface to bind to the antigen. This detection antibody is linked to an enzyme, and in the final step, a substance called an enzyme substrate is added, and the

enzyme converts to colored or fluorescent product molecules, which are detected by a plate reader. Sandwich ELISA is depicted in the graphic below:



Aside from ELISA, there are other technologies available for protein analysis today, such as Western blotting, mass spectrometry, chromatography, surface plasmon resonance, Raman-enhanced signal detection, immuno-PCR, and biobarcode assay. However, the proteins detectable by these conventional, analog immunoassay technologies represent a mere fraction of the 10,000-15,000 secreted proteins in circulation in human blood. While a number of techniques have been used to attempt to increase sensitivity of detection, we believe all of these approaches have limitations, including:

- dilution of colored or fluorescent product molecules due to large volume of liquid in traditional-sized wells, limiting sensitivity;
- narrow dynamic range (i.e., the range of concentration of proteins being detected), that may require sample dilution, diluting molecules and increasing sample volume requiring additional enzymes to reach detection limit;
- low detection limit of readers restricts sensitivity and ability to detect low abundance proteins, particularly when proteins are at normal physiological levels; and
- limited success in increasing sensitivity of detection due to procedural complexity and length.

Genomic Analysis

Over the past few decades, scientists have developed a variety of genomic analysis methods to measure an increasing number of genomic biomarkers aimed at detecting diseases. The most widely used method for genetic testing is PCR, which involves amplifying, or generating billions of copies of, the DNA sequence in question and then detecting the DNA with the use of fluorescent dyes. PCR is used to amplify the nucleic acid through the use of enzymes and repeated heating and cooling cycles, with fluorescent dyes incorporated during each amplification cycle. The expression of the nucleic acid is then inferred based on the number of amplification cycles required for the target to become detectable. PCR is sometimes referred to as an analog technology because the number of cycles of amplification, rather than a direct measure, is used to infer the level of gene expression. The wide availability of PCR chemistry makes it a popular approach for measuring the expression of nucleic acids, but the use of enzymes in numerous cycles of amplification can introduce distortion and bias into the data, potentially compromising the reliability of results, particularly at low concentrations.

Our Simoa Technology

Our Simoa technology significantly advances conventional sandwich ELISA technology and is capable of unprecedented protein detection sensitivity.

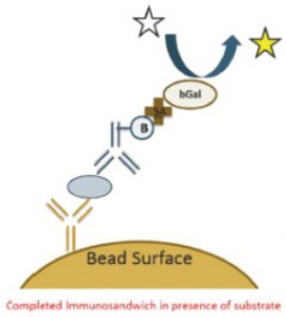
Simoa Bead-Based Technology

Simoa bead-based digital immunoassays utilize the basic principles of conventional bead-based sandwich ELISA and require two antibodies: one for capture, which is applied to the beads, and one for detection. Unlike ELISA, which runs the enzyme-substrate reaction on all molecules in one well, Simoa bead-based reactions are run on individual molecules in tiny microwells, 40 trillionths of a milliliter that are 2.5 billion times smaller than traditional ELISA wells. Traditional ELISA analog measurements increase in intensity only as the concentration of a sample increases. Simoa bead-based digital technology measurements, however, are independent of sample concentration intensity and rely on a binary signal/no signal readout, enabling detection sensitivity that was not previously possible.

Our Simoa bead-based platform is highly flexible, designed to enable practical high-sensitivity protein analysis for academic researchers looking at novel proteins all the way through to high throughput analysis performed by large biopharmaceutical organizations. The following chart describes the steps through which our Simoa bead-based technology detects proteins:

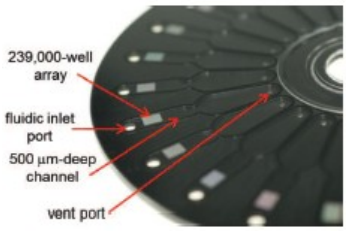
Simoa Bead-Based Analytic Process

Sample Preparation of ELISA Sandwich



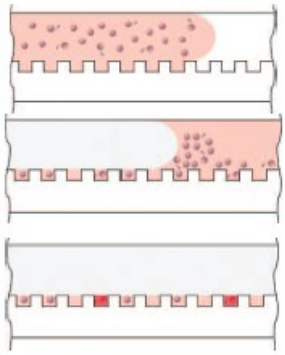
Simoa bead-based technology uses beads coated with capture antibodies that bind specifically to the protein being measured. After an enzyme-linked detection antibody binds to the protein, the enzyme substrate is added (as depicted by the white star in the graphic on the left). The enzyme associated with the enzyme-linked detection antibody then reacts with the enzyme substrate causing the enzyme substrate to become fluorescent (as depicted by the change in color of the star in the graphic).

Injection of Bead/Substrate Solution into Simoa Disk



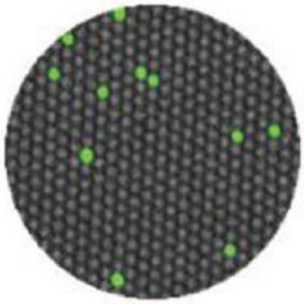
This mixture of beads and enzyme substrate is then injected into our proprietary Simoa disk, which contains 24 arrays of microwells arranged radially. Each 3 × 4 millimeter array contains approximately 239,000 microwells, each of which is large enough to accommodate only a single bead.

Bead/Substrate Solution Settles and Wells are Sealed



The bead/substrate solution is drawn across the array and the beads settle by gravity onto the surface of the array, and a fraction of them fall into the microwells. The remainder lie on the surface, and oil is introduced into the channel to displace the substrate solution and excess beads, and to seal the wells.

Simoa Readout



The entire array is then imaged using ultrasensitive digital imaging, and the sealed wells that contain beads associated with captured and enzyme labeled protein molecules are identified.

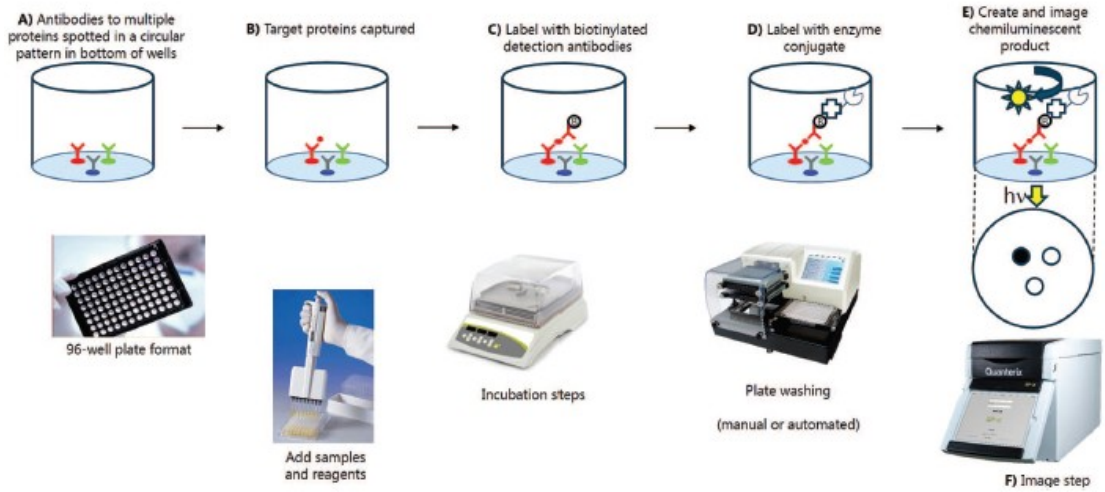
The ability to multiplex, or simultaneously measure multiple proteins (or other biomarkers) in a single assay, can be important to researchers to maximize the biological information from a sample and to develop more specific diagnostic tests. However, one of the main issues with multiplexing can be the loss of sensitivity. Our Simoa platforms maintain single plex precision, while competitive platforms lose sensitivity when multiplexing is used. Multiplexing is achieved with our Simoa bead-based technology by using beads labeled with different fluorescent dyes specific to the biomarker being analyzed. After the assay is run, the array of microwells is imaged across the wavelengths of the different labeled beads. The results are measured for each protein captured by each of the different beads. In 2017, we commercially launched a Simoa neurology 4-plex assay (NfL, tau, GFAP and UCH-L1) for the study of neurodegenerative conditions and traumatic brain injury. In 2020, we introduced a Simoa 4-plex assay (Aβ40, Aβ42, GFAP, NfL) designed to measure key biomarkers of Alzheimer's disease and related disorders. Whereas other assay technologies require CSF to detect all four of these markers, or are limited to only single-plex measurement in serum and plasma, due to Simoa's sensitivity, we believe this is the only assay that can detect all of these biomarkers directly from serum and plasma samples in a multiplex assay format. This is a significant advantage in terms of ease of use, patient comfort, speed and cost-effectiveness. While we have demonstrated the ability to identify and differentiate up to 35 different bead subpopulations on the HD-X, which is a prerequisite to our ability to develop assays with the capacity to detect an equivalent number of proteins in a single sample, we believe that the ability to multiplex at high levels and maintain single-plex sensitivity and precision is currently limited using bead-based technology due to constraints in the number of bead-containing wells for each plex that are imaged on the Simoa disk. However, our bead-based assay technology was used by researchers to demonstrate a novel workflow to expand multiplexing through a process of sequential incubation steps. We plan to explore this and other methods to potentially expand the multiplexing capabilities of our Simoa assay technology to enable plexing of 10-20 plex over the next several years.

Simoa Planar Array Technology

Simoa planar array immunoassays utilize the basic principles of conventional microplate-based sandwich ELISA and require two antibodies: one for capture, which is applied to the beads, and one for detection. Unlike ELISA, which runs the enzyme-substrate reaction on all molecules coating the entire bottom surface in one well, Simoa planar array reactions are run on spatially segregated micro-spots within the bottom of microtiter plate wells that concentrate the signal to a surface area 1,000 times smaller than a traditional ELISA. The small spot size and spatial segregation of each spot enables multiplexing up to 12 different assays within a single sample well.

Our Simoa planar array platform is highly flexible, designed to enable practical high-sensitivity multiplex protein analysis for drug discovery and development applications as well as translational biomarker research. The following chart describes the steps through which our Simoa planar array technology detects proteins:

Simoa Planar Array Analytic Process



A) Analyte-specific capture antibodies are printed in microspots (100 microns) in a circular pattern in the bottom of a 96-well microtiter plate. Each microspot contains capture antibodies that are specific for different analytes. Up to 12 spatially resolved microspots can be printed in each well.

B) Samples are added to the plate and incubated with a benchtop plate shaker to bind the target analyte molecules to the microspots. Unbound molecules are removed by washing the plate with a benchtop plate washer or manual wash manifold.

C) A mixture of biotinylated detection antibodies are added to the plate to form the antibody sandwich. Excess detection antibodies are removed by washing.

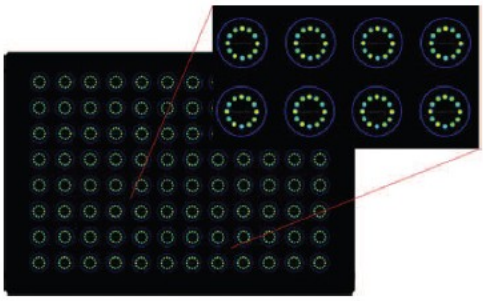
D) Streptavidin-HRP (horseradish peroxidase enzyme) conjugated is added to the plate to bind to the biotin groups forming the complete immunocomplex followed by a washing step.

E) A high-sensitivity chemiluminescent substate reagent is added to each well. The enzyme associated with the enzyme linked detection antibody then reacts with the enzyme substrate causing the enzyme substrate to emit light.

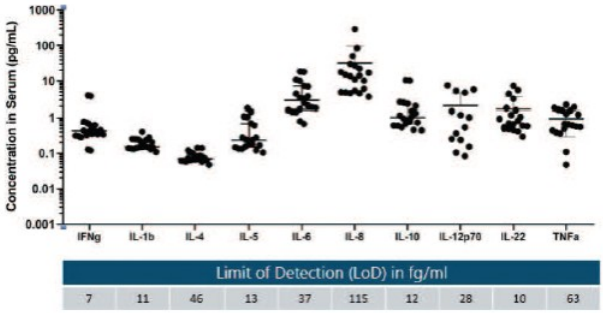
F) The plate is placed into the Quanterix SP-X imaging system. A scientific-grade CCD camera images the entire plate and all micro-spots simultaneously. The low background of the plate surface and the high-sensitivity of the camera enable detection of very low levels of light with a high dynamic range. The imaging software utilizes algorithms to optimize exposure time

and combine multiple images in the image analysis. Protein concentrations are determined by comparing the intensity of microspots to known analytical standards.

Below is an image of a 96-well Simoa planar array plate containing 12 microspots. Each microspot represents a different analyte measured in each sample well.



We believe the Simoa planar array technology is well-suited for researchers who value the ability to measure critical immunomodulatory biomarkers in patient serum and plasma with ultra-sensitive detection in a multiplex assay format. The figure below demonstrates 10-plex detection of key cytokines in human serum from normal healthy donors with corresponding assay Limit of Detection (LoD) listed in femtogram per ml.



Nucleic Acid Testing

Our initial focus has been on the use of Simoa technology to detect protein biomarkers. However, our Simoa bead-based technology has also been used to detect nucleic acids in biological samples. While methods for measuring nucleic acid molecules have advanced substantially, currently available techniques still have drawbacks. For example, PCR is a sensitive method that is widely used for measuring gene expression. However, PCR carries the potential for data distortion and bias from the repeated addition of enzymes, and heating and cooling cycles needed to amplify a copy of the nucleic acid being measured. In nucleic acid analysis, we believe that Simoa has the potential to provide the same sensitivity as traditional PCR-based assays with the following benefits:

- no need for amplification of the targeted nucleic acid, which can result in amplification distortion and bias;
- reduced cross-contamination because of direct detection of single molecules vs. the detection of a large number of copies of the nucleic acid; and
- the ability to detect some samples without requiring purification of the nucleic acid, such as in environmental water or serum samples.

For detection of nucleic acids with our Simoa bead-based technology, instead of coating the beads with capture antibodies as is done for detecting proteins, the beads are coated with nucleic acid capture probes. Samples with the target nucleic acid molecules are then added and are captured by the beads. Nucleic acid detection probes (instead of detection antibodies) are then added and attach to the target nucleic acid molecules which are then labeled using an enzyme substrate that is detected and counted using the Simoa disk and instrument.

Our Market Opportunities

Our commercial strategy is to pursue the application of our Simoa technology to the life science research/pharma and diagnostics markets.

Life Science Research/Pharma Markets

We have initially targeted the large and growing life science research and pharma markets. We have chosen these markets to target initially because of the reduced regulatory and reimbursement risk. We believe our Simoa platforms are well-positioned to capture a significant share of these markets because of superior sensitivity, automated workflow capabilities, multiplexing and the ability to work with a broader range of sample types.

Proteomics, the study of the proteins produced by the body, is important to understanding disease, and researchers study proteins to understand the biological basis for disease and how to improve diagnosis and treatment. The proteins detectable by conventional, analog immunoassay technologies represent a mere fraction of the proteins that can be detected by Simoa technology, and we believe that Simoa can inspire a new level of research into these previously undetectable proteins and their role in disease. By substantially lowering the limit of detection of protein biomarkers, our Simoa platforms hold significant potential to expand research into the diseases associated with the thousands of proteins that were previously undetectable, as well as into earlier detection of the proteins currently detectable by other technologies only after they have reached levels that reflect more advanced disease or injury. Simoa technology provides researchers the ability to see the nuanced continuum of health to disease more efficiently and effectively than any other technology commercially available today, offering the potential for the first time to better understand the onset of disease cascades and catalyzing a new era of medical and life science research, drug discovery and disease prevention.

In addition, as pharmaceutical companies look for ways to more efficiently and effectively develop and obtain regulatory approval for drugs, use of biomarkers in clinical drug trials is becoming more prevalent. Biomarkers are increasingly being used as clinical endpoints in clinical trials. Drug developers can also use diagnostics to stratify patients and select only those patients for whom a drug is expected to be most effective and safe. Using Simoa's unprecedented sensitivity to measure previously undetectable levels of target biomarkers prior to and following administration of a drug, drug developers can non-invasively and objectively determine whether a drug candidate is having a desired impact on the target biomarker. In addition, researchers can also use Simoa to monitor a drug candidate's unwanted effect on "off-target" biomarkers and predict side effects, addressing the significant issue of drug toxicity, which is a leading cause of death in the United States. With Simoa's sensitivity and its ability to detect many biomarkers in blood, plasma and other non-invasive samples that cannot be detected by many other technologies, we believe that we are uniquely positioned to take advantage of this opportunity.

Based on industry estimates, we believe the proteomics life science research/pharma total addressable market is approximately $20 billion.

Diagnostics

The diagnostic market represents a significant commercial opportunity for our Simoa technology as well. We believe existing biomarker diagnostics can be improved by Simoa's sensitivity to enable earlier detection of diseases and injuries, and that new diagnostics may be developed using protein biomarkers that are not detectable using conventional, analog immunoassay technologies but are detectable using Simoa technology. We also believe that the ultra-sensitive protein detection provided by our Simoa platforms can enable the development of a new category of non-invasive

diagnostic tests and tools based on blood, serum and other fluids that have the potential to replace current more invasive, expensive and inconvenient diagnostic methods, including spinal tap, diagnostic imaging and biopsy.

Simoa technology also has significant potential in the emerging field of screening and diagnostics. A screen, aid to diagnostic, or diagnostic test is a biomarker test that is specifically linked to a therapeutic drug that can help predict how a patient will respond to the drug. Drug developers can use these tests to stratify patients and select only those patients for whom a drug is expected to be most effective and safe. Such tests have demonstrated the ability to both improve the probability of approval and accelerate approval of new drugs. Not only could Simoa be used to develop tests to stratify patients in clinical trials and for treatment, but Simoa's sensitivity can also enable the development of tests based on protein biomarkers that can actively and regularly monitor whether an approved drug is having the desired biological effect. This would quickly and efficiently enable doctors to adjust the course of treatment as appropriate by increasing or decreasing dosages or even switching therapies.

The ability of our Simoa platforms to detect and quantify normal physiological levels of low abundance proteins that are undetectable using conventional, analog immunoassay technologies could enable our technology to be used to monitor protein biomarker levels of seemingly healthy, asymptomatic people, and potentially to signal and provide earlier detection of the onset of disease. This has the potential to facilitate a paradigm shift in healthcare, from an emphasis on treatment to a focus on earlier detection, monitoring, prognosis and, ultimately, prevention.

We recently launched our first diagnostic LDTs in our Accelerator Laboratory. In July 2022, we launched an LDT to quantitatively measure pTau-181 in plasma as an aid in diagnostic evaluation of Alzheimer's disease, and in January 2023, we launched an LDT to quantitatively measure NfL in serum as an aid in the evaluation of individuals for possible neurodegenerative conditions or other causes of neuronal or central nervous system damage.

There has also been significant interest from third parties to use our technology to develop applications for the diagnostic market. Following our acquisition of Uman, we entered into a licensing and supply arrangement with Siemens Healthineers for access to Uman's proprietary NfL antibodies, which will allow Siemens to begin developing blood-based NfL clinical diagnostic tests for future commercialization. Additionally, in September 2020, we entered into a non-exclusive License Agreement with Abbott Laboratories, pursuant to which we granted Abbott a non-exclusive, worldwide, royalty-bearing license under our bead-based single molecule detection patents for IVD use.

Based on industry estimates, we believe the proteomics diagnostic total addressable market is approximately $55 billion.

See "Government Regulation" and "Risk Factors—Risks Related to Governmental Regulation and Diagnostic Product Reimbursement" for a discussion regarding the regulatory approvals that may be required for use of our products for diagnostic purposes, and related risks.

Our Key Focus Areas

We have focused the application of our Simoa technology on areas of high growth and high unmet need and where existing platforms have significant shortcomings that our technology addresses, including neurology and oncology, as well as cardiology, infectious disease and inflammation.

Neurology

We believe that the ability of our Simoa technology to detect neurological biomarkers in blood at ultra-low levels, which have traditionally only been detectable in CSF, has the potential to rapidly advance neurology research and drug development, and transform the way brain diseases and injuries are diagnosed and treated. Prior to the launch of our pTau-181 LDT for clinical use in July 2022, the brain was the only organ in the body for which there was not a blood-based diagnostic test. The challenge with developing blood-based tests for the brain is that the blood-brain barrier, which is formed by endothelial cells lining the cerebral microvasculature, is very tight and severely restricts the movement of proteins and other substances between these endothelial cells and into blood circulation. Accordingly, diagnosis of brain disease and injury has traditionally required either brain imaging or a spinal tap to collect CSF, both of which are costly

and highly invasive for the patient. The sensitivity of the Simoa technology has enabled researchers to discover that extremely small amounts of critical neural biomarkers diffuse through the blood-brain barrier and are released into the blood during injury and in connection with many neurodegenerative brain diseases. However, the concentrations of many these neural biomarkers in the blood can be so low that they are difficult to detect by conventional, analog immunoassay technologies.

To date, there have been over 1,400 neurology-related scientific publications using our Simoa technologies, and we believe that ultra-sensitive digital detection of neural-related biomarkers in the blood is becoming an essential research and development tool for an increasing range of neurological disorders, including Alzheimer's disease, multiple sclerosis, frontotemporal dementia, Parkinson's disease, and traumatic brain injury (TBI). The goal of this research is to eventually develop accurate diagnostic tools, predictive health screens and, ultimately, more effective treatments. The importance of neurological biomarkers, such as NfL, pTau-181, pTau-217, GFAP and Ab42/40, has increased dramatically in recent years. In addition, biomarkers are being increasingly used as an adjunct by pharmaceutical companies in clinical trials to help increase the potential for regulatory approval, particularly in neurological indications. With Simoa's sensitivity and its ability to detect many neurological biomarkers in blood and plasma that cannot be detected by many other technologies, we believe that we are uniquely positioned to take advantage of this opportunity, in particular with respect to Alzheimer's disease and multiple sclerosis.

Dementia/Alzheimer's Disease

Dementia is a collective name for brain syndromes that affect memory, thinking, behavior and emotion. According to *Alzheimer's Disease International*, as of 2021, there were more than 55 million people worldwide living with dementia, a figure expected to increase to over 139 million by 2050, and the annual global cost of dementia is now above $1.3 trillion. Alzheimer's disease is a progressive neurodegenerative disorder that affects cognition, function and behavior and is the most common cause of dementia.

In November 2022 at the 15th Clinical Trials on Alzheimer's Disease (CTAD) conference, Eisai Co., Ltd. and Biogen Corporation presented results from the Phase 3 clinical trial (Clarity AD) of lecanemab, an investigational drug aimed at slowing the progression of cognitive decline caused by Alzheimer's disease. Target engagement and activity of the drug in downstream processes was explored with a panel of fluid biomarkers, including plasma pTau-181, GFAP and NfL, using Quanterix's ultrasensitive Simoa assay kits. In January 2023, the FDA approved lecanemab for the treatment of patients with mild cognitive impairment or mild dementia due to Alzheimer's disease.

In 2021, Lilly presented new data from its Phase 2 TRAILBLAZER-ALZ study of its Alzheimer's disease drug candidate donanemab, which employed our ultra-sensitive Simoa technology to measure plasma pTau-217, using antibodies developed by Lilly. Lilly reported a significant reduction in blood levels of phosphorylated Tau protein after treatment with donanemab, and that a reduction in plasma pTau-217 levels correlated with the slowing of cognitive decline. In addition, following the FDA approval of its Alzheimer's disease drug ADUHELM™, Biogen conducted Simoa biomarker studies on Phase 3 EMERGE and ENGAGE trial samples, utilizing Simoa technology to measure plasma pTau-181. Preliminary data was reported that showed a dose-dependent reduction in plasma pTau-181 levels following treatment with ADUHELM, which correlated with decreases in amyloid PET and a slowing of cognitive decline across four independent assessment tools.

In October 2021, the FDA granted our Simoa pTau-181 blood test Breakthrough Device designation as an aid in diagnostic evaluation of Alzheimer's disease. The FDA's Breakthrough Device designation is granted to products that have the potential to offer more effective diagnosis of life-threatening diseases with an unmet medical need. The program is designed to enable accelerated development, assessment and review processes, with the intention to provide patients with more timely access to breakthrough technologies or devices. Proposed indications under the Breakthrough Device designation include use of the test results in adult patients, aged 50 years and over, presenting with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline as an aid in diagnostic evaluation for Alzheimer's disease.

In March 2022, we were awarded funding of $2.3 million by the Alzheimer's Drug Discovery Foundation (ADDF) in support of a proposal "Clinical Implementation of Blood-Based Biomarkers for Alzheimer's Disease: Clinical Validation, IVD Product Development, and Market Development." ADDF is a philanthropic foundation which

aims to accelerate Alzheimer's drug and diagnostics development. The project is aimed at clinically validating a multi-biomarker blood test for detection of Alzheimer's disease in a large prospective trial that includes both primary care and specialist memory clinical settings. The multi-biomarker approach is based on studies that have shown that combining the signals from multiple biomarkers relevant to Alzheimer's pathophysiology provides greater diagnostic accuracy than any single biomarker alone. The Simoa pTau-181 assay will be part of the multi-biomarker test, as well as our GFAP, NfL, Ab42, and Ab40 assays. The latter four assays are multiplexed into a single test that measures all biomarkers simultaneously. Thus, this validation study will serve to validate pTau-181 as a standalone test and will also leverage Simoa's multiplexing capability to combine additional biomarkers for even greater accuracy.

In addition to the ADDF clinical validation program, we are nearing completion of a second prospective clinical trial (BioHermes) in partnership with the Global Alzheimer's Platform Foundation (GAPF). GAPF is a non-profit organization dedicated to speeding the delivery of innovative therapies to Alzheimer's patients by reducing the time and cost of Alzheimer's disease clinical trials. The BioHermes trial is being conducted across 17 clinical sites in the United States and is examining blood test accuracy across 1,000 cognitively normal and mildly impaired Alzheimer's patients in comparison with amyloid PET scan. This study is expected to support a regulatory filing for FDA clearance of our pTau-181 test pursuant to the Breakthrough Device designation.

Multiple Sclerosis

Multiple sclerosis is a chronic disease affecting the central nervous system (the brain and spinal cord). Multiple sclerosis occurs when the immune system attacks nerve fibers and myelin sheathing (a fatty substance which surrounds/insulates healthy nerve fibers) in the brain and spinal cord. This attack causes inflammation, which destroys nerve cell processes and myelin, altering electrical messages in the brain. Multiple sclerosis is unpredictable and affects each patient differently – some individuals may be mildly affected, while others may lose their ability to write, speak or walk. According to the National MS Society, more than 2.3 million people have a diagnosis of multiple sclerosis globally. In the U.S. alone, the National MS Society recently completed a prevalence study estimating nearly 1,000,000 people over the age of 18 live with a diagnosis of multiple sclerosis.

Evidence of the potential clinical utility of NfL as a biomarker in multiple sclerosis is progressing rapidly, and Simoa's role in that progression has been foundational. The Simoa NfL assay pioneered measurement of NfL in blood, and in the past five years, the Simoa NfL assay has been used in hundreds of published studies. In 2022, Simoa technology supported 35 scientific presentations at the 38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), the world's largest meeting dedicated to advancing research for multiple sclerosis. In 2021, Simoa technology supported 31 scientific presentations at ECTRIMS. In 2020, Simoa supported 42 presentations at ECTRIMS. At ECTRIMS in 2019, there were nearly 50 presentations in which our Simoa NfL assay was used.

As an example, in one 2019 presentation, Novartis presented positive data from its Phase III ASCLEPIOS I and II studies of its multiple sclerosis drug candidate, ofatumumab. One of the secondary endpoints included serum levels of NfL as measured using our Simoa NfL assay. Novartis presented data that showed that, starting at three months after initiation of ofatumumab treatment, and then at 12 and 24 months timepoints, patients given ofatumumab had significantly lower blood levels of NfL, compared to those in the comparator arm of teriflunomide treated patients.

In another ECTRIMS presentation in 2019, Roche presented retrospective data from its Phase III OPERA I, OPERA II and ORATORIO trials of its approved multiple sclerosis drug OCREVUS (ocrelizumab). In the data presented at ECTRIMS, it was shown that treatment with OCREVUS lowered blood NfL levels and increased the proportion of patients reaching healthy donor range for NfL in both relapsing multiple sclerosis and primary progressive multiple sclerosis. Roche believes that this data helps advance the understanding of NfL as a potential biomarker of disease activity and for treatment monitoring and may provide insight into the neuroprotective effects of the drug.

In an article published by Bjornevik, et al. in *JAMA Neurology* in September 2019, researchers presented data that showed that levels of serum NfL, as measured by the Simoa NfL assay, were increased six years before the clinical onset of multiple sclerosis. The researchers concluded that these data indicate that multiple sclerosis may have a

prodromal phase lasting several years and that neuroaxonal damage occurs during this phase, emphasizing the importance of early diagnosis and treatment.

In a study published in *Science* in January 2022, researchers leveraged Simoa's ability to detect the NfL at ultra-low levels to show that Epstein-Barr virus (EBV) increases susceptibility toward developing multiple sclerosis. Researchers of the study tested the hypothesis that multiple sclerosis is caused by EBV in a cohort comprising more than 10 million young adults on active duty in the U.S. military, 955 of whom were diagnosed with multiple sclerosis during their period of service. Risk of multiple sclerosis increased 32-fold after infection with EBV, but was not increased after infection with other viruses, including the similarly transmitted cytomegalovirus. Serum levels of NfL, a biomarker of neuroaxonal degeneration, increased only after EBV seroconversion, suggesting that EBV played a role in nerve cell damage.

In April 2022, the FDA granted our Simoa NfL plasma test Breakthrough Device designation as a prognostic aid in assessing the risk of disease activity in patients diagnosed with relapsing-remitting multiple sclerosis (RRMS). The test has shown promise to be used in conjunction with clinical, imaging and laboratory findings as an aid in identifying RRMS patients who are at lower or higher risk for relapse within four years. We believe this prognostic information could be clinically useful in tailoring the therapeutic approach to more effectively treat the disease.

Traumatic Brain Injury (TBI)

TBIs lead to approximately five million individuals visiting emergency rooms per year in the United States alone, often with broad and inconclusive diagnosis. Current methods of TBI diagnosis involve CT scans that fail to diagnose approximately 90% of mild TBI. Simoa technology has demonstrated the sensitivity to identify relevant neurological biomarkers, such as NfL, tau, GFAP and UCH-L1, to more adequately address diagnosis of TBIs and overall brain health.

Leading researchers in neurology have used Simoa technology to study biomarkers in the blood of athletes after concussion in many high-impact sports. Simoa can measure critical neural biomarkers in blood that correlate repeated head trauma from both concussions and subconcussive events with poor patient outcomes, including the potential development of Chronic Traumatic Encephalopathy (CTE), which currently can only be diagnosed after death via a brain autopsy. A publication by a National Institute of Health researcher indicates that measuring tau in the blood with Simoa may help identify concussed individuals requiring additional rest before they can safely return to play.

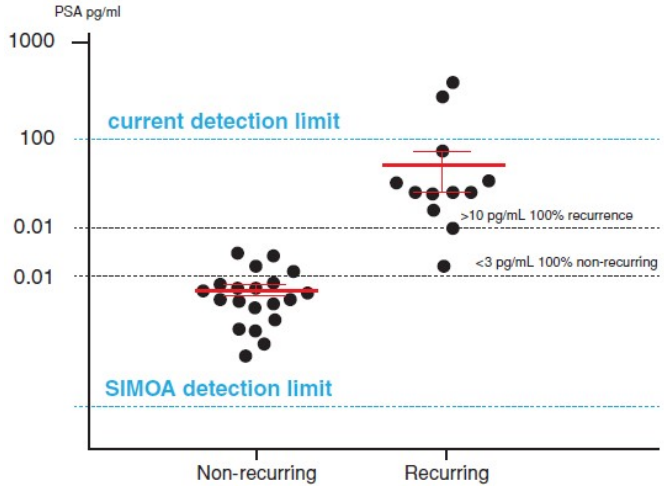
Oncology

Our ultra-sensitive Simoa technology has the potential to detect increased levels of oncology biomarkers during the very early stages in disease development. Biomarkers can be useful tools for diagnostics, prognostics and predictive cancer detection. However, many traditional assay technologies can only detect these biomarkers after the disease has progressed and the patient has become symptomatic. Simoa's highly sensitive detection capability may result in earlier detection, better monitoring and treatment and improved prognoses for patients. Additionally, Simoa technology has shown early promise as a liquid biopsy alternative to more invasive diagnostic procedures.

Cancer immunotherapy is a promising new area that is significantly affecting cancer remission rates. One challenge of immunotherapy approaches is that the elicited immune responses are not always predictable and can vary from person to person and protocol to protocol. There exists a significant need to develop biomarker tools to monitor these drugs and their effects. Circulating (serum and plasma) protein biomarkers have the potential to be used in the field of immuno-oncology to stratify patients, predict response, predict recurrence, reveal mechanism of action and monitor for adverse effects. One technical challenge facing the immuno-oncology drug development process has been the availability of immunoassays with sufficient sensitivity to measure immunomodulatory biomarkers directly in serum and plasma. We have developed a number of tumor biomarker and immune modulation assays (cytokines and chemokines) that can be used to monitor tumor proliferation and host immune response. In particular key immune regulatory cells (T-regs, dendritic cells, macrophages) secrete very low amounts of the protein Interferon gamma (IFN-gamma) and these levels cannot be reliably measured in serum and plasma using conventional, immunoassay technology, however they can be tracked with our Simoa IFN-gamma assay. Additionally, we have developed an ultra-sensitive assay for IL-6, which

is one of the cytokines commonly measured for monitoring cytokine release syndrome as an adverse effect in immunotherapies. Several studies have shown that our ultrasensitive assays can be valuable tools for monitoring immuno-oncology drugs and protocols.

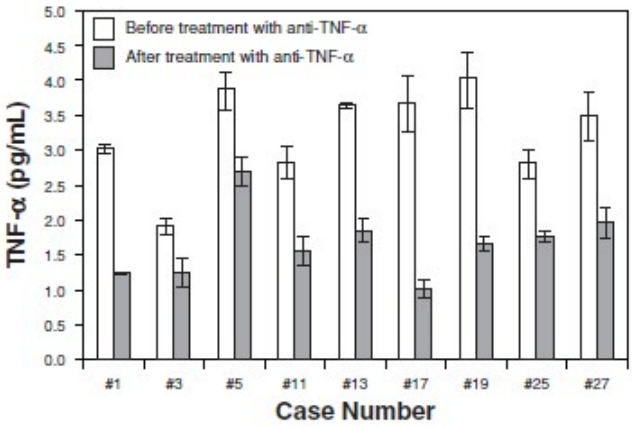
We also believe residual cancer cell detection post-surgery or post-treatment may significantly improve outcomes for a variety of cancer types, by helping identify and segment patients at a greater risk of reoccurrence post-surgery due to residual cancer. For example, we have developed an ultra-sensitive biomarker assay for Prostate Specific Antigen (PSA) that is over 1,000-fold more sensitive than conventional ELISA assays. This assay is the only currently available technology that can detect levels of PSA in blood samples of prostate cancer patients shortly following radical prostatectomy, and we and researchers from Johns Hopkins and NYU conducted a pilot study on the utility of this assay to predict recurrence of prostate cancer after this procedure. In this study, the blood of prostate cancer patients taken three to six months following a radical prostatectomy at least five years earlier was analyzed with Simoa. The majority of samples had PSA levels below the detectable limits of traditional PSA assays. Our Simoa technology, however, was able to detect and quantify PSA levels in all samples. As shown in the following graph, the study demonstrated that the PSA assay using our Simoa technology has the potential to be highly predictive of prostate cancer recurrence over a five-year period. This has the potential to be a powerful prognostic tool, and allowing adjuvant radiation treatment to be targeted only to the men who actually would benefit.



Inflammation

Inflammation underlies the response of the body to injury in a variety of diseases. Simoa assays can measure inflammatory and anti-inflammatory molecules in serum and plasma with unprecedented sensitivity. This has the potential to enable new discoveries into the role of inflammation in the biology of health and disease. Our Simoa technology measures low levels of inflammatory proteins, including cytokines and chemokines, that characterize a range of inflammatory diseases, including Crohn's disease, asthma, rheumatoid arthritis and neuro-inflammation. We believe the sensitivity of Simoa technology can provide a clearer picture of the underlying state of the immune response and disease progression.

Our Simoa technology also has the potential to be used by companies developing anti-inflammatory drugs to quantify the effect a drug has on a particular inflammatory cytokine and to monitor therapeutic efficacy. For example, we conducted a study in conjunction with the Mayo Clinic using our Simoa technology on patients with clinically active Crohn's disease undergoing anti-TNF-α therapy with Remicade, Humira or Enbrel. As shown in the graph below, researchers were able to detect and quantify the TNF-α levels of the patients before and after treatment. These levels were all below the LoD of traditional immunoassays.



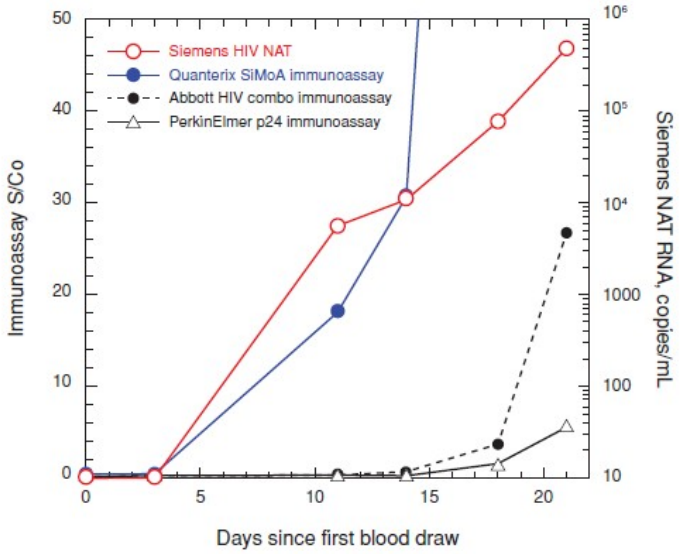
We believe that a better understanding of the inflammatory response will be critical to future opportunities for wellness screening and disease response monitoring. Anti-inflammatory drugs are expensive and can have serious side effects, such as increased risk of infection. By monitoring biomarkers indicative of response, clinicians may be able to adjust dose to reduce side effects or increase efficacy.

Infectious Disease

The ability to detect infectious disease biomarkers before the onset of an immune response, where a virus is most contagious and multiplying rapidly, is critical for controlling the spread of disease. We believe that our Simoa technology has the potential to have a significant impact in reducing the spread of infectious diseases by making early stage detection more specific and widely available.

Today, early detection of infectious disease is conducted using nucleic acid testing to detect the nucleic acid of the viral or bacterial organism because the levels of infectious disease specific antigens are too low in the early stage of disease to be detected by traditional immunoassay technology. However, the sensitivity of our single molecule detection capabilities enables the detection of extremely low levels of infectious disease specific antigens with sensitivity that can rival the use of nucleic acid testing in this application, without the potential biases inherent in amplification technologies, such as PCR.

For example, we have developed a simple Simoa assay with more than 4,000-fold greater sensitivity than conventional ELISA assays capable of detecting the HIV-specific antigen, p24. This Simoa p24 sensitivity matches the sensitivity of more expensive and complex nucleic acid testing methods. The following graph shows a comparison that we conducted in 2011 of the Simoa p24 assay with a commercially available nucleic acid testing method, as well as two commercially available p24 immunoassay methods for early detection of HIV infection. The Simoa p24 assay detects infection as early as the nucleic acid testing method (11 days from initial blood draw), and a full week before the earliest signs of infection by the conventional p24 immunoassay methods. This early detection of acute HIV infection can be critical for controlling the spread of HIV, as HIV is ten times more infectious in the acute phase.



In addition, we believe the detection of a specific protein is more relevant to the determination of the pathogenic effect than detection of the organism itself because someone may carry a pathogenic organism with no pathogenic effect. Researchers have demonstrated that Simoa technology can detect *Clostridium difficile* (*C. diff*) toxins A and B with sensitivities similar to the PCR detection of the *C. diff* organism itself. Because the *C. diff* organism does not always produce toxins, PCR methods that detect the *C. diff* organism suffer from very high false positive rates, which may result in incorrect diagnoses and the overuse of antibiotics. We believe that using Simoa to detect the toxins rather than the organism has the potential to provide a higher level of sensitivity and specificity, greatly reducing false positives.

Cardiology

Heart disease and related cardiovascular ailments remain the leading cause of death in the United States, contributing to nearly one in four deaths in the United States, according to the CDC. A significant need remains for early prediction of heart attacks and other cardiac events. Simoa's highly sensitive digital measurement capabilities have the potential to be used to predict early cardiac disease.

Our Products and Services

Our Quanterix commercial portfolio includes research use only (RUO) instruments, assay kits and other consumables, and contract research services offered through our Accelerator Laboratory, as follows:

Product	Key attributes
HD-X 	• Commercially launched the next-generation HD-X in the second half of 2019 to replace the HD-1 launched in 2014 • Simoa bead-based platform technology • Most widely referenced ultra-sensitive multiplex immunoassay platform on market • Fully automated, floor-standing instrument • Wide dynamic range • Multiplexing capability (up to 4-plex) with small sample volume • Up to 400 samples per eight-hour shift • Homebrew capabilities
SR-X 	• Commercially launched in December 2017 • Simoa bead-based platform technology • Reader only, benchtop instrument with lower price point • Similar sensitivity, dynamic range and homebrew capabilities as HD-X • Multiplexing capability: SR-X currently has up to 4-plex capability • Sample prep and assay protocol flexibility
SP-X 	• Commercially launched in April 2019 • Simoa planar array platform technology • Reader only, benchtop instrument with lower price point • Similar sensitivity, dynamic range and homebrew capabilities as HD-X • Multiplexing capability: SP-X currently has up to 10-plex capability • Sample prep and assay protocol flexibility

Product	Key attributes
Simoa assays and other consumables 	• Menu of approximately 36 single-plex and multi-plex bead-based assay kits includes assays for biomarkers in the areas of neurology, infectious disease, immunology and oncology • Menu of Simoa planar array reagent kits includes approximately 115 biomarkers ranging from 1-10 analytes per assay in the areas of immunology and oncology research • Homebrew kits containing reagents and supporting user guides enabling customers to develop custom assays • Proprietary Simoa disk with 24 arrays, each containing approximately 239,000 microwells for Simoa bead-based assays
NfL antibodies and NfL ELISA kits 	• Sold through our wholly-owned subsidiary, Uman, which we acquired in 2019 • NfL capture/detection antibodies with unparalleled sensitivity and specificity • NfL ELISA kits for CSF (CE-certified in Europe; RUO outside of Europe) • NfL ELISA kits for serum (RUO) • Licensing and supply arrangement with Siemens Healthineers that will allow Siemens to begin developing blood-based NfL clinical tests for future commercialization
Services 	• Contract research services provided through our Accelerator Laboratory • Over 1,900 projects completed to date • Extended warranty and service contracts • CLIA-certified lab available – LDT for pTau-181 launched in July 2022 and LDT for NfL launched in January 2023

Instruments and Consumables

HD-X

We commercially launched our HD-X instrument in the second half of 2019. The HD-X is an upgraded version of the Simoa HD-1, our very first instrument, which was launched in January 2014. The HD-X was designed to deliver significant productivity and operational efficiency improvements, as well as greater user flexibility. The HD-X uses our Simoa bead-based technology and is the most sensitive automated multiplex protein detection platform commercially available. Assays for the HD-X are fully automated (i.e., from sample in to result out), and results for up to 66 samples are available in approximately one hour. Samples can be input into the instrument via 96-well microtiter plates or sample tubes where the system can multiplex and process tests in a variety of assay protocol configurations.

Specialized software controls the Simoa instrumentation, analyzes the digital images produced, and provides customers with detailed analysis of their samples, such as the concentration of multiple biological molecules. The HD-X software automates the processes for running the instrument and analyzing data from the user-defined protocols. Proprietary image analysis software is embedded in the system, which converts the raw images into signals for each biological molecule being analyzed within a sample. Data reduction software automatically converts those signals to concentrations for the different biological molecules.

By the end of 2022, approximately 79% of the HD installed base were HD-X instruments.

SR-X

We commercially launched the SR-X instrument in the fourth quarter of 2017. The SR-X utilizes the same Simoa bead-based technology and assay kits as the HD-X in a compact benchtop form with a lower price point designed to address the needs of researchers who value the ultra-sensitive detection capabilities enabled by Simoa.

In contrast to the fully automated workflow of the HD-X, the assay incubation and washing steps for the SR-X are performed outside of the instruments using conventional liquid handling methods. The offline sample prep provides additional flexibility to enable researchers to apply Simoa detection in an expanded range of applications including direct detection of nucleic acids. The SR-X system automates the steps loading Simoa beads onto Simoa disks with subsequent imaging, detection and data reduction. Processing time for imaging a 96 well plate is approximately 2.5 hours.

SP-X

We commercially launched the SP-X instrument in April 2019. The SP-X uses the Simoa planar array technology developed initially by Aushon Biosystems (Aushon), which we acquired in 2018, for multiplex chemiluminescent immunoassay measurement, which we refined by leveraging our proprietary sophisticated Simoa image analysis and data analysis algorithms to provide sensitivity similar to that found in our Simoa bead-based platform. The Simoa planar array technology utilizes a 96-well microtiter plate with up to 10 different assay measurements performed in each well of the plate from as little as 12.5 microliters of sample.

Similar to the SR-X, the assay prep workflow utilized for the SP-X involves assay incubation and washing steps performed outside of the instrument using the same conventional liquid handling methods as the SR-X. The SP-X instrument automates the imaging, detection and data reduction process. Processing time for imaging a 96 well plate is less than five minutes.

Simoa Assays and Consumables

Recurring revenue is derived through the sale of consumables used to run assays on our instruments and from our growing menu of Simoa digital biomarker assays. The current menu of approximately 36 analyte-specific single-plex and multi-plex assay kits for our bead-based instruments includes assays for biomarkers in the areas of neurology, infectious disease, immunology and oncology for both human and mouse samples. The current menu of assay kits for the planar array instrument includes approximately 115 biomarkers ranging from 1-10 analytes per assay in the areas of immunology and oncology research.

In addition to these assays we have developed, both of the Simoa platforms allow ease and flexibility in assay design, enabling our customers to develop their own proprietary in-house assays, called homebrew assays, using our homebrew assay kits. These kits include all components required for customers to run tests using their own antibodies. Our consumables portfolio for our bead-based platform also includes our proprietary Simoa disks that are unique to our bead-based platform, as well as cuvettes and disposable tips. Our goal is to continue to add to our assay kits to extend our application base.

We have staffed our assay development and manufacturing teams to do the upfront work of antibody sourcing, assay development and optimization, sample testing and validation, transfer to manufacturing and final documentation.

We outsource some of our assay development activities to other antibody and/or assay development providers and expect to continue to do so to achieve our aggressive menu expansion goals.

NfL Antibodies and NfL ELISA Kits

Uman is our wholly owned subsidiary that supplies NfL antibodies and ELISA kits for NfL detection. Uman's NfL antibodies are widely recognized by researchers and biopharmaceutical and diagnostics companies worldwide as the premier solution for the detection of NfL to advance the development of therapeutics and diagnostics for neurodegenerative conditions. Through Uman we sell proprietary NfL capture and detection antibodies, as well as two NfL ELISA kits for CSF, one of which is CE-certified in Europe and one RUO NfL ELISA kit for serum.

Services

Through our Accelerator Laboratory, which includes a CLIA-certified laboratory, we provide customers a contract research option. Researchers, academics and principal investigators can work with our scientists to test specimens with existing Simoa assays, or prototype, develop and optimize new assays. The Accelerator Laboratory supports multiple projects and services, including:

- *Sample testing.* Utilizing commercially available Simoa kits, we have run large studies for customers with thousands of specimens and small experiments with just a few samples. The sample protocol can be tailored precisely to the customer's needs and even large studies can be run quickly. We have extensive experience testing many different sample types where biomarkers may be present at very low levels.

- *Homebrew assay development.* Utilizing proprietary or commercially available reagents in combination with our Homebrew Assay Development Kit, we can rapidly develop a prototype assay exhibiting improved sensitivity compared to traditional ELISA. The Accelerator Laboratory can also be used to screen reagents to identify the optimal assay format or expand prototype efforts for further assay optimization or validation to ultimately deliver the highest level of performance.

- *Custom development.* After identifying the optimal assay and conditions, the Accelerator Laboratory can be used to generate qualified bulk reagents or custom assay kits, providing customer access to validated kits for assays not yet commercially available on the Simoa platform.

- *LDT Testing.* We have recently begun offering LDT testing through our CLIA-certified laboratory. In July 2022, we launched an LDT to quantitatively measure pTau-181 in plasma as an aid in diagnostic evaluation of Alzheimer's disease, and in January 2023, we launched an LDT to quantitatively measure NfL in serum as an aid in the evaluation of individuals for possible neurodegenerative conditions or other causes of neuronal or central nervous system damage.

To date, we have completed over 1,900 projects for more than 400 customers from all over the world using our Simoa platforms. In addition to being an important source of revenue, we have also found the Accelerator Laboratory to be a catalyst for placing additional instruments, as a number of customers for whom we have provided contract research services have subsequently purchased an instrument from us.

We also generate revenues through extended-warranty and service contracts for our installed base of instruments.

Research and Development

We continually seek to improve our platform and technology to enable more sensitive detection and measurement of biological molecules. This evaluation includes examining new assay formats and instrumentation improvements and upgrades to increase the performance of our Simoa assays and instruments. We also intend to selectively expand our assay menu to extend the scope of applications for our platform to biomarkers of significant

interest to the scientific community. Our assay menu expansion is driven by a number of factors, including input from key opinion leaders, customer feedback, homebrew projects, Accelerator Laboratory projects, new publications on biomarkers of industry interest, and feedback from our sales and marketing team. We also intend to continue to develop and market new instruments with different and/or improved capabilities in order to further broaden our market reach.

Sales and Marketing

We distribute our Simoa instruments and consumables via direct field sales and support organizations located in North America and Europe and through a combination of our own sales force and third-party distributors in additional major markets, including Australia, Brazil, China, Czech Republic, India, Hong Kong, Israel, Japan, New Zealand, Qatar, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan, and UAE. In addition, we sell Uman's NfL antibodies and NfL ELISA kits directly and in conjunction with a distributor worldwide. Our domestic and international sales force informs our current and potential customers of current product offerings, new product and new assay introductions, and technological advances in Simoa systems, workflows, and notable research being performed by our customers or us. As our primary point of contact in the marketplace, our sales force focuses on delivering a consistent marketing message and high level of customer service, while also attempting to help us better understand evolving market and customer needs.

As of December 31, 2022, we had 125 full-time employees in sales, sales support and marketing, including technical field application scientists and field service personnel. This staff is primarily located in North America and Europe. We expect we will expand our sales, support, and marketing efforts in the future by expanding our direct footprint in Europe as well as developing a comprehensive distribution and support network in China where significant new market opportunities exist. Additionally, we believe that there is significant opportunity in other Asia-Pacific region countries such as South Korea and Australia as well as in South America. We are expanding into these regions via initial penetration with distributors and then subsequent support with Quanterix-employed sales and support personnel.

Our sales and marketing efforts are targeted at key opinion leaders, laboratory directors and principal investigators at leading biotechnology and pharmaceutical companies and governmental research institutions.

In addition to our selling activities, we align with key opinion leaders at leading institutions and clinical research laboratories to help increase scientific and commercial awareness of our technologies, demonstrate the benefits relative to existing technologies and accelerate adoption. We also seek to increase awareness of our products through participation at trade shows, academic conferences, online webinars and dedicated scientific events attended by prominent users and prospective customers.

Our instruments require a capital investment by our customers. The sales process typically involves numerous interactions and demonstrations with multiple people within an organization. Some potential customers conduct in-depth evaluations of the instruments including running experiments in the Accelerator Laboratory and comparing results from competing systems. In addition, in most countries, sales to academic or governmental institutions require participation in a tender process involving preparation of extensive documentation and a lengthy review process. As a result of these factors and the budget cycles of our customers, our sales cycle, the time from initial contact with a customer to our receipt of a purchase order, can often be six to 12 months, or longer.

Manufacturing and Supply

We outsource the development and manufacturing of our Simoa bead-based instruments to third-party manufacturers, and we develop and manufacture our planar array instrument and all assay kits in our own facilities.

Instruments

The HD-X instrument is manufactured by STRATEC Biomedical AG (STRATEC), based in Birkenfeld, Germany, and is manufactured and shipped from their Birkenfeld and Beringen, Switzerland facilities. The SR-X is manufactured by Paramit Corporation (Paramit), based in Morgan Hill, California, and is shipped to our global customers by Paramit. See "—Key Agreements" for a description of our agreements with STRATEC and Paramit.

Installation of, and training on, our instruments is provided by our employees in the markets where we conduct direct sales, and by distributors in those markets where we operate with distributors.

We believe this manufacturing strategy is efficient and conserves capital. However, in the event it becomes necessary to utilize a different contract manufacturer for the HD-X or the SR-X, we would experience additional costs, delays and difficulties in doing so, and our business could be harmed.

The SP-X instruments are manufactured, tested, shipped and supported by us from our Billerica, Massachusetts facility. All internal components are sourced domestically except one significant component that is sourced in Germany. These components are sourced from a limited number of suppliers, including certain single-source suppliers. Although we believe that alternatives would be available, it would take time to identify and validate replacement components, which could negatively affect our ability to supply instruments on a timely basis.

Consumables

We assemble our assay kits for our bead-based platform in our Billerica, Massachusetts facility. Reagents for our bead-based assays include all components required to run an enzyme based immunoassay, such as beads, capture and detector reagents, enzyme reagents and enzyme substrate. These reagents are sourced from a limited number of suppliers, including certain single-source suppliers. Although we believe that alternatives would be available, it would take time to identify and validate replacement reagents for our assay kits, which could negatively affect our ability to supply assay kits on a timely basis. In an effort to mitigate this risk through inventory control, we are working to increase the shelf life of our bead-based assays to 12 months or more.

Simoa disks for our bead-based platform are supplied through a single source supplier pursuant to a long-term supply agreement with STRATEC Consumables, a subsidiary of STRATEC Biomedical. We believe that this agreement provides for a sufficient notification period to allow for supply continuity and the identification and tech transfer to a new supplier in the event either party wishes to terminate the relationship. Our cuvettes for our bead-based platform are single sourced through STRATEC Biomedical, and the disposable tips used in our bead-based platform are commercially available.

We assemble our 96 well sample plate kits for our planar array platform in our Billerica, Massachusetts facility. Reagents for our planar array assays include all components required to run an enzyme-based chemiluminescent immunoassay, such as capture antibody printed plates and detector reagents, enzyme reagents and enzyme substrate. These reagents are sourced from a limited number of suppliers, including certain single-source suppliers. Although we believe that alternatives would be available, it would take time to identify and validate replacement reagents for our assay kits, which could negatively affect our ability to supply assay kits on a timely basis. Because our planar array assays have a shelf life of 12 months, we believe we are able to mitigate this risk through inventory control.

NfL antibodies and NfL ELISA Kits

The storage of Uman's proprietary NfL antibody producing hybridomas as well as the cultivation and purification of the antibodies is outsourced to a contract manufacturer, and bulk material of purified antibodies is delivered to Uman's site in Umeå, Sweden. Functional testing and verification of concentration are performed at Uman before the material is approved for use in production activities. The antibodies can be aliquoted and sold as single reagents or used for the production of Uman's NfL ELISA kits. The antibody reagents are labeled and released to market after testing. The contract manufacturer of antibodies is audited regularly, and we have entered into a written supply agreement with the contract manufacturer. The current shelf-life of the antibodies is 18 months.

All components in Uman's NfL ELISA kits are manufactured in-house at Uman from starting materials sourced from suppliers that have been evaluated and approved. Uman has entered into supply agreements with critical suppliers. All incoming goods are subject to receipt control and any deviations related to quality deficiencies are registered. The kit components include buffers (sample diluents and wash solutions), ELISA 96-well plates coated with a capture antibody, detector antibodies, streptavidine conjugates, substrates (TMB) and stop reagents. The kit components are labeled (either RUO or CE) and assembled. The final ELISA kit products are subject to quality control procedures, which include

testing of human CSF or human serum quality control samples to assure a high batch consistency. After testing and batch record review, the material is released to market. The current shelf-life of the kits is 18 months (NF-light ELISA (CSF)) or 13 months (NF-light Serum ELISA).

Key Agreements

Development Agreement and Supply Agreement with STRATEC

In August 2011, we entered into a Strategic Development Services and Equity Participation Agreement with STRATEC, pursuant to which STRATEC undertook the development of the Simoa HD instrument. In September 2011, we also entered into a Supply and Manufacturing Agreement with STRATEC (the STRATEC Supply Agreement), pursuant to which STRATEC agreed to supply HD instruments to us, and we agreed to procure those instruments exclusively from STRATEC, subject to STRATEC's ability to supply the instruments. We are responsible for obtaining any regulatory approval necessary to sell the instruments. We agreed to purchase a certain number of instruments in the seven years following the acceptance of the first validation instrument. The STRATEC Supply Agreement was amended in November 2016 to reduce the number of HD instruments we were committed to procure from STRATEC, and this commitment has been met. The instrument price stipulated in the STRATEC Supply Agreement was established based on certain specified assumptions and is subject to certain adjustments.

The STRATEC Supply Agreement is terminable by either party on 12 months' notice to the other party. The STRATEC Supply Agreement may also be terminated on the insolvency of a party or the uncured material breach of a party, or, by us, on a change of control of our company (subject to certain obligations to compensate STRATEC on such termination). On termination by us for STRATEC's insolvency or uncured material breach or termination by STRATEC for convenience, we are granted a nonexclusive royalty free license of STRATEC intellectual property to manufacture the instruments. In certain of these circumstances, we could be obligated to issue warrants to purchase our common stock.

Paramit Manufacturing Services Agreement

In November 2016, we entered into a Manufacturing Services Agreement (the Paramit Agreement) with Paramit. Under the terms of the Paramit Agreement, we engaged Paramit to produce and test our SR-X instrument on an as-ordered basis. We also engaged Paramit to supply spare parts for the SR-X instrument. Paramit has no obligation to manufacture our instrument without a purchase order and no obligation to maintain inventory in excess of any open purchase orders or materials in excess of the amount Paramit reasonably determines will be consumed within 90 days or within the lead time of manufacturing our instrument, whichever is greater. We have an obligation to purchase any material or instruments deemed in excess pursuant to the Paramit Agreement. The price is determined according to a mutually agreed-upon pricing formula. The parties agreed to review the pricing methodology yearly or upon a material change in cost.

The Paramit Agreement had an initial three-year term with automatic one year extensions. It is terminable by either party for convenience with written notice to the other party given at least nine months prior to the end of the then-current term. The agreement may also be terminated by us with three months' notice to Paramit upon the occurrence of (i) a failure of Paramit to obtain any necessary governmental licenses, registrations or approvals required to manufacture our instrument or (ii) an assignment by Paramit of its rights or obligations under the agreement without our consent. The Paramit Agreement is terminable by Paramit with 30 days' notice to us in the event of a material breach after written notice and a 60-day opportunity to cure the breach.

Competition

We compete with both established and development-stage life science companies that design, manufacture and market instruments for proteomics discovery and clinical research applications. For example, companies such as Bio-Techne, Luminex, MesoScale Discovery, Gyros, O-Link, SEER, Somalogic, MilliporeSigma, Bio-Rad Laboratories, Thermo Fisher Scientific, and others, have products for protein measurements in biofluids that compete in certain segments of the market in which we sell our products. Our Accelerator Laboratory competes with other research

laboratories such as Covance, Q2 Solutions, Rules Based Medicine, Monogram Biosciences, PPD Laboratories, and others, some of whom are customers of ours. In addition, as we or our partners expand the applications for our products to include diagnostics, we expect to compete with companies such as Siemens, Abbott, Roche, Ortho Clinical Diagnostics and Thermo Fisher Scientific. Furthermore, our technology and products are showing promise for non-invasive early disease detection, and in the future, we could experience competition from companies that develop and market imaging and other molecular detection technologies. In addition, a number of other companies and academic groups are in the process of developing novel technologies for the life science research and diagnostic markets. Many of the companies with which we compete or will compete have substantially greater resources than we have.

The life science instrumentation and lab services industries are highly competitive and expected to grow more competitive with the increasing knowledge gained from ongoing research and development. We believe the principal competitive factors in our target markets include:

- sensitivity;
- cost of instruments and consumables;
- assay menu;
- reputation among customers and key opinion leaders;
- innovation in product offerings;
- accuracy and reproducibility of results; and
- customer support infrastructure.

We believe that we are well positioned with respect to these competitive factors and expect to enhance our position through ongoing global expansion, innovative new product introductions and ongoing collaborations and partnerships with key opinion leaders.

Intellectual Property

Our core Simoa bead-based technology, directed to general methods and devices for single molecule detection, originated at Tufts University (Tufts), in the laboratory of Professor David Walt, who is the founder of Quanterix and a current member of our Board of Directors. Prof. Walt and his students pioneered the single molecule array technology, including technologies that enabled the detection of single enzyme labels in arrays of microwells, thereby facilitating the ultra-sensitive detection of proteins, nucleic acids, and cells. We have exclusively licensed from Tufts the relevant patent filings related to these technologies. (See "—License Agreement with Tufts University" below). In addition to licensed patents, we have developed our own portfolio of issued patents and patent applications directed to commercial products and technologies for potential development. Our portfolio also includes issued patents and patent applications acquired as part of our 2018 acquisition of Aushon Biosystems. We believe our proprietary platforms are a core strength of our business and our strategy includes the continued development of our patent portfolio.

Our patent strategy is multilayered, providing coverage of aspects of the core technology as well as specific uses and applications, some of which are reflected in our current products and some of which are not. The first layer is based on protecting the fundamental methods for detecting single molecules independent of the specific analyte to be detected. The second layer covers embodiments of the core technology directed to the detection of specific analytes. The third layer protects novel instrumentation, consumables, and manufacturing processes used in applying the invention to certain commercial products or future product opportunities. The fourth layer is concerned with specific uses of the core technology (e.g., biomarkers and diagnostics). Our patent strategy is both offensive and defensive in nature, seeking to protect not only technology we currently practice but also alternative, related embodiments.

Simoa and Related Technology

As of March 1, 2023, we had exclusively licensed 17 patents and two patent applications from Tufts. These patents and patent applications include eight issued U.S. patents and two pending U.S. patent applications, three granted European patents, three granted Japanese patents, two granted Canadian patents and one granted Australian patent.

A first patent family licensed from Tufts is directed to methods for detecting single molecules. This patent family includes seven granted U.S. patents, one pending U.S. patent application, three granted European patents (each nationalized and active in seven or eight countries), three granted Japanese patents, two granted Canadian patents and one granted Australian patent. The standard patent expiration date for U.S. patents in this family is February 16, 2027, and for the non-U.S. patents is February 20, 2027 or August 30, 2027.

A second patent family licensed from Tufts is directed to methods for detecting the presence of target analytes in multiple samples. This patent family includes one granted U.S. patent. The standard patent expiration date for the U.S. patent in this family is August 22, 2025.

A third patent family licensed from Tufts is directed to methods for detecting short nucleic acids. This patent family includes one pending U.S. patent application. The standard patent expiration date for any U.S. patents that may issue in this family is May 29, 2039.

As of March 1, 2023, we owned 29 issued U.S. patents and 17 pending U.S. patent applications, eight granted European patents and three pending European patent applications, six granted Japanese patents and one pending Japanese patent application, four granted Chinese patents and two pending Chinese patent application, four granted Canadian patents and one pending Canadian patent application, and one registered Hong Kong patent application.

A first patent family owned by us is directed to methods for determining a measure of the concentration of analyte molecules or particles in a fluid sample, and in particular to methods for analyte capture on beads, including multiplexing. This patent family includes four granted U.S. patents and two pending U.S. patent applications, three granted European patents (nationalized and active in eight countries) and one pending European application, two granted Japanese patents, two granted Chinese patents, and one granted Canadian patent. The standard patent expiration date for the U.S. patents in this family is March 24, 2030, and for the non-U.S. patents is March 1, 2031.

A second patent family owned by us is directed to methods and systems for determining a measure of the concentration of analyte molecules or particles in a fluid sample, and in particular to methods or systems for determining concentration based on either counting or measured intensity (extending the dynamic range). This patent family includes five granted U.S. patents and one pending U.S. patent application, one granted European patent (nationalized and active in seven countries), two granted Japanese patents, one granted Chinese patent, and one granted Canadian patent. The standard patent expiration date for the U.S. patents in this family is March 24, 2030, and for the non-U.S. patents is March 1, 2031.

A third patent family owned by us is directed to methods for determining a measure of the concentration of analyte molecules or particles in a fluid sample, and in particular to methods for analyte capture on beads with or without dissociation. This patent family includes two granted U.S. patents. The standard patent expiration date for the U.S. patents in this family is September 28, 2028.

A fourth patent family owned by us is directed to methods for determining a measure of the concentration of analyte molecules or particles in a fluid sample, and in particular to methods for determining concentration using multiple binding ligands for the same analyte molecule. This patent family includes one granted U.S. patent. The standard patent expiration date for the U.S. patent in this family is March 24, 2030.

A fifth patent family owned by us is directed to instruments and consumables. This patent family includes two granted U.S. patents and one pending U.S. patent application, one granted European patent (nationalized and active in eleven countries) and one pending European patent application, two granted Japanese patents, one granted Chinese patent and one pending Chinese patent applications, one registered Hong Kong patent application, and one granted

Canadian patent. The standard patent expiration date for the U.S. patents in this family is February 25, 2031, and for any non-U.S. patents is January 27, 2032.

A sixth patent family owned by us is directed to methods and materials for covalently associating a molecular species with a surface. This patent family includes one pending U.S. patent application. The standard patent expiration date for any U.S. patents that may issue from this family is May 9, 2034.

A seventh patent family owned by us is directed to methods for improving the accuracy of capture based assays. This patent family includes one pending U.S. patent application. The standard patent expiration date for any U.S. patents that may issue from this family is January 13, 2036.

An eighth patent family owned by us is directed to methods and systems for reducing and/or preventing signal decay. This patent family includes one pending U.S. patent application. The standard patent expiration date for any U.S. patents that may issue from this family is September 20, 2038.

A ninth patent family owned by us is directed to methods and systems for highly sensitive assays, including methods and systems for improving capture object loading efficiency and/or use of low numbers of capture objects in assays. This patent family includes one pending U.S. patent application, one pending European patent application, one pending Japanese patent application, one pending Chinese patent application, and one pending Canadian patent application. The standard patent expiration date for any patents that may issue from this family is April 14, 2041.

In addition to the nine patent families described above, we own or co-own nine additional patent families directed to the measurement of particular types of analytes, including β-amyloid peptide, tau protein, toxin B of *C. difficile*, neurofilament light, glial fibrillary acidic protein, ubiquitin carboxyl-terminal hydrolase L1, antigens from infectious organisms such as viruses (e.g., coronaviruses), and DNA or RNA molecules. Among the granted patents and pending patent applications in these nine families are two granted U.S. patents directed to methods for determining treatment protocols and/or a prognosis of a patient's recovery from a brain injury based on measurements of tau protein in blood and one granted U.S. patent and one granted European patent (nationalized and active in three countries) directed to detection of *C. difficile*. Any patents that may issue from these patent applications would have standard expiration dates between 2032 and 2041.

With the acquisition of Aushon in January 2018, we acquired their patent portfolio for our planar array technology. As of March 1, 2023, the acquired patent portfolio includes at least ten issued U.S. patents and one pending U.S. patent application, one granted Canadian patent, and two granted European patents (nationalized and active in eight countries).

We have licensed additional patents and patent applications from third parties. These include a portfolio of patent filings we licensed from Harvard University directed to additional single molecule assay technologies originated in the laboratory of Professor David Walt, who is the founder of Quanterix and a current member of our Board of Directors.

A first patent family exclusively licensed by us from Harvard University is directed to assays that provide digital measurement methods to detect proteins and other biomolecules, e.g., at low- to mid-attomolar concentrations. This patent family includes one pending International Patent Application. The standard patent expiration date for any patents that may issue from this family is June 22, 2041.

A second patent family exclusively licensed by us from Harvard University is directed to single molecule assays for ultrasensitive detection of analytes. The standard patent expiration date for any patents that may issue from this family will be in 2042.

A third patent family exclusively licensed by us from Harvard University is directed to high-sensitivity methods for detection and quantification of target analytes in liquid samples (e.g., biological or environmental samples). The standard patent expiration date for any patents that may issue from this family is August 15, 2039.

A fourth patent family non-exclusively licensed by us from Harvard University is directed to methods and compositions to detect *Mycobacterium tuberculosis* antigens, e.g., lipoarabinomannan (LAM) and/or Ag85B (Rv1886c), in a sample (e.g., a human urine sample) for diagnosis of tuberculosis. The standard patent expiration date for any patents that may issue from this family is December 17, 2040.

In addition to pursuing patents on our technology, we have taken 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.

License Agreement with Tufts University

In June 2007, as amended in April 2013, August 2017, and September 2020, we entered into a license agreement with Tufts, pursuant to which we obtained an exclusive, worldwide license to research, develop, commercialize, use, make, or have made, import or have imported, distribute or have distributed, offer or have offered, and sell or have sold products and services covered by patent rights to the Simoa bead-based technology owned by Tufts, as well as a non-exclusive license to related know-how. The rights licensed to us are for all fields of use and are sublicensable for a fee.

Under the terms of the agreement, as amended, we paid a one-time, non-refundable upfront fee and issued Tufts shares of our common stock. In addition, in connection with the April 2013 amendment, we issued Tufts shares of our Series C-1 Preferred Stock, which converted into shares of our common stock in connection with our initial public offering. We are required to pay Tufts low single-digit royalties on all net sales of products and services that use the licensed technology, as well as a portion of any sublicensing revenues. We are also obligated to pay annual maintenance fees, which are fully creditable against any royalty payments made by us, and a milestone payment upon any sublicense by us. We were also required to reimburse Tufts for all patent prosecution cost incurred prior to the agreement and for all future patent prosecution costs.

The term of the license agreement will continue on a country-by-country basis so long as there is a valid claim of a licensed patent in such country. Tufts may terminate the agreement or convert to a non-exclusive license in the event (1) we fail to pay any undisputed amount when required and fail to cure such non-payment within 60 days after receipt of notice from Tufts, (2) we are in breach of any material provision of the agreement and fail to remedy such breach within 60 days after receipt of notice from Tufts, (3) we do not demonstrate diligent efforts to develop a product incorporating the licensed technology, (4) we are found on five separate audits to have underpaid pursuant to the terms of the agreement, (5) we cease to carry on the business related to the licensed technology either directly or indirectly, or (6) we are adjudged insolvent, make an assignment for the benefit of creditors or have a petition in bankruptcy filed for or against us that is not removed within 60 days. We may terminate the agreement at any time upon at least 60 days' written notice. Upon termination of the agreement, all rights revert to Tufts.

Government Regulation

The majority of our products are currently intended for research use only (RUO) applications, although our customers may use our products to develop their own products that are subject to regulation by the FDA or the Center for Medicare & Medicaid Services (CMS). Although most in vitro diagnostic products intended for RUO are not currently required to obtain premarket clearance or approval by the FDA, products labeled as RUO are subject to the FDA's premarket review requirements if they are determined to be intended for use for clinical rather than research purposes. Consequently, other than our two laboratory developed tests intended for clinical testing, our products are labeled and intended "For Research Use Only. Not for Diagnostic Procedures."

The FDA has issued Final Guidance for Industry and Food and Drug Administration Staff on "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only" (the RUO/IUO Guidance). The purpose of an FDA guidance document is to provide the FDA's current thinking on when IVD products are properly labeled for RUO or for investigational use only (IUO) and when products labeled RUO or IUO will be viewed by the FDA as intended for clinical use, but as with all FDA guidance documents, this guidance does not establish legally enforceable responsibilities and should be viewed as recommendations unless specific regulatory or statutory

requirements are cited. The RUO/IUO Guidance explains that the FDA will review the totality of the circumstances when evaluating whether equipment and testing components are properly labeled as RUO. Merely including a labeling statement that a product is intended for research use only will not necessarily exempt the device from the FDA's premarket notification and clearance process (510(k)), premarket approval, or other requirements, if the circumstances surrounding the distribution of the product indicate that the manufacturer intends its product to be used for clinical diagnostic use. These circumstances may include written or verbal marketing claims or links to articles regarding a product's performance in clinical applications, a manufacturer's provision of technical support for clinical validation or clinical applications, or solicitation of business from clinical laboratories, all of which could be considered evidence of intended uses that conflict with RUO labeling. Although the RUO/IUO Guidance was not intended as a compliance requirement, we believe that our labeling and promotion of our products, including the custom assay RUO products developed by the Accelerator Laboratory, is consistent with the RUO/IUO Guidance because we have not promoted our products for clinical use in humans.

IVD tests intended for clinical diagnostic use are regulated by the FDA as medical devices, however, the FDA has traditionally not regulated certain laboratory tests referred to as laboratory developed tests (LDTs) (as discussed further below). The FDA defines a medical device in part as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article which is intended for the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease in man. This means that the FDA will regulate the development, testing, manufacturing, marketing, post-market surveillance, distribution, advertising and labeling of our clinical IVD devices (other than our LDTs) and we will be required to register as a medical device manufacturer and list our marketed products.

The FDA classifies medical devices into one of three classes on the basis of the intended use of the device, the risk associated with the use of the device for that indication, as determined by the FDA, and on the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices, which have the lowest level of risk associated with them, are subject to general controls. Class II devices are subject to general controls and special controls, including performance standards and guidance documents setting out labeling and testing requirements. Class III devices, which have the highest level of risk associated with them, are subject to general controls and premarket approval, including any conditions imposed as part of the approval. Most Class I devices and some Class II devices are exempt from a requirement that the manufacturer submit a premarket notification (510(k)) and receive clearance from the FDA, which is otherwise a premarketing requirement for Class I and Class II devices that are not exempt. Class III devices may not be commercialized until a premarket approval application (PMA) is submitted to and approved by the FDA. Novel devices that have not been classified require either approval of a PMA or FDA review of a de novo classification request before they can be marketed.

510(k) Clearance Pathway

To obtain 510(k) clearance for Class I and Class II devices that are not exempt, a sponsor must submit to the FDA a premarket notification demonstrating that the device is substantially equivalent (SE) to a predicate device legally marketed in the U.S. for which a PMA was not required. Substantial equivalence means that the device has the same intended use as the predicate device and either (a) has the same technological characteristics as the predicate device or (b) has different technological characteristics but does not raise difference questions of safety and effectiveness and information in the premarket notification demonstrates the device is as safe and effective as the predicate. The FDA is supposed to make a SE determination within 90 days of the FDA's receipt of the 510(k), but it often takes longer if the FDA requests additional information. Most 510(k)s do not require supporting data from clinical trials, but the FDA may request such data. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or possibly a pre-market approval.

Premarket Approval Pathway

A PMA must be submitted if a new device cannot be cleared through the 510(k) process. The PMA process is generally more complex, costly and time consuming than the 510(k) process. A PMA must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the

FDA's satisfaction a reasonable assurance that the device is safe and effective for its intended use. After a PMA is sufficiently complete, the FDA will accept the application for filing and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the accepted application, although review of the application generally can take between one and three years. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. Although the FDA is not bound by the advisory panel decision, the panel's recommendations are important to the FDA's overall decision making process. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with its quality system regulations (QSRs). New premarket approval applications or premarket approval application supplements are also required for product modifications that affect the safety and efficacy of the device.

De Novo Classification

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose.

However, a de novo classification request allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the de novo classification request, but the review often takes longer if the FDA requests additional information. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

Emergency Use Authorization

In emergency situations, such as a pandemic, the FDA has the authority to allow unapproved medical products or unapproved uses of cleared or approved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear warfare threat agents when there are no adequate, approved, and available alternatives.

Under this authority, the FDA may issue an emergency use authorization (EUA) for an unapproved device if the following four statutory criteria have been met: (1) a serious or life-threatening condition exists; (2) evidence of effectiveness of the device exists; (3) a risk-benefit analysis shows that the benefits of the product outweigh the risks; and (4) no other alternatives exist for diagnosing, preventing or treating the disease or condition. Evidence of effectiveness includes medical devices that "may be effective" to prevent, diagnose, or treat the disease or condition identified in a declaration of emergency issued by the Secretary of the Department of Health and Human Services (HHS). The "may be effective" standard for EUAs requires a lower level of evidence than the "effectiveness" standard that FDA uses for product approvals in non-emergency situations. The FDA assesses the potential effectiveness of a possible EUA product on a case-by-case basis using a risk-benefit analysis. In determining whether the known and potential benefits of the product outweigh the known and potential risks, the FDA examines the totality of the scientific evidence to make an overall risk-benefit determination. Such evidence, which could arise from a variety of sources, may include (but is not limited to) results of domestic and foreign clinical trials, *in vivo* efficacy data from animal models, *in vitro* data, as well as the quality and quantity of the available evidence.

Once granted, an EUA will remain in effect and generally terminate on the earlier of (1) the determination by the Secretary of HHS that the public health emergency has ceased or (2) a change in the approval status of the product such that the authorized use(s) of the product are no longer unapproved. After the EUA is no longer valid, the product is no longer considered to be legally marketed and one of the FDA's non-emergency premarket pathways would be necessary to resume or continue distribution of the subject product.

The FDA also may revise or revoke an EUA if the circumstances justifying its issuance no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect the public health or safety.

Clinical Trials

Clinical trials are usually required to support a PMA and are sometimes required for a 510(k) or a de novo classification request. In the U.S., if the device is determined to present a "significant risk," the manufacturer may not begin a clinical trial until it submits an investigational device exemption (IDE) application and obtains approval of the IDE from the FDA. Non-significant risk device studies do not require FDA approval of an IDE application. Both significant risk and non-significant risk clinical trials are also subject to the review, approval and oversight of an institutional review board (IRB). The clinical trials must be conducted in accordance with the FDA's IDE regulations and good clinical practices. A clinical trial may be suspended by the FDA, the sponsor or an IRB at its institution at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the trial. Even if a clinical trial is completed, the results may not demonstrate the safety and efficacy of a device to the satisfaction of the FDA, or may be equivocal or otherwise not be sufficient to obtain approval of a device. Clinical trials are also subject to a requirement to submit certain information to the ClincialTrials.gov database maintained by the National Institutes of Health.

Breakthrough Device Designation

FDA Breakthrough Device designation is granted to certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal is to give patients and doctors timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval. The Breakthrough Devices Program offers device companies an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help companies receive feedback from the FDA and identify areas of agreement in a timely way. Recipients may also receive prioritized review of their submission. Although Breakthrough Device designation or access to any other expedited program may expedite the development or clearance/authorization/approval process, it is not guaranteed to do so, and, more importantly, it does not change the standards for clearance/authorization/approval. Designation for any expedited review procedure does not ensure that we will ultimately obtain regulatory clearance or approval for such product.

FDA Enforcement

After a medical device is placed on the market, numerous regulatory requirements apply. These include among other things:

- establishment registration and device listing;
- the QSR, which requires manufacturers, including third-party contract manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

- labeling regulations and the FDA prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses and other requirements related to promotional activities;

- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury, or if their device malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;

- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the Federal Food, Drug, and Cosmetics Act that may present a risk to health; and

- post market surveillance regulations, which apply to certain Class II or III devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include sanctions, including but not limited to, warning letters; fines, injunctions, consent decrees and civil penalties; recall or seizure of the device; operating restrictions, partial suspension or total shutdown of production; refusal to grant PMA approvals of new devices; withdrawal of PMA approvals; and civil or criminal prosecution.

Clinical Laboratory Improvement Amendments of 1988, Regulation of LDTs and State Regulation

We own and operate a CLIA-certified laboratory. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) are federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States (with the exception of research testing that does not report patient specific results). A clinical laboratory is defined by CLIA as any facility that performs laboratory testing on specimens obtained from humans 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. CLIA requires such laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification also is a prerequisite to be eligible to bill state and federal health care programs, as well as many private insurers, for laboratory testing services.

In addition, CLIA requires certified laboratories to enroll in an approved proficiency testing program for each of the specialties and subspecialties for which it is certified. If a laboratory fails to achieve a passing score on a proficiency test, then its CLIA certificate may be suspended, limited or revoked, or other sanctions may be imposed.

As a condition of CLIA certification, laboratories are subject to survey and inspection every other year (except laboratories with only a certificate of waiver or certificate of provider-performed microscopy procedures are not subject to biennial inspections), in addition to being subject to additional random inspections. The biennial survey is conducted by CMS, a CMS agent (typically a state agency), or a CMS-approved accreditation organization.

High complexity, CLIA-certified laboratories, such as ours, frequently develop testing procedures to provide diagnostic results to customers. These tests have been traditionally offered by high-complexity laboratories for the last few decades as LDTs, the validation and performance of which are subject to CMS oversight through its enforcement of CLIA. The FDA also has claimed that it has regulatory authority over LDTs under the agency's medical device authorities, but has not exercised enforcement with respect to most LDTs offered by high complexity laboratories, and not sought to require these laboratories to comply with FDA regulations regarding medical devices. In 2010, the FDA announced that it had decided to exercise regulatory authority over these LDTs, and that it planned to issue guidance to the industry regarding its regulatory approach. At that time, the FDA indicated that it would use a risk-based approach to regulation and would direct more resources to tests with wider distribution and with the highest risk of injury, but that it would be sensitive to the need to not adversely impact patient care or innovation. To date, the FDA has not issued such guidance, and has indicated that Congress should enact legislation to address improved oversight of diagnostics,

including LDTs, rather than the FDA addressing the issue through administrative proposals. However, FDA has increased its oversight of what it perceived as especially high-risk LDTs, and in October 2018 the FDA issued a safety communication warning against the use of unapproved LDTs that describe relationships between gene variants and particular drugs (pharmacogenomic tests). FDA also regulated LDTs for Covid-19 under its EUA authority and related guidance. HHS initially issued a policy in August 2020 stating that FDA could not require premarket review (including EUAs) for LDTs. But this HHS policy was revoked in November 2021, reinstating FDA's prior approach for oversight of Covid-19 LDTs. Thus, while FDA generally exercises enforcement discretion for LDTs it continues to exercise oversight over certain high-risk tests. In addition, over the past several years, several bills to impose a new FDA regulatory framework with similarities to the current medical device framework for "in vitro clinical tests," which would include both in vitro diagnostics and LDTs, have been introduced. We cannot predict the ultimate timing or form of any such legislation or future FDA guidance or regulation or their potential impact. Any new regulatory approach for LDTs by the FDA, whether through legislation or regulation, would likely lead to an increased regulatory burden, including additional costs and delays in introducing new tests. While the ultimate impact of any changes to the FDA's current approach is unknown, it may be extensive and may result in significant change.

In addition, some states require that any laboratory be licensed by the appropriate state agency in the state in which it operates. Laboratories must also hold state licenses or permits, as applicable, from various states including, but not limited to, California, New York, Pennsylvania, Rhode Island and Maryland, to the extent that they accept specimens from one or more of these states, each of which requires out-of-state laboratories to obtain licensure.

If a laboratory is out of compliance with state laws or regulations governing licensed laboratories or with CLIA, it may be subject to enforcement actions that may include suspension, limitation or revocation of the license or CLIA certificate, assessment of financial penalties or fines, or imprisonment. Loss of a laboratory's CLIA certificate or state license may also result in the inability to receive payments from state and federal health care programs as well as private third-party payors.

When we perform clinical diagnostic testing, we are subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as well as additional federal and state laws that impose a variety of fraud and abuse prohibitions on healthcare providers, including clinical laboratories.

Europe/Rest of World Government Regulation

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of our product for clinical diagnostic use in those countries. The regulations in other jurisdictions vary from those in the U.S. and may be easier or more difficult to satisfy and are subject to change. For example, in the European Union (the E.U.) new regulations recently entered into force that introduce greater regulation of medical devices and IVDs. The new IVD regulation (the IVD Regulation) is significantly different from the 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 the Nf-L ELISA assay kit of our subsidiary Uman 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 Nf-L ELISA assay kit 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. 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. When all requirements are met, a notified body will be contacted, and the certification initiated.

The NF-light Serum ELISA is currently sold only as a RUO product (not intended for diagnostic use). Work is on-going to prepare a technical file compliant with the IVD Regulation for this product as well.

Other Governmental Regulation

Privacy and Data Security Laws and Regulations

As a business with a global footprint, compliance with evolving regulations and standards in privacy and data security has resulted, and may continue to result, in increased costs, new compliance challenges, and the threat of increased regulatory enforcement activity. Our business relies on the secure electronic transmission, storage and hosting of sensitive information, including personal information, protected health information, financial information, intellectual property and other sensitive information related to our customers and workforce.

For example, in the U.S., the collection, maintenance, protection, use, transmission, disclosure and disposal of certain personal information and the security of medical devices are regulated at the U.S. federal and state, international and industry levels. U.S. federal and state laws protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by health care providers. Privacy and Security Rules under HIPAA, as amended, and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), govern the use, disclosure, and security of protected health information by "Covered Entities," (which are health care providers that submit electronic claims, health plans, and health care clearinghouses) and by their "Business Associates" (which is anyone that performs a service on behalf of a Covered Entity involving the use or disclosure of protected health information and is not a member of the Covered Entity's workforce). Rules under HIPAA and HITECH include specific security standards and breach notification requirements. HHS (through the Office of Civil Rights) has direct civil enforcement authority against Covered Entities and Business Associates with regard to both the Security and Privacy Rules. The U.S. Department of Justice has criminal enforcement authority against Covered Entities, Business Associates, and certain other entities and individuals. In addition, State Attorneys General may being enforcement actions under HIPAA. Generally Quanterix is not a Covered Entity, however, we may operate as a Business Associate to Covered Entities under certain circumstances.

In addition to the regulation of personal health information, a number of states have also adopted laws and regulations that may affect our privacy and data security practices for other kinds of personally identifiable information, such as state laws that govern the use, disclosure and protection of sensitive personal information, such as Social Security numbers, or that are designed to protect credit card account data. State consumer protection laws may also establish privacy and security standards for use and management of personally identifiable information, including information related to consumers and care providers.

Outside the U.S., we are impacted by the privacy and data security requirements at the international, national and regional level, and on an industry specific basis. Legal requirements in foreign countries relating to the collection, storage, handling and transfer of personal data and potentially intellectual property continue to evolve with increasingly strict enforcement regimes. More privacy and security laws and regulations are being adopted, and more are being enforced, with potential for significant financial penalties. In the E.U., stringent data protection and privacy rules which substantially impact the use of patient data across the healthcare industry became effective in May 2018. The E.U. General Data Protection Regulation (GDPR) applies uniformly across the E.U. and includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances and significant fines for non-compliance. The GDPR also requires companies processing personal data of individuals residing in the E.U. to comply with E.U. privacy and data protection rules.

Because the laws and regulations continue to expand, differ from jurisdiction to jurisdiction, and are subject to evolving (and at times inconsistent) governmental interpretation, compliance with these laws and regulations may require significant additional expenditures or changes in products or business that increase competition or reduce revenue. Noncompliance could result in the imposition of fines, penalties, or orders to stop noncompliant activities.

Environmental Health and Safety Laws

We are subject to federal, state, and local laws and regulations related to the protection of the environment, the health and safety of employees and the handling, transportation, storage and disposal of medical specimens, infectious and hazardous waste and radioactive materials. For example, the U.S. Occupational Safety and Health Administration (OSHA), has established extensive requirements relating specifically to workplace safety for healthcare employers in the U.S. This includes requirements to develop and implement multi-faceted programs to protect workers from exposure to blood-borne pathogens, including preventing or minimizing any exposure through needle stick injuries. OSHA also regulates the use of hazardous chemicals in the workplace. Likewise, we are subject to EPA and state requirements relating to the management and disposal of hazardous waste, and state requirements relating to the disposal of regulated medical waste. For purposes of transportation, some biological materials and laboratory supplies are classified as hazardous materials and are subject to regulation by one or more of the following agencies: the U.S. Department of Transportation, the U.S. Public Health Service, the United States Postal Service and the International Air Transport Association. We generally use third-party vendors to dispose of regulated medical waste, hazardous waste and radioactive materials that we may use during our research.

Employees and Human Capital

As of December 31, 2022, we had 370 full-time employees, of which 125 work in sales, sales support, field service, and marketing, 85 work in engineering and research and development, 104 work in manufacturing and operations and 56 work in general and administration. Of our 370 full-time employees, 309 were located in the United States and 61 were located in 11 foreign countries. None of our employees are represented by a labor union or subject to a collective bargaining agreement. We have a unique culture that stresses the impact our work has on the eradication of human diseases. We invest in creating a diverse, inclusive and safe work environment where our employees can deliver their workplace best every day.

Our success depends upon our ability to attract and retain highly qualified management and technical employees. Talent management is critical to our ability to execute our long-term growth strategy, and we seek to cultivate a superior pool of talent by providing career growth, on-the-job learning opportunities and competitive compensation. We are committed to an inclusive culture which values equality, opportunity and respect. In support of our inclusive culture, we sponsor an internal Diversity, Equity and Inclusion Committee comprised of employees and executives, provide respectful workplace training to strengthen employee understanding and consciously strive to recruit a diverse talent pool across all levels of the organization. As of December 31, 2022, approximately 44% of our employees were women and approximately 36% were non-white.

Workforce Compensation and Pay Equity

We provide robust compensation and benefits programs to help meet the needs of our employees. We provide our full-time employees with highly competitive salaries, as well a bonus and/or commission plan, a matching 401(k) Plan, healthcare and insurance benefits, paid time off and family leave. We also provide all of our employees with targeted equity-based grants with vesting conditions designed to facilitate retention through the opportunity to benefit financially from our growth and profitability.

Company Culture

We expect all of our employees and contractors to observe the highest levels of business ethics, integrity, mutual respect, tolerance and inclusivity. Our employee handbook and Corporate Code of Conduct and Ethics set forth policies reflecting these values and also provide direction for registering complaints in the event of any violation of our policies. An “open door” policy is maintained at all levels of the organization, and any form of retaliation against an employee is strictly prohibited.

Employee Engagement and Wellness

The success of our business is fundamentally connected to the physical and mental well-being of our people. Accordingly, we are committed to the health, safety and wellness of our employees and contractors. We provide our

employees with a wide range of benefits, including benefits directed to their health, safety and long-term financial security.

Corporate Information

We were incorporated under the laws of the State of Delaware in April 2007 under the name "Digital Genomics, Inc." In August 2007, we changed our name to "Quanterix Corporation." Our principal executive offices are located at 900 Middlesex Turnpike, Billerica, Massachusetts 01821, and our telephone number is (617) 301-9400.

Information Available on the Internet

Our Internet website address is *www.quanterix.com*. The information contained on, or that can be accessed through, our website is not a part of or incorporated by reference in this Annual Report on Form 10-K. We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference. We make available free of charge through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (Exchange Act). We make these reports available through the "Investors—Financial Information—SEC Filings" section of our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the SEC. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. Our electronically filed reports and other information that we file with the SEC can be viewed on the SEC's website at *http://www.sec.gov*.

Item 1A. RISK FACTORS

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page ii of this Annual Report on Form 10-K for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risk Factor Summary

Our business is subject to numerous risks and uncertainties. The following summary highlights some of the risks to be considered with respect to our business and prospects. This summary is not complete and the risks summarized below are not the only risks we face. Readers should review and carefully consider the risks and uncertainties described in more detail below, which includes a more complete discussion of these risks.

- 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.
- 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.
- If our products fail to achieve and sustain sufficient market acceptance, our revenue will be adversely affected.
- Sales of our assays for neurological indications have become increasingly important to our business, and any significant decrease in sales of such assays could have a material adverse effect on our business.

- We may fail to achieve the intended cost savings, revenue improvement, and related benefits from our Restructuring Plan.
- We may not be able to obtain the anticipated product and quality-related benefits from our assay improvement program.
- Failure to remediate a material weakness in, or inherent limitations associated with, our internal accounting controls could result in material misstatements in our financial statements.
- Because a significant portion of our revenue comes from a few large customers, any significant decrease in sales to these customers, due to industry consolidation or otherwise, could harm our operating results.
- Our long-term results depend upon our ability to improve existing products, develop or acquire new technology, and develop, introduce and market new products successfully.
- If defects are discovered in our products, we may incur additional unforeseen costs, our products may be subject to recalls, customers may not purchase our products, our reputation may suffer, and ultimately our sales and operating earnings could be negatively affected.
- We may seek to enter into strategic collaborations and licensing arrangements with third parties, but we may not be successful in establishing or maintaining such arrangements.
- We generate a substantial portion of our revenue internationally and we expect this will continue in the future; as a result, our business is subject to various risks relating to our international activities, which could adversely affect our business, operating results and financial condition.
- We rely on a single contract manufacturer to manufacture and supply our Simoa HD-X instrument and rely on a different single contract manufacturer to manufacture and supply our Simoa SR-X. If either of these manufacturers should fail to perform, or not perform satisfactorily, our ability to supply these instruments would be negatively and adversely affected.
- We rely on a limited number of suppliers or, in some cases, one supplier, for some of our materials and components used in our consumable products and our SP-X instrument, and we may not be able to find replacements or immediately transition to alternative suppliers if any of these suppliers fail to perform, which could have a material adverse effect on our business, financial condition, results of operations and reputation.
- Epidemic diseases, such as COVID-19 and its variants, and other events could negatively affect various aspects of our business, make it more difficult to meet our obligations to our customers and/or result in reduced demand from our customers, each of which could have a material adverse effect on our business, financial condition, results of operations or cash flows.
- If the FDA determines that our products are subject to regulation as medical devices or if we seek to market our products for clinical diagnostic or health screening use, we will be required to obtain regulatory clearance(s) or approval(s) and may be required to cease or limit sales of our then-marketed products, which could materially and adversely affect our business, financial condition and results of operations. Any such regulatory process would be expensive, time-consuming and uncertain both in timing and in outcome.
- 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.

- If we do not comply with governmental regulations applicable to our CLIA-certified laboratory, we may not be able to continue our operations or continue offering our LDTs.

- If we are unable to protect our intellectual property, our ability to maintain any technological or competitive advantage over our competitors and potential competitors may be reduced and our business may be harmed.

- If we or any of our partners are sued for infringing intellectual property rights of third parties, the resulting litigation would be costly and time-consuming, and an unfavorable outcome in that litigation could have a material adverse effect on our business.

- We may not be able to protect our intellectual property rights throughout the world, which could have a materially adverse effect on our business.

- Our stock price may fluctuate significantly.

Risks Related to Our Financial Condition

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 $96.7 million, $57.7 million and $31.5 million for the years ended December 31, 2022, 2021, and 2020, respectively. As of December 31, 2022, we had an accumulated deficit of $402.2 million. We cannot predict if or when we will achieve profitability or if or when we will be able to sustain such profitability once achieved. We expect that our losses will continue at least through the next 24 months as we continue to invest funds for technology development, including our assay redevelopment program designed to improve our ability to manufacture and deliver high-quality assays at scale and execute our strategy for our entry into translational pharma and clinical 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.

Our quarterly and annual operating results and cash flows have fluctuated in the past and might continue to fluctuate, which could cause the value of our common stock to fluctuate or decline significantly.

Numerous factors, many of which are outside of our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. These fluctuations may make financial planning and forecasting difficult. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. In addition, one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others. As a result, 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.

Our future capital needs are uncertain and we may need to raise additional funds in the future.

We believe that our existing cash and cash equivalents as of December 31, 2022, together with our cash generated from commercial sales, will enable us to fund our operating expenses and capital expenditure requirements for the foreseeable future. However, our future funding requirements will depend on many factors, including:

- continued market acceptance of our products and the ability of our products to meet our customers' expectations;

- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- the extent to which we achieve intended cost savings, revenue improvement and related benefits from our Restructuring Plan;
- the extent to which we are able to successfully complete our assay improvement program to enhance product quality;
- the cost of our research and development activities;
- our ability to enter into collaborations in the future, and the success of any such collaborations;
- potential opportunities to strategically acquire and integrate companies or technologies that may be complementary to our business;
- the cost and timing of potential regulatory clearances or approvals that may be required in the future for our products; and
- the effect of competing technological and market developments.

If we need additional capital in the future, we may not be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Future debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or equity financing may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could have a material adverse effect on our financial condition, operating results and business.

Failure to remediate a material weakness in, or inherent limitations associated with, internal accounting controls could result in material misstatements in our financial statements.

Our management has identified material weaknesses in our internal control over financial reporting related to the operating effectiveness of our internal controls associated with (i) the accounting for inventory, including excess and obsolescence reserves, (ii) the accounting for salary and commissions expense, (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, and (iv) the accounting for property and equipment, net. See “Item 9A. Controls and Procedures”. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company’s annual or interim financial statements will not be prevented or detected on a timely basis. As a result, management has concluded that, due to such material weaknesses, our disclosure controls and procedures were not effective as of December 31, 2022.

Our efforts to improve our internal controls are ongoing; however, there are inherent limitations in all control systems and no evaluation of controls can provide absolute assurance that all deficiencies have been detected. If we are unable to maintain effective internal control over financial reporting, or after having remediated such material weaknesses, fail 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 are currently implementing a plan intended to remediate the material weaknesses described above. The implementation of this plan could be costly and distract management from other activities. There can be no assurance that we will not conclude in the future that we have not effectively remediated these material weaknesses and they continue to exist or that we will not identify any significant deficiencies or other material weaknesses that will impair our ability to report our financial condition and results of operations accurately or on a timely basis.

Our ability to use net operating losses to offset future income may be subject to certain limitations.

As of December 31, 2022, we had federal net operating loss (NOLs) carryforwards to offset future taxable income of approximately $309.7 million, which begin to expire in 2026. A lack of future taxable income would adversely affect our ability to utilize these NOLs. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have already experienced ownership changes as defined under Section 382 of the Code. Depending on the timing of any future utilization of our NOLs, the amount that can be utilized each year may be limited as a result of such previous ownership changes. In addition, future changes in our stock ownership, including changes that may be outside of our control, could result in additional ownership changes under Section 382 of the Code. Our NOLs may also be impaired under similar provisions of state law. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Risks Related to Our Business

If our products fail to achieve and sustain sufficient market acceptance, our revenue will be adversely affected.

Our success depends on our ability to develop and market products that are recognized and accepted by our customers and potential customers as reliable, enabling and cost-effective. Continued market acceptance of our Simoa technology platform and products and other platforms and products we may develop in the future will depend on many factors, including our ability to convince potential customers that our technology is an attractive alternative to other available technologies. Historically, a significant part of our sales and marketing efforts has been directed at demonstrating the advantages of our technology to industry leaders and encouraging such leaders to publish or present their evaluation of our system. We also need to demonstrate to current and prospective customers that our products can help them accomplish their objectives in a cost-effective and efficient manner. If we are unable to continue to motivate leading researchers to use Simoa technology or other technologies we may develop, or if such researchers are unable to achieve or unwilling to publish or present significant experimental results using our systems, acceptance and adoption of our systems may be slowed and our ability to retain and grow our customer base and increase our revenue would be adversely affected.

Our future success is dependent upon our ability to retain and further penetrate our existing customer base and attract new customers.

Our success will depend upon our ability to successfully retain, respond to the evolving needs of, and increase our market share among, existing customers and add new customers. Identifying, cultivating, engaging and marketing to customers requires substantial time, expertise and expense and involves a number of risks, including that:

- we may not have the ability to attract, retain and manage the sales, marketing and service personnel necessary to expand market acceptance for our Simoa technology or other platforms we may develop in the future;
- the time and cost of maintaining and growing a specialized sales, marketing and service force may be better spent elsewhere; and
- our sales, marketing and service force may be unable to accomplish their goals.

We have utilized third parties to assist with sales, distribution and customer support in certain regions of the world. When we enter into such arrangements, there is no guarantee that we will be successful in attracting desirable sales and distribution partners. There is also no guarantee that we will be able to enter into such arrangements on favorable terms. Any failure of our sales and marketing efforts, or those of any third-party sales and distribution partners, would adversely affect our business.

Sales of our assays for neurological indications have become increasingly important to our business, and any significant decrease in sales of such assays could have a material adverse effect on our business.

Neurology has been one of our primary focus areas for commercialization of our Simoa technology and the services that we provide to our customers. Sales from neurological-related biomarkers have become an increasingly important part of our business. There can be no assurance that we will continue to derive meaningful revenues from the sale of our neurological products, from services related to neurodegenerative conditions or from sales of instruments driven by customers desiring access to our technology for work relating to neurological conditions. The adoption by our customers of competitive technologies for detecting biomarkers of neurodegenerative conditions could negatively impact our revenues and have a material adverse effect on our business.

We may fail to achieve the intended cost savings, revenue improvement, and related benefits from our Restructuring Plan.

In August 2022, we announced a plan of restructuring and strategic re-alignment, which included the elimination of 119 positions, or 25% of our workforce at the time, and other cost-savings measures (the Restructuring Plan). We incurred expenses of approximately $3.8 million related to the Restructuring Plan in the third and fourth quarter of 2022, substantially all of which were cash expenditures for severance and other costs relating to the Restructuring Plan. Overall, as a result of the Restructuring Plan we expect to realize estimated annualized operating expense savings of approximately $25 million. However, these estimates are subject to a number of assumptions, and actual results may differ. There is no guarantee that the Restructuring Plan will achieve its intended benefits. For example, our cost restructuring and business re-alignment efforts may not result in the anticipated savings or other economic benefits and could result in total costs and expenses that are greater than expected, each of which could have an adverse effect on our business. As part of the Restructuring Plan, we do not currently, nor do we intend to in the future, occupy the additional space acquired under the Bedford facilities lease agreement. We are reviewing our alternatives with respect to this space. These alternatives may include sub-leasing all, or a portion, of the Bedford facilities. We believe that the Billerica office, laboratory and manufacturing space will be sufficient to meet our needs for the foreseeable future. Refer to Note 12 to the consolidated financial statements for further details related to the Bedford lease. The Restructuring Plan may cause disruption to our business operations, and we may fail to effectively execute on the Restructuring.

We may not be able to obtain the anticipated product and quality-related benefits from our assay improvement program.

In connection with the Restructuring Plan, we have implemented an assay improvement program designed to improve our ability to manufacture and deliver high-quality assays at scale. We made initial progress toward this initiative in 2022, and we expect that the program will be completed in 2023. We may not be able to obtain the anticipated product and quality-related benefits from these efforts. Further, we may be delayed in completing this program. Delays in completing the assay improvement program or our inability to fully realize the anticipated product and quality-related benefits could materially and adversely affect our revenue and cash flows and could undermine customer confidence in our products and adversely affect our business.

The sales cycle for our Simoa instruments can be lengthy and variable, which makes it difficult for us to forecast revenue and other operating results.

The sales process for our Simoa instruments generally involves numerous interactions with multiple individuals within an organization, and often includes in-depth analysis by potential customers of our technology and products and a lengthy review process. Our customers' evaluation processes often involve a number of factors, many of which are

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. Given the length and uncertainty of our sales cycle, we have in the past experienced, and expect in the future to experience, fluctuations in our sales on a period-to-period basis. In addition, any failure to meet customer expectations could result in customers choosing to retain their existing systems, using existing assays not requiring capital equipment, or purchasing systems other than ours.

Because a significant portion of our revenue comes from a few large customers, any significant decrease in sales to these customers, due to industry consolidation or otherwise, could harm our operating results.

One customer accounted for 13% of our total revenue for the year ended December 31, 2022, and several other customers accounted for a significant portion of our total revenue. The loss of a significant amount of business from one or more of our major customers would have a material adverse effect on our business. There can be no assurance that there will not be a loss or reduction in business from one or more of our major customers. In addition, we cannot assure that net sales from customers that have accounted for significant net sales in the past, either individually or as a group, will reach or exceed historical levels in any future period.

Our long-term results depend upon our ability to improve existing products and introduce and market new products successfully.

We generally sell our products in industries that are characterized by rapid technological changes, frequent new product introductions and changing industry standards. Accordingly, our business is dependent on the continued improvement of our existing Simoa products and our development of new products utilizing Simoa or other technology we develop or acquire. As we introduce new products or refine, improve or upgrade versions of existing products, we cannot predict the level of market acceptance or the amount of market share these products will achieve, if any. We cannot guarantee that we will not experience material delays in the introduction of new products in the future. In addition, introducing new products could result in a decrease in revenues from our existing products. Consistent with our strategy of offering new products and product refinements, we have invested substantial capital on research and development, and we expect to continue to use a substantial amount of capital for product research and development. Our research and development initiatives can be costly and time-consuming, and they may fail to achieve the intended benefits. We may need more capital for product research and development than is available on terms favorable to us, if at all. If we do not develop new products and product enhancements based on technological innovation on a timely basis, our products may become obsolete over time and our revenues, cash flow, profitability and competitive position will suffer.

If defects are discovered in our products, we may incur additional unforeseen costs, our products may be subject to recalls, customers may not purchase our products, our reputation may suffer, and ultimately our sales and operating earnings could be negatively affected.

Our Simoa products are complex and may contain undetected errors or defects, especially when first introduced or as new versions or new products are released. New products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after commercial shipment. We continue to invest funds for technology development and quality assurance, including our assay redevelopment program, which is designed to improve our ability to manufacture and deliver high-quality assays at scale. However, there can be no assurance that we will be successful in our efforts to avoid our products containing undiscovered defects. Defects or errors in our products may discourage customers from purchasing our products. Disruptions affecting the introduction or release of, or other performance problems with, our products may damage our customers' businesses and could harm their and our reputation. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted or other significant customer relations problems may arise. We may also be subject to warranty and liability claims for damages related 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. 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.

We may seek to enter into additional strategic collaborations and licensing arrangements with third parties, but we may not be successful in establishing or maintaining such arrangements.

We may seek to enter into additional strategic collaborations and licensing agreements with third parties to develop products based on our Simoa technology, such as for certain IVD purposes. However, we may not be successful in doing so. Establishing collaborations and licensing arrangements is difficult and time-consuming, and discussions may not lead to collaborations or licenses on favorable terms, if at all. Even if we establish such relationships, if our partners do not prioritize and commit sufficient resources to develop and sell products based on our Simoa technology, such relationships may never result in the successful development or commercialization of products based on our Simoa technology.

Our reliance on distributors for sales of our products outside of the United States could limit or prevent us from selling our products and could impact our revenue.

We have established exclusive distribution agreements for our Simoa instruments and related consumable products within 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, 2022, 2021, and 2020, approximately 38%, 36% and 31%, respectively, of our total revenue was generated from customers located outside of North America. We believe that a substantial percentage of our future revenue will continue to come from international sources as we expand our overseas operations and develop opportunities in additional areas. Engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing U.S. or foreign regulatory requirements and laws;
- difficulties and costs of staffing and managing foreign operations;
- a shortage of high-quality salespeople and distributors;
- pricing pressure that we may experience internationally;

- difficulties in maintaining consistency with our internal guidelines;
- difficulties in enforcing our intellectual property rights and in defending against third-party threats and intellectual property enforcement actions against us or any of our distributors, suppliers or collaborators;
- reduced or varied protection for intellectual property rights in some countries;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act, data privacy requirements, such as the GDPR, labor laws and anti-competition regulations;
- export or import restrictions and supply chain disruptions;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- foreign currency exchange rate fluctuations;
- the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity;
- the impact of political and economic instability and conflict, which could lead to uncertainty and instability in global financial markets;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
- the imposition of new trade restrictions; and
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers.

Historically, most of our revenue has been denominated in U.S. dollars. In the future, we may sell our products and services in local currency outside of the United States. As our operations in countries outside of the United States grow, our results of operations and cash flows may be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. For example, if the value of the U.S. dollar increases relative to foreign currencies, in the absence of a corresponding change in local currency prices, our revenue could be adversely affected as we convert revenue from local currencies to U.S. dollars. If we dedicate significant resources to our international operations and are unable to manage these risks effectively, our business, operating results and financial condition will suffer.

We could be adversely affected by 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 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, as a result, we cannot guarantee that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. 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.

We rely on a single contract manufacturer to manufacture and supply our Simoa HD-X instrument and rely on a different single contract manufacturer to manufacture and supply our Simoa SR-X instrument. If either of these manufacturers should fail to perform, or not perform satisfactorily, our ability to supply these instruments would be negatively and adversely affected.

We currently rely on a single contract manufacturer, STRATEC, an analytical and diagnostic systems manufacturer located in Germany, to manufacture and supply all of our Simoa HD-X instruments. In addition, we currently rely on a single contract manufacturer, Paramit, a contract manufacturer located in California, to manufacture and supply all of our SR-X instruments. Since our contract with STRATEC does not commit them to supply quantities beyond the amounts included in our forecasts and our contract with Paramit does not commit them to carry inventory or make available any particular quantities, these contract manufacturers may give other customers' needs higher priority than ours, and we may not be able to obtain adequate supplies in a timely manner or on commercially reasonable terms. If either of these manufacturers were not able to supply instruments, our business would be harmed.

In the event it becomes necessary to utilize a different contract manufacturer for the HD-X instrument or the SR-X instrument, we would experience additional costs, delays and difficulties in doing so as a result of needing to identify and enter into an agreement with a new supplier as well as needing to prepare such new supplier to meet the logistical requirements associated with manufacturing our instruments, and our business would suffer. We may also experience additional costs and delays in the event we need access to or rights under any intellectual property of STRATEC.

In addition, certain of the components used in our instruments are sourced by these manufacturers from limited or sole suppliers. If they were to lose such suppliers, there can be no assurance that they would be able to identify or enter into agreements with alternative suppliers on a timely basis on acceptable terms, if at all. An interruption in our ability to sell and deliver instruments to customers could occur if our manufacturers encounter delays or difficulties in securing these components, or if the quality of the components supplied do not meet specifications, or if they cannot then obtain an acceptable substitute. If any of these events occur, our business and operating results could be harmed.

We rely on a limited number of suppliers or, in some cases, one supplier, for some of our materials and components used in our consumable products and services and our SP-X instrument, and we may not be able to find replacements or immediately transition to alternative suppliers if any of these suppliers fail to perform, which could have a material adverse effect on our business, financial condition, results of operations and reputation.

We rely on limited or sole suppliers for certain reagents and other materials and components that are used in our consumable products and services and in our SP-X instrument. While we have long-term contracts with some critical suppliers, we do not have contracts with all suppliers and instead rely on periodically forecasting our needs for such materials and entering into standard purchase orders with our suppliers. In addition, our use of many of the materials used in our consumable products is limited to research use only. As we expand into diagnostic applications for our products, we will need to secure diagnostic rights to such materials. If we were to lose suppliers or were unable to secure required rights for materials from suppliers, there can be no assurance that we will be able to identify or enter into

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.

Increased demand may cause us to experience delays in production or backlogs in deliveries that could limit the growth of our revenue or increase our losses.

A significant unforecasted increase in demand for our products may result in delays or shortfalls in our production and backlogs in deliveries. If we are unable to keep up with demand for our products, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors' products. Our inability to successfully manufacture our products would have a material adverse effect on our operating results.

The life sciences research and diagnostic markets are highly competitive. If we fail to effectively compete, our business, financial condition and operating results will suffer.

We face significant competition in the life sciences research and diagnostic markets. We currently compete with both established and early-stage companies that design, manufacture and market systems and consumable supplies. Many of our current competitors have competitive advantages over us, including:

- greater name and brand recognition;
- substantially greater financial and human resources;
- broader product lines;
- larger sales forces and more established distributor networks;
- more substantial intellectual property portfolios;
- larger and more established customer bases and relationships; and
- better established, larger scale and lower cost manufacturing capabilities.

We cannot guarantee that our products will compete favorably or that we will be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets. In addition, we cannot guarantee that our competitors do not have or will not develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

Integrating any business, product or technology we acquire can be expensive and time-consuming and can disrupt and adversely affect our ongoing business, including product sales, and distract our management.

We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses, such as our 2018 acquisition of Aushon and our 2019

acquisition of Uman. Our ability to successfully integrate any business, product or technology we acquire depends on a number of factors, including, but not limited to, our ability to:

- minimize the disruption and distraction of our management and other employees, including our sales force, in connection with the integration of any acquired business, product or technology;
- minimize disruption in relationships with customers, distributors or suppliers as a result of such a transaction;
- avoid acquisition of unanticipated liabilities related to acquired companies;
- maintain and increase sales of our existing products;
- establish or manage the transition of the manufacture and supply of any acquired product;
- identify and add the necessary sales, marketing, manufacturing, regulatory and other related personnel, capabilities and infrastructure that are required to successfully integrate any acquired business, product or technology;
- manage the transition and migration of acquired personnel and all commercial, financial, legal, regulatory and other pertinent information relating to any acquired business, product or technology;
- comply with legal, regulatory and contractual requirements applicable to any acquired business, product or technology; and
- maintain and extend intellectual property protection for any acquired product or technology.

If we are unable to perform the above functions or otherwise effectively integrate any acquired businesses, products or technologies, our business, financial condition and operating results will suffer.

Foreign acquisitions (such as our acquisition of Uman) involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

Epidemic diseases, such as COVID-19 and its variants, and other events could negatively affect various aspects of our business, make it more difficult to meet our obligations to our customers and/or result in reduced demand from our customers, each of which could have a material adverse effect on our business, financial condition, results of operations or cash flows.

Our business could be adversely affected by the effects of a widespread outbreak of contagious disease, such as COVID-19 and its variants, or as a result of natural disasters or other catastrophic events. Potential impacts to our business include disruptions to or restrictions on our employees' and customers' ability to travel, temporary closures of the facilities of our suppliers or customers, delays in installation of instruments and delays in shipments to and from affected countries. Any such travel restrictions and business closures could adversely impact our operations locally and worldwide, including our ability to manufacture, sell or distribute our products, as well as cause temporary closures of our foreign distributors, or the facilities of suppliers or customers. Any material disruption of our employees, distributors, suppliers or customers in impacted countries could impact our global sales and operating results. In addition, if any of these events adversely

affect the economies and financial markets of countries in which we sell our products and services, resulting in an economic downturn, demand for our products could be affected and could adversely impact our operating results.

Risks Related to Government Regulation and Diagnostic Product Reimbursement

If the FDA determines that our products are subject to regulation as medical devices or if we seek to market our products for clinical diagnostic or health screening use, we will be required to obtain regulatory clearance(s) or approval(s) and may be required to cease or limit sales of our then marketed products, which could materially and adversely affect our business, financial condition and results of operations. Any such regulatory process would be expensive, time-consuming and uncertain both in timing and in outcome.

We focused initially on the life sciences research market. This includes offering products for use by laboratories associated with academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies. Accordingly, the majority of our products are labeled as "Research Use Only". While we focused initially on the life sciences research market and RUO products only, our strategy includes expanding our product line to encompass products that are intended to be used for the diagnosis of disease, including LDTs and IVD devices, either alone or in collaboration with third parties. Other than our LDTs, such IVD products, once developed and offered, will be subject to regulation by the FDA, or comparable international agencies, as medical devices including requirements for regulatory clearance or approval of such products before they can be marketed.

The process of obtaining regulatory clearances to market a medical device can be costly and time consuming, and we or our collaborators may not be able to obtain these clearances or approvals on a timely basis, if at all. In general, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved PMA, unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other pre-amendment, 510(k)-exempt, 510(k) cleared products, or PMA-approved products that have subsequently been down-classified. If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is novel, it is automatically classified into Class III, and the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the de novo classification process. Pursuant to amendments to the statute in 2012, a manufacturer can also submit a petition for a direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

Class III devices, which are high risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products internationally for such uses, we may be subject to rigorous international regulation in the future. In these circumstances, we may rely significantly on our foreign independent distributors or collaborators to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

If we or our collaborators are required to obtain a PMA or 510(k) clearance for products based on our technology, we or they would be subject to a substantial number of additional requirements for medical devices, including establishment registration, device listing, QSRs —which cover the design, testing, production, control, quality assurance, labeling, packaging, servicing, sterilization (if required), and storage and shipping of medical devices (among other activities) —product labeling, advertising, recordkeeping, post-market surveillance, post-approval studies, adverse event reporting, and correction and removal (recall) regulations. One or more of the products we or a collaborator may develop using our technology may also require clinical trials in order to generate the data required for a PMA, de novo classification request or 510(k) premarket notification. Complying with these requirements may be time-consuming and

expensive. We or our collaborators may be required to expend significant resources to ensure ongoing compliance with the FDA regulations and/or take satisfactory corrective action in response to enforcement action, which may have a material adverse effect on the ability to design, develop, and commercialize products using our technology as planned. Failure to comply with these requirements may subject us or a collaborator to a range of enforcement actions, such as warning letters, injunctions, civil monetary penalties, criminal prosecution, recall and/or seizure of products, and revocation of marketing authorization, as well as significant adverse publicity. If we or our collaborators fail to obtain, or experience significant delays in obtaining, regulatory approvals for IVD products, such products may not be able to be launched or successfully commercialized in a timely manner, or at all.

LDTs are a subset of IVD tests that are offered as services by high complexity clinical laboratories and designed, manufactured and used within a single laboratory. In July 2022, we launched an LDT to quantitatively measure pTau-181 in plasma as an aid in diagnostic evaluation of Alzheimer's disease, and in January 2023, we launched an LDT to quantitatively measure NfL in serum as an aid in the evaluation of individuals for possible neurodegenerative conditions or other causes of neuronal or central nervous system damage. The FDA maintains that LDTs are medical devices and has for the most part exercised enforcement discretion for most LDTs, meaning that the FDA has not required LDTs to obtain premarket approval or clearance or comply with post-market medical device requirements. A significant change in the way that the FDA regulates any LDTs that we, our collaborators or our customers develop using our technology could affect our business. The FDA has considered the appropriate way to regulate such tests, but after publishing several draft guidances in 2014 and holding a number of public hearings and workshops, no final guidance has been issued, as the FDA indicated the agency would defer to a legislative approach. Congress has considered several bills that would have imposed a new FDA regulatory framework (with many similarities to the current device framework) for LDTs and IVD devices, but to date, has not passed such legislation. However, if Congress or the FDA requires laboratories to undergo premarket review and comply with other applicable FDA requirements in the future, the cost and time required to commercialize an LDT will increase substantially, and may reduce the financial incentive for laboratories to develop LDTs, which could reduce demand for our instruments and our other products. The FDA could also take enforcement action against us if it determines the tests we have currently launched as LDTs do not fall within the agency's definition of an LDT and therefore do not fall within the scope of the agency's enforcement discretion for LDTs.

Foreign jurisdictions have laws and regulations similar to those described above, which may adversely affect our ability to market our products as planned in such countries. The number and scope of these requirements are increasing. As in the United States, the cost and time required to comply with regulatory requirements may be substantial, and there is no guarantee that we will obtain the necessary authorization(s) required to make our products commercially viable. In addition, the imposition of foreign requirements may also have a material adverse effect on the commercial viability of our operations.

Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products, including RUO products, in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall 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. The FDA requires that certain recalls (including field corrections and removals) be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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 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. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Moreover, leadership, personnel and structural changes within the FDA as well as recent and future federal election outcomes could result in significant legislative and regulatory reforms impacting the FDA's regulation of our products. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

In addition, in the E.U. new regulations recently entered into force that result in greater regulation of medical devices and IVDs. The IVD Regulation is significantly different from the IVD Directive that it replaces in that it ensures that the new requirements apply uniformly and on the same schedule across the member states, includes a risk-based classification system and increases the requirements for conformity assessment. The CE registration for Uman's Nf-L ELISA assay kit for cerebral spinal fluid was approved in March 2014 under the IVD Directive. Under the IVD Directive the assay is classified as a general IVD product, class I and required self-certification with no involvement of a notified body/authority. The IVD Regulation introduces a new classification system for IVDs and assessment by a notified body is required for class B, C and D products. Uman's Nf-L ELISA assay kit for CSF is classified as a class B product and must fully comply with (and have a CE mark issued under) the IVD Regulation by May 2027. The new requirements include an ISO 13485 certification of the quality system (which Uman received July 2018) and increased technical evidence and follow-up of performance of the specific product (e.g. clinical evidence and post-market activities). The work to evaluate and to meet the new technical requirements is on-going.

In order to continue to sell our products in the E.U., we must maintain our CE marks and comply with the IVD Regulation. Our failure to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the European Economic Area (EEA) countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our notified body, which could impair our ability to market products in the EEA in the future. Any changes to the membership of the E.U., such as the departure of the United Kingdom, may impact the regulatory requirements for the impacted countries and impair our business operations and our ability to market products in such countries.

If we do not comply with governmental regulations applicable to our CLIA-certified laboratory, we may not be able to continue our Accelerator laboratory operations or continue offering our LDTs.

The operation of our CLIA-certified laboratory is subject to regulation by numerous federal, state and local governmental authorities in the United States. This laboratory holds a CLIA certificate of compliance and is licensed by the Commonwealth of Massachusetts and the State of Maryland, and we may obtain other state licenses if required in the future. Failure to comply with federal or state regulations or changes in those regulatory requirements could result in a substantial curtailment or even prohibition of the operations of our laboratory and could have an adverse effect on our business. CLIA is a federal law that regulates clinical laboratories that perform testing on 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. To maintain CLIA certification, laboratories are subject to survey and inspection every two years. Moreover, CLIA inspectors may make unannounced 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 could have a material adverse effect on our business.

We expect to rely on third parties in conducting any required future studies of diagnostic products that may be required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily.

We do not have the ability to independently conduct clinical trials or other studies that may be required to obtain FDA and other regulatory clearance or approval for future diagnostic products. Accordingly, we expect that we would rely on third parties, such as clinical investigators, contract research organizations, consultants, and collaborators to conduct such studies if needed. For example, we are currently working with the Alzheimer's Drug Discovery Foundation and the Global Alzheimer's Platform Foundation on prospective clinical trials for our assays. Our reliance on these third parties for clinical and other development activities would reduce our control over these activities. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised, we may not be able to obtain regulatory clearance or approval.

If diagnostic procedures that are enabled by our technology are subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, our business could be harmed.

The ability of us, our customers or our collaborators to commercialize diagnostic tests based on our technology, including our recently launched LDTs, will depend in part on the extent to which coverage and reimbursement for these tests will be available from government health programs, private health insurers and other third-party payors. In the United States, the principal decisions about reimbursement for new technologies are often made by CMS. Private payors often follow CMS's reimbursement policies to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payments for particular products and procedures. We cannot be sure that coverage will be available for any diagnostic tests based on our technology, and, if coverage is available, the level of reimbursement. Payor coverage and reimbursement decisions may impact the demand for those tests. If coverage is not available or the reimbursement amount is inadequate, any tests for which marketing authorization is received may not be able to be successfully commercialized.

Current and future legislation may increase the difficulty and cost to obtain marketing approval of and to commercialize any products based on our technology and affect the prices that may be obtained.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the ACA), is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. As a result, certain sections of the ACA have not been fully implemented or were effectively repealed. The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels and the number of insured individuals, may lead to uncertainty or delay in the purchasing decisions of our customers, which may in turn negatively affect our product sales. If there are not adequate reimbursement levels, our business and results of operations could be adversely affected.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we or our collaborators will receive for any cleared or approved product. Any reduction in payments from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare

reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any of our products for which we receive marketing approval.

In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. Any such initiatives may result in decreased profits to us, lower reimbursements by payors for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

Risks Related to Our 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 and detective security controls and seek to enhance such controls by, for example, augmenting the monitoring and alerting functions, network design, and automatic countermeasure operations of our technical systems. We also periodically assess the adequacy of our hardware and systems and are planning to upgrade hardware and systems where appropriate. These information technology and telecommunications systems support a variety of functions, including manufacturing operations, quality control, customer service support, finance and other general administrative activities.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications, systems or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses, and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, those measures may be inadequate and failures or significant downtime of our information technology or telecommunications systems or those used by our third-party suppliers could prevent us from operating our business and managing the administrative aspects of our business. Loss of data or a material delay in our access to our data due to a security breach or other interruption could also prevent us from operating our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business.

Cybersecurity breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, and intellectual property and proprietary business information owned or controlled by ourselves or our customers. This data encompasses a wide variety of business-critical information including research and development information, operational information, commercial information, and business and financial information. We face four primary risks relative to protecting this critical information: loss of access; inappropriate disclosure; inappropriate modification; and inadequate monitoring of our controls over the first three risks.

The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses, breaches, interruptions due to employee error, malfeasance, faulty password management, lapses in compliance with privacy and security mandates, or other

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, there can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would 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. A significant cyber incident, including system failure, security breach, disruption by malware or other damage, could interrupt or delay our operations, result in a violation of applicable cybersecurity and privacy and other laws, damage our reputation, cause a loss of customers or expose sensitive customer data, or give rise to monetary fines and other penalties, which could be significant.

Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Third parties may attempt to fraudulently induce employees or other persons into disclosing usernames, passwords or other sensitive information, which may in turn be used to access our information systems, commit identity theft or carry out other unauthorized or illegal activities. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. We engage third-party vendors and service providers to store and otherwise process some of our data, including sensitive and personal information. Our vendors and service providers may also be the targets of the risks described above, including cyberattacks, malicious software, phishing schemes, and fraud. Our ability to monitor our vendors and service providers' data security is limited, and, in any event, third parties may be able to circumvent those security measures, resulting in the unauthorized access to, misuse, disclosure, loss or destruction of our data, including sensitive and personal information, and disruption of our or third-party service providers' systems. We and our third-party service providers may face difficulties in identifying, or promptly responding to, potential security breaches and other instances of unauthorized access to, or disclosure or other loss of, information. Any hacking or other attack on our or our third-party service providers' or vendors' systems, and any unauthorized access to, or disclosure or other loss of, information suffered by us or our third-party service providers or vendors, or the perception that any of these have occurred, could result in legal claims or proceedings, loss of intellectual property, liability under laws that protect the privacy of personal information, negative publicity, disruption of our operations and damage to our reputation, which could divert our management's attention from the operation of our business and materially and adversely affect our business, revenues and competitive position. Moreover, we may need to increase our efforts to train our personnel to detect and defend against cyber- or phishing-attacks, which are becoming more sophisticated and frequent, and we may need to implement additional protective measures to reduce the risk of potential security breaches, which could cause us to incur significant additional expenses.

Any such security breach or interruption, as well as any action by us or our employees or contractors that might be inconsistent with the rapidly evolving data privacy and security laws and regulations applicable within the United States and elsewhere where we conduct business, could result in enforcement actions by U.S. states, the U.S. federal government or foreign governments, liability or sanctions under data privacy laws that protect personally identifiable information, regulatory penalties, other legal proceedings such as but not limited to private litigation, the incurrence of significant remediation costs, disruptions to our development programs, business operations and collaborations, diversion of management efforts and damage to our reputation, which could harm our business and operations. Because of the rapidly moving nature of technology and the increasing sophistication of cybersecurity threats, our measures to prevent, respond to and minimize such risks may be unsuccessful.

In addition, our insurance may be insufficient to cover our losses resulting from cyber-attacks, breaches, or other interruptions, and any incidents may result in loss of, or increased costs of, such insurance. The successful assertion of one or more large claims against us that exceed available insurance coverage, the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, or denials of coverage, could have a material adverse effect on our business, including our financial condition, results of operations and reputation.

We are currently subject to, and may in the future become subject to additional, U.S. federal and state laws and regulations imposing obligations on how we collect, store and process personal information. Our actual or perceived failure to comply with such obligations could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our future customer base, and thereby decrease our revenue.

In the ordinary course of our business, we currently, and in the future will, collect, store, transfer, use or process sensitive data, including personally identifiable information of employees, and intellectual property and proprietary business information owned or controlled by ourselves and other parties. The secure processing, storage, maintenance, and transmission of this critical information are vital to our operations and business strategy. We are, and may increasingly become, subject to various laws and regulations, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate. The regulatory environment related to data privacy and security is increasingly rigorous, with new and constantly changing requirements applicable to our business, and enforcement practices are likely to remain uncertain for the foreseeable future. These laws and regulations may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may have a material adverse effect on our business, financial condition, results of operations and prospects.

In the United States, various federal and state regulators, including governmental agencies like the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the California Consumer Privacy Act (the CCPA), which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales 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 significantly expands the CCPA, including by introducing additional obligations such as data minimization and storage limitations and granting additional rights to consumers. In 2021, Virginia and Colorado both passed comprehensive state data privacy laws. In addition, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we would become subject if it is enacted. These and future laws and regulations may increase our compliance costs and potential liability.

Furthermore, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information (known as "protected health information") and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can require complex factual and statistical analyses and may be subject to changing interpretation. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the HIPAA, HITECH and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services, and for extensive breaches, notice may need to be made to the media. Such a notice could harm our reputation and our ability to compete.

In addition, the European Parliament and the Council of the E.U. adopted the GDPR in 2016 to replace the European Union Data Protection Directive and related country-specific legislation. The GDPR took effect in May 2018

and governs the collection and use of personal data in the E.U. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the E.U. to the United States, enhances enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the infringer, whichever is greater. While we have taken steps to comply with the GDPR, including reviewing our security procedures and entering into data processing agreements with relevant contractors, we cannot guarantee that our compliance efforts will be fully successful.

Further, unauthorized access, loss or dissemination of sensitive information could also disrupt our operations, including our ability to conduct research and development activities, process and prepare company financial information, manage various general and administrative aspects of our business, any of which could adversely affect our reputation and our business. In addition, there can be no assurance that we will promptly detect any such disruption or security breach, if at all. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our products could be delayed.

We face risks related to handling of hazardous materials and other regulations governing environmental, health and safety.

Our operations are subject to complex and stringent federal, state and local environmental, health, safety and other laws and regulations that both public officials and in some circumstances private individuals may seek to enforce. Our activities that are subject to these laws and regulations include, among other things, our use of hazardous materials and the generation, transportation, disposal and storage of waste. Although we have secured clearance from the EPA historically, and currently are operating in compliance with applicable EPA rules and regulations, our business could be adversely affected if we discover that we or an acquired business is not in material compliance with these rules and regulations. In the future, we may pursue the use of other surfactant substances that will require clearance from the EPA, and we may fail to obtain such clearance. Existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to us, whether retroactively or prospectively, that may have a negative effect on our business and results of operations. It is also impossible to eliminate completely the risk of accidental environmental contamination or injury to individuals. In such an event, we could be liable for any damages that result, which could adversely affect our business.

Risks Related to Intellectual 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.

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 been generated through the use of U.S. government funding and are therefore subject to certain federal regulations. For example, some of the issued U.S. patents we own and all of the intellectual property rights licensed to us under our license agreement with Tufts have been generated using U.S. government funds. As a result, the U.S. government has certain rights to intellectual property embodied in our current or future products pursuant to the Bayh-Dole Act of 1980 (the Bayh-Dole Act). These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if the government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government, elect title, and file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturing may limit our ability to license the applicable patent rights on an exclusive basis under certain circumstances.

If we enter into future arrangements involving government funding, and we make inventions as a result of such funding, intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh-Dole Act. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of certain of its rights could harm our competitive position, business, financial condition, results of operations and prospects.

Our Simoa bead-based technology is licensed to us by Tufts University. Any loss of our rights to this technology 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;
- making milestone payments;
- paying annual maintenance fees for the underlying patents;
- using commercially reasonable efforts to develop and sell a product using the licensed technology and developing a market for such product;
- paying and/or reimbursing fees related to prosecution, maintenance and enforcement of patent rights; and
- providing certain reports.

If we breach any of these obligations, Tufts may have the right to terminate the license, which could result in our being unable to develop, manufacture and sell products using our Simoa bead-based technology or a competitor gaining access to the Simoa technology. Termination of our license agreement with Tufts would have a material adverse effect on our business.

In addition, we are a party to a number of other agreements that include licenses to intellectual property, including non-exclusive licenses. We expect that we may need to enter into additional license agreements in the future. Our business could suffer materially and adversely, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

We may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our current or future products, and we cannot provide any assurances that we would be able to do so.

We may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our current or future products, and we cannot provide any assurances that third-party patents do not exist that might be enforced against our current or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. If we could not obtain a license, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation.

Licensing of intellectual property involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain the licensing arrangements on acceptable terms,

we may be unable to successfully develop and commercialize the affected product, or the dispute may have an adverse effect on our results of operation.

In addition to agreements pursuant to which we in-license intellectual property, we have in the past and expect in the future to grant licenses under our intellectual property. Like in-licenses, out-licenses are complex, and disputes may arise between us and our licensees. Moreover, our licensees may breach their obligations, or we may be exposed to liability due to our failure or alleged failure to satisfy our obligations. Any such occurrence could have an adverse effect on our business.

If we or any of our partners are sued for infringing intellectual property rights of third parties, the resulting litigation would be costly and time-consuming, and an unfavorable outcome in that litigation could have a material adverse effect on our business.

Our success also depends on our ability to develop, manufacture, market and sell our products and perform our services without infringing upon the proprietary rights of third parties. Numerous U.S.- and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we are developing products and services. As part of a business strategy to impede our successful commercialization and entry into new markets, competitors have claimed, and may claim in the future, that our products and/or services infringe their intellectual property rights and have suggested, and may suggest in the future, that we enter into license agreements. Any such claims made to date are, we believe, without merit.

Even if such claims are without merit, we could incur substantial costs and divert the attention of our management and technical personnel in defending ourselves against claims of infringement made by third parties or settling such claims. Any adverse ruling by a court or administrative body, or perception of an adverse ruling, may have a material adverse impact on our ability to conduct our business and our finances. Moreover, third parties making claims against us may be able to obtain injunctive relief against us, which could block our ability to offer one or more products or services and could result in a substantial award of damages against us. In addition, since we sometimes indemnify customers, collaborators or licensees, we may have additional liability in connection with any infringement or alleged infringement of third-party intellectual property.

Because patent applications can take many years to issue, there may be pending applications, some of which are unknown to us, that may result in issued patents upon which our products or proprietary technologies may infringe. Moreover, we may fail to identify issued patents of relevance or incorrectly conclude that an issued patent is invalid or not infringed by our technology or any of our products. There is a substantial amount of litigation involving patent and other intellectual property rights in our industry. If a third party claims that we or any of our licensors, customers or collaboration partners infringe upon a third party's intellectual property rights, we may have to:

- seek to obtain licenses that may not be available on commercially reasonable terms, if at all;
- abandon any infringing product or redesign our products or processes to avoid infringement;
- pay substantial damages including, in an exceptional case, treble damages and attorneys' fees, which we may have to pay if a court decides that the product or proprietary technology at issue infringes upon or violates the third-party's rights;
- pay substantial royalties or fees or grant cross-licenses to our technology; or
- defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

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, which can be expensive and time-consuming. An adverse result in any such litigation proceedings could put one or more of our patents at risk of being invalidated, found to be unenforceable or interpreted narrowly, and it could put our patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Many of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise any funds necessary to continue our operations, continue our internal research programs, in-license needed technology, or enter into development partnerships that would help us bring our products to market.

In addition, patent litigation can be very costly and time-consuming. An adverse outcome in such litigation or proceedings may expose us or any of our future development partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all.

Our issued patents could be found invalid or unenforceable if challenged in court, which could have a material adverse impact on our business.

If we or any of our partners were to initiate legal proceedings against a third party to enforce a patent covering one of our products or services, the defendant in such litigation could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement, or failure to claim patent eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO even outside of the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the challenged patent. Such a loss of patent protection would 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.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products.

Under the America Invents Act (the AIA), as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This requires us to be cognizant of the time from invention to the filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patent holder may file a patent infringement suit and provide additional opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our owned and in-licensed U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings, compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, such as *Impression Products, Inc. v. Lexmark International, Inc., Association for Molecular Pathology v. Myriad Genetics, Inc.*, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Alice Corporation Pty. Ltd. v. CLS Bank International*, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We use third-party software that may be difficult to replace or may cause errors or failures of our products that could lead to lost customers or harm to our reputation.

We use software licensed from third parties in our products. In the future, this software may not be available to us on commercially reasonable terms, or at all. Any loss of the right to use any of this software could result in delays in the production of our products until equivalent technology is either developed by us, or, if available, is identified, obtained and integrated, which could harm our business. In addition, any errors or defects in third-party software or other third-party software failures could result in errors, defects or cause our products to fail, which could harm our business and be costly to correct. Many of these providers attempt to impose limitations on their liability for such errors, defects or failures, and if enforceable, we may have additional liability to our customers or third-party providers that could harm our reputation and increase our operating costs.

We will need to maintain our relationships with third-party software providers and to obtain software from such providers that does not contain any errors or defects. Any failure to do so could adversely impact our ability to deliver reliable products to our customers and could harm our reputation and results of operations.

Risks Related to Our Common Stock and Being a Public Company

Our stock price has fluctuated significantly and may continue to fluctuate significantly.

The market price of shares of our common stock has been and could continue to be subject to wide fluctuations in response to many factors listed in this section, and others beyond our control, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- announcements by us, our partners or our competitors of new products, significant contracts, restructuring plans, strategic partnerships, joint ventures, collaborations, acquisitions, commercial relationships or capital commitments;
- competition from existing products or new products that may emerge;
- failure to meet or exceed financial estimates and projections of the investment community or that we may provide to the public;
- issuance of new or updated research or reports by securities analysts or recommendations with respect to our stock;
- positive or adverse regulatory announcements;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

- 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;
- any future sales of our common stock or other securities;
- any change to the composition of our board of directors or key personnel;
- general economic conditions and slow or negative growth of our markets;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional debt or equity financing efforts; and
- other factors described in this Risk Factors section of this Annual Report on Form 10-K.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and life science companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have on occasion instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to regularly publish reports on us, we could lose visibility in the public markets, which could cause our stock price or trading volume to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have not paid dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the shareholders in the foreseeable future. Consequently, in the foreseeable future, shareholders will likely only experience a gain from an investment in our common stock if the price of our common stock increases.

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 our board of directors. Our corporate governance documents include provisions:

- authorizing our board of directors 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 of directors may determine;
- specifying that special meetings of our stockholders can be called only by our board of directors 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 of directors;
- providing that directors may be removed only for cause;
- providing that our board of directors may create new directorships and that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- establishing that our board of directors is divided into three classes with each class serving staggered three-year terms;
- providing that our board of directors may amend our restated by-laws without stockholder approval; 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 Delaware General Corporation Law, which prevents some stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock.

Any provision of our restated certificate of incorporation, restated by-laws or Delaware law 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.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

We currently lease approximately 91,600 square feet of office, laboratory and manufacturing space at our headquarters in Billerica, Massachusetts. The premises covered by this lease serve as our principal office and laboratory space. The initial term of the Billerica lease is eleven years and five months beginning on April 1, 2019, and we have the option to extend the lease for two additional five-year periods. In addition, in the first quarter of 2022, we executed a lease for 85,800 square feet of office and laboratory space in Bedford, Massachusetts. The initial term of the Bedford

lease is eight years and nine months beginning on May 1, 2022. We do not currently occupy the Bedford facilities. As part of the Restructuring Plan, we decided not to utilize the Bedford facilities as part of our own operations and intend to sublease the vacant space. We believe that the Billerica office, laboratory and manufacturing space will be sufficient to meet our needs for the foreseeable future. Refer to Note 12 to the consolidated financial statements for further details related to the Bedford facilities.

Item 3. LEGAL PROCEEDINGS

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation consisting of intellectual property, contractual, employment and other matters. While the outcome of any such actions or proceedings cannot be predicted with certainty, as of December 31, 2022, we were not party to any material legal proceedings.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on The Nasdaq Global Market under the symbol "QTRX."

Stockholders

As of February 28, 2023, there were approximately 27 stockholders of record of our common stock.

Unregistered Sales of Securities

There were no unregistered sales of equity securities during the fourth quarter ended December 31, 2022.

Issuer Purchases of Equity Securities

Not applicable.

Item 6. RESERVED

Not applicable.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information management believes to be relevant to understanding the financial condition and results of operations of Quanterix Corporation for the years ended December 31, 2022, and 2021. For a full understanding of our financial condition and results of operations, this discussion should be read in conjunction with our consolidated financial statements and accompanying notes included in Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

For additional information on our financial condition as of December 31, 2021 and results of operations for the year ended December 31, 2021 as compared to the year ended December 31, 2020, refer to Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2021.

Overview

We are a life sciences company that has developed next-generation, ultra-sensitive digital immunoassay platforms that advance life sciences research and diagnostics. Our platforms are based on our proprietary digital "Simoa" detection technology. Our Simoa bead-based and planar array platforms enable customers to reliably detect protein biomarkers in extremely low concentrations in blood, serum and other fluids that, in many cases, are undetectable using conventional, analog immunoassay technologies, and also allow researchers to define and validate the function of novel protein biomarkers that are only present in very low concentrations. These capabilities provide our customers with insight into the role of protein biomarkers in human health that has not been possible with other existing technologies and enable researchers to unlock unique insights into the continuum between health and disease. We believe this greater insight will enable the development of novel therapies and diagnostics and facilitate a paradigm shift in healthcare from an emphasis on treatment to a focus on earlier detection, monitoring, prognosis and, ultimately, prevention.

Our instruments are designed to be used either with assays fully developed by us, including all antibodies and supplies required to run the tests, or with "homebrew" kits where we supply some of the components required for testing, and the customer supplies the remaining required elements. Accordingly, our installed instruments generate a recurring revenue stream. As the installed base of the Simoa instruments increases, total consumables revenue overall is expected to increase.

We commercially launched our first immunoassay platform, the Simoa HD-1, in January 2014. The HD-1 is based on our bead-based technology, and assays run on the HD-1 are fully automated. We initiated commercial launch of the SR-X instrument in December 2017. The SR-X utilizes the same Simoa bead-based technology and assay kits as the HD-1 in a compact benchtop form with a lower price point, more flexible assay preparation, and a wider range of applications. In July 2019, we launched the Simoa HD-X, an upgraded version of the Simoa HD-1, which replaces the HD-1. The HD-X has been designed to deliver significant productivity and operational efficiency improvements, as well as greater user flexibility. We began shipping and installing HD-X instruments at customer locations in 2019, and by the end of 2022, approximately 79% of the HD instrument installed base were HD-X instruments.

With our acquisition of Aushon in 2018, we acquired a CLIA certified laboratory, as well as their proprietary sensitive planar array detection technology. Leveraging our proprietary sophisticated Simoa image analysis and data analysis algorithms, we further refined the planar array technology to develop the SP-X instrument to provide sensitivity similar to that found in our Simoa bead-based platform. We commercially launched the SP-X instrument in April 2019.

Our wholly owned subsidiary UmanDiagnostics AB (Uman), a Swedish company located in Umeå, Sweden, supplies neurofilament light (Nf-L) antibodies and ELISA kits, which are widely recognized by researchers and biopharmaceutical and diagnostics companies world-wide as the premier solution for the detection of Nf-L to advance the development of therapeutics and diagnostics for neurodegenerative conditions.

We also provide contract research services for customers through our CLIA-certified Accelerator Laboratory. The Accelerator Laboratory provides customers with access to Simoa technology, and supports multiple projects and services, including sample testing, homebrew assay development and custom assay development. To date, we have completed over 1,900 projects for more than 400 customers from all over the world using our Simoa platforms.

We sell our instruments, consumables and services to the life science, pharmaceutical and diagnostics industries through a direct sales force and support organizations in North America and Europe, and through distributors or sales agents in select markets, including Australia, Brazil, China, Czech Republic, India, Hong Kong, Israel, Japan, New Zealand, Qatar, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan, and UAE. In addition, Uman sells Nf-L antibodies and Nf-L ELISA kits directly, and in conjunction with us and another distributor worldwide. We have an

extensive base of customers in world class academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies.

Although the COVID-19 pandemic negatively affected revenues in 2020 and the first part of 2021, we have seen less of an impact related to COVID-19 as customers began returning to normal operations beginning in mid-2021. However, we expect COVID-19 related challenges may continue for the foreseeable future and potentially increase if variants result in new shutdowns.

During the COVID-19 pandemic, we determined that our cytokine assay technology could provide researchers with important and differentiated tools to study disease progression, cytokine release syndrome, and patient-treatment response in the fight against COVID-19 and developed a SARS antibody test and SARS antigen test, each of which was run on our HD-X instrument. In December 2020, the FDA issued an EUA for our Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test, and in January 2021, the FDA issued an EUA for our Simoa SARS-CoV-2 N Protein Antigen Test. In September 2021, the FDA expanded the EUA for our Simoa SARS-CoV-2 N Protein Antigen Test to include testing with nasal swabs and saliva and for asymptomatic serial testing with nasal swab samples. In 2022, we voluntarily withdrew the EUA for these tests.

Restructuring and Strategic Re-Alignment

Following a strategic review and assessment of our operations and cost structure, on August 8, 2022, we announced a plan of restructuring and strategic re-alignment (the Restructuring Plan). As part of this plan, we began an assay redevelopment program with the ultimate objective of improving our ability to manufacture and deliver high-quality assays at scale. The plan aligns our investments to best serve the needs of customers, focuses innovation efforts on key platforms and provides the foundation for our entry into translational pharma and clinical markets, which we believe will be required to access new growth categories. The Restructuring Plan included the elimination of 119 positions and other cost-saving measures. The workforce reduction was substantially completed by the end of the third quarter of 2022. As part of the Restructuring Plan, we are also reviewing alternative uses of the additional facility space that we currently lease in Bedford, Massachusetts. These alternatives may include termination of the lease, or sub-leasing all, or a portion, of the Bedford facilities. During the year ended December 31, 2022, we recorded an impairment expense of $16.3 million on our long-lived assets related to the Bedford facilities, as well as a $1.1 million impairment expense related to software projects. Overall, as a result of the Restructuring Plan, we expect to realize estimated annualized operating expense savings of approximately $25 million.

As of December 31, 2022, we had cash and cash equivalents of $338.7 million. Since inception, we have incurred annual net losses. Our net loss was $96.7 million and $57.7 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $402.2 million and stockholders' equity of $358.9 million. We expect to continue to incur significant expenses and operating losses at least through the next 24 months. We expect our expenses will increase substantially as we:

- expand our sales and marketing efforts to further commercialize our products;
- strategically acquire and integrate companies or technologies that may be complementary to our business;
- expand our research and development efforts to improve our existing products and develop and launch new products, particularly if any of our products are deemed by the FDA to be medical devices or otherwise subject to additional regulation by the FDA;
- seek PMA or 510(k) clearance from the FDA for our existing products or new products if or when we decide to market products for use in the prevention, diagnosis or treatment of a disease or other condition;
- hire additional personnel and grow our employee headcount;
- enter into collaboration arrangements, if any, or in-license other products and technologies; and
- add operational, financial and management information systems.

Financial Operations Overview

Revenue

Under Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 606 - *Revenue from Contracts with Customers* (ASC 606), an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. We assess if these options provide a material right to the customer and if so, they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying license relative to the option exercise price, including assumptions about technical feasibility and the probability of developing a candidate that would be subject to the option rights. The exercise of a material right is accounted for as a contract modification for accounting purposes.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices (SSP) on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation, we consider applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. We validate the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

We generate product revenue primarily from sales of our HD-X, SR-X, and SP-X instruments and related reagents and other consumables. We currently sell our products for RUO applications and our customers are primarily laboratories associated with academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies. Sales of our consumables have consistently increased due to an increasing number of instruments being installed in the field, all of which require certain of our consumables to run customers' specific tests. Consumable revenue consists of sales of complete assays which are developed internally by us, plus sales of "homebrew" kits which contain all the elements necessary to run tests with the exception of the specific antibodies utilized which are separately provided by the customer.

Service and other revenue consists of testing services provided by us in our Accelerator Laboratory on behalf of certain research customers, in addition to warranty and other service-based revenue. Services provided in our Accelerator Laboratory include sample testing, homebrew assay development and custom assay development.

Collaboration and license revenue consists of revenue associated with licensing our technology to third parties and for related services.

Grants received by us that do not require the transfer of goods or services to a customer are accounted for by analogy to International Accounting Standards (IAS) 20, *Accounting for Government Grants and Disclosure of Government Assistance* (IAS 20). Under IAS 20, we recognize revenue as the matching expense or asset is incurred or capitalized.

Cost of Products, Services and Collaboration Revenue

Cost of goods sold for products consists of HD-X, HD-1, and SR-X instrument costs from the manufacturer and related reagents and other consumables. Cost of goods sold for SP-X consists of costs based on the internal assembly of this item. Raw material part costs; inbound freight, shipping and handling costs associated with purchased goods; contract manufacturer costs; personnel costs; royalties; overhead and other direct costs related to those sales are classified as cost of goods sold for products.

Cost of goods sold for services consists of raw materials, personnel costs, royalties as well as overhead and other direct costs associated with operating the Accelerator Laboratory on behalf of customers, in addition to costs related to warranties and other costs of servicing equipment at customer sites.

Cost of collaboration revenue consists of royalty expense due to third parties from revenue generated by collaboration or license deals.

Research and Development Expenses

Research and development expenses consist of personnel costs, research supplies, third-party development costs for new products, materials for prototypes, and allocated overhead costs that include facility and other overhead costs. We have made substantial investments in research and development since our inception, and plan to continue to make substantial investments in the future. Our research and development efforts have focused primarily on the tasks required to support development and commercialization of new and existing products and improved product quality. We believe that our continued investment in research and development is essential to our long-term competitive position and expect these expenses to increase in future periods. Additionally, costs incurred related to grant revenue are recorded as research and development expenses.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel costs for our sales and marketing, finance, legal, human resources and general management, costs associated with shipping and handling for product sales, other general and administrative costs, as well as professional services costs, such as marketing, advertising, legal and accounting services in addition to allocated overhead costs that include facility and other overhead costs.

The classification of shipping and handling costs for product sales varies from company to company with some companies recording these as selling, general, and administrative expenses and others recording such expenses within costs of goods sold for products. To the extent the classification of these shipping and handling costs differs from the classification used by other companies, our gross margins may not be comparable with those reported by such other companies. Shipping and handling costs for product sales included within selling, general and administrative expenses were $7.2 million and $6.9 million for the years ended December 31, 2022 and 2021, respectively, and our gross margin was 44.4% and 55.8% for the years ended December 31, 2022 and 2021, respectively. If these shipping and handling costs had been included in cost of goods sold for products, our non-GAAP gross margin would have been 37.5% and 49.6% for the years ended December 31, 2022 and 2021, respectively. See “Non-GAAP Financial Measures” below.

We expect, but cannot guarantee, that annual selling, general and administrative expenses will not increase significantly over the next 12 to 14 months.

Non-GAAP Financial Measures

To supplement our financial statements presented on a GAAP basis, we present non-GAAP gross profit and non-GAAP gross margin, which are calculated by including shipping and handling costs for product sales within cost of goods sold instead of within selling, general and administrative expenses. Management uses these non-GAAP measures to evaluate our operating performance in a manner that allows for meaningful period-to-period comparison and analysis of trends in our business and our competitors. Management believes that presentation of non-GAAP gross margin provides useful information to investors in assessing our operating performance within our industry and in order to allow

comparability to the presentation of other companies in our industry where shipping and handling costs are included in cost of goods sold for products. Management also uses non-GAAP gross margin as a factor in assessing the Company's progress against the Restructuring Plan. The non-GAAP financial information presented here should be considered in conjunction with, and not as a substitute for, the financial information presented in accordance with GAAP.

Set forth below is a reconciliation of non-GAAP gross profit, non-GAAP gross margin and non-GAAP operating expenses to their most directly comparable GAAP financial measures.

Reconciliation of Non-GAAP Financial Measures:

	Year Ended December 31,	
	2022	2021
GAAP gross profit	$ 46,806	$ 61,728
Shipping and handling costs	(7,206)	(6,892)
Non-GAAP gross profit	$ 39,600	$ 54,836
GAAP Revenue	$ 105,522	$ 110,556
GAAP Gross margin (gross profit as % of revenue)	44.4%	55.8%
Non-GAAP gross margin (non-GAAP gross profit as % of revenue)	37.5%	49.6%
GAAP total operating expenses	$ 148,510	$ 120,314
Shipping and handling costs	(7,206)	(6,892)
Non-GAAP total operating expenses	$ 141,304	$ 113,422
GAAP loss from operations	$ (101,704)	$ (58,586)
Non-GAAP loss from operations	$ (101,704)	$ (58,586)

Goodwill, Intangibles and Long-Lived Assets Impairment Expenses

Goodwill, intangibles and long-lived assets impairment expense consists primarily of impairment charges recorded due to an impairment event. We perform an impairment assessment annually, or whenever events or circumstances indicate that the carrying amount of the asset (asset group) may not be recoverable, of goodwill, intangibles and long-lived assets under the guidance of US GAAP accounting standards ASC 350 - *Intangibles – Goodwill and Other* (ASC 350) and ASC 360 - *Property, Plant and Equipment* (ASC 360). If impairment is indicated, we measure the amount of the impairment loss as the amount by which the carrying amount exceeds the fair value of the asset. Fair value is generally determined using a discounted future cash flow analysis. During the year ended December 31, 2022, the Company recorded a goodwill impairment charge of $8.2 million and impairment expense of $17.4 million for other long-lived assets due to impairment indicators identified. As of December 31, 2022, there was no remaining goodwill. There were no impairment charges recorded for the year ended December 31, 2021.

Critical Accounting Policies, Significant Judgments and Estimates

Our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K are prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs and expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Changes in accounting estimates may occur from period to period. Accordingly, actual results could differ significantly from the estimates made by our management. We evaluate our estimates and assumptions on an ongoing basis. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

We believe that the following critical accounting policies involve a greater degree of judgment and complexity than our other significant accounting policies. Accordingly, these are the policies we believe are the most critical to understanding and evaluating our consolidated financial condition and results of operations. Our significant accounting policies are more fully described in "Significant Accounting Policies" in Note 2 in the notes to our consolidated financial statements.

Revenue Recognition

We recognize revenue when a customer obtains control of a promised good or service. The amount of revenue recognized reflects consideration that we expect to be entitled to receive in exchange for these goods and services, incentives and taxes collected from customers, that are subsequently remitted to governmental authorities.

Product Revenue

Our products are composed of analyzer instruments, assay kits and other consumables such as reagents. Products are sold directly to biopharmaceutical and academic research organizations or are sold through distributors in EMEA and Asia Pacific regions. The sales of instruments are generally accompanied by an initial year of implied service-type warranties and may be bundled with assays and other consumables and may also include other items such as training and installation of the instrument and/or an extended service warranty. Revenues from the sale of products are recognized at a point in time when we transfer control of the product to the customer, which is upon installation for instruments sold to direct customers, and based upon shipping terms for assay kits and other consumables. Revenue for instruments sold to distributors is generally recognized based upon shipping terms (either upon shipment or delivery).

Service and Other Revenue

Service revenues are composed of contract research services, initial implied one-year service-type warranties, extended services contracts and other services such as training. Contract research services are provided through our Accelerator Laboratory and generally consist of fixed fee contracts. Revenues from contract research services are recognized at a point in time when we complete and deliver our research report on each individually completed study, or over time if the contractual provisions allow for the collection of transaction consideration for costs incurred plus a reasonable margin through the period of performance of the services. Revenues from service-type warranties are recognized ratably over the contract service period.

During the first quarter of 2022, we entered into a Master Collaboration Agreement with Eli Lilly and Company (Lilly) establishing a framework for future projects focused on the development of Simoa immunoassays (the Lilly Collaboration Agreement). We also entered into a Statement of Work under the Lilly Collaboration Agreement to perform assay research and development services within the field of Alzheimer's disease. In connection with the Lilly Collaboration Agreement, we received a non-refundable up-front payment of $5.0 million during the first quarter of 2022, and under the Statement of Work received $1.5 million per calendar quarter during 2022, beginning with the first quarter of 2022. The revenue was recognized over a one-year period. The Lilly Collaboration Agreement automatically renews on a quarterly basis unless Lilly provides 100 days' termination notice.

Concurrent with the execution of the Lilly Collaboration Agreement, we entered into a Technology License Agreement (the Lilly License) under which Lilly granted to the Company a non-exclusive license to Lilly's proprietary P-tau217 antibody technology for potential near-term use in research use only products and services and future in vitro diagnostics applications within the field of Alzheimer's disease. In consideration of the license, we paid an upfront fee, are required to make milestone payments based on the achievement of predetermined regulatory and commercial events, and will pay a royalty on net sales of licensed products.

We concluded that the Lilly Collaboration Agreement (including the Statement of Work) and the Lilly License represented a single contract with a customer, and we are accounting for the agreements as service revenue recognized over time as the services are delivered. The transaction price for the Lilly Collaboration Agreement was $10.9 million. Contingent amounts due to Lilly, under the Lilly License, represent variable consideration payable to a customer and will be recognized as reductions to service revenue up to the amount of the transaction price recognized, when probable.

During the year ended December 31, 2022, we recognized approximately $10.9 million of revenue from the Lilly Collaboration Agreement.

Collaboration and License Revenue

We may enter into agreements to license the intellectual property and know-how associated with our instruments in exchange for license fees and future royalties (as described below). The license agreements provide the licensee with a right to use the intellectual property with the license fee revenues recognized at a point in time as the underlying license is considered functional intellectual property. We have recognized royalty revenue based on sales or usage related to our licensing technology and intellectual property.

Payment Terms

Our payment terms vary by the type and location of customer and the products or services offered. Payment from customers is generally required in a term ranging from 30 to 45 days from date of shipment or satisfaction of the performance obligation with no discounts for early payment. Occasionally we do provide extended payment terms or financing arrangements to customers.

Disaggregated Revenue

When disaggregating revenue, we consider all of the economic factors that may affect revenues. The following tables disaggregate our revenue from contracts with customers based on their location by revenue type:

	Year Ended December 31, 2022			
(in thousands)	**North America**	**EMEA**	**Asia Pacific**	**Total**
Product revenues:				
Instruments	$ 9,254	8,362	7,388	$ 25,004
Consumable and other products	25,894	14,514	4,396	44,804
Total	$ 35,148	$ 22,876	$ 11,784	$ 69,808
Service and other revenues:				
Service-type warranties	$ 5,581	$ 2,779	$ 480	$ 8,840
Research services	22,493	1,013	147	23,653
Other services	1,144	722	136	2,002
Total	$ 29,218	$ 4,514	$ 763	$ 34,495
Collaboration and license revenue:				
Collaboration and license revenue	$ 274	$ 323	$ 52	$ 649

(in thousands)	Year Ended December 31, 2021 North America	EMEA	Asia Pacific	Total
Product revenues:				
Instruments	$ 12,138	$ 8,178	$ 5,657	$ 25,973
Consumable and other products	34,997	16,122	3,970	55,089
Total	$ 47,135	$ 24,300	$ 9,627	$ 81,062
Service and other revenues:				
Service-type warranties	$ 4,334	$ 2,039	$ 255	$ 6,628
Research services	12,101	2,600	124	14,825
Other services	1,372	695	109	2,176
Total	$ 17,807	$ 5,334	$ 488	$ 23,629
Collaboration and license revenue:				
Collaboration and license revenue	$ 360	$ 288	$ —	$ 648

Our contracts with customers may include promises to transfer multiple products and services to a customer. In accordance with ASC 606, we combine any performance obligations that are immaterial with one or more other performance obligations that are material to the contract. For arrangements with multiple performance obligations, we allocate the contract transaction price, including discounts, to each performance obligation based on its relative standalone selling price. Judgment is required to determine the standalone selling price for each distinct performance obligation. We determine standalone selling prices based on prices charged to customers in observable transactions, and use a range of amounts to estimate standalone selling prices for each performance obligation. We may have more than one range of standalone selling price for certain products and services based on the pricing for different customer classes.

Variable consideration in our contracts primarily relates to (i) sales- and usage-based royalties related to the license of intellectual property in collaboration and license contracts and (ii) certain non-fixed fee research services contracts. ASC 606 provides for an exception to estimating the variable consideration for sales- and usage-based royalties related to the license of intellectual property, such that the sales- or usage-based royalty will be recognized in the period the underlying transaction occurs. We have recorded sales- or usage-based royalty revenue for the years ended December 31, 2022 and 2021 related to the intellectual property licensed by Uman. We recognize revenues from sales- or usage-based royalty revenue at the later of when the sales or usage occurs and the satisfaction or partial satisfaction of the performance obligation to which the royalty has been allocated.

The aggregate amount of transaction price that is allocated to performance obligations that have not yet been satisfied or are partially satisfied as of December 31, 2022 is $10.1 million. Of the performance obligations not yet satisfied or that are partially satisfied, $8.6 million is expected to be recognized as revenue in the next 12 months, with the remainder to be recognized within the 24 months thereafter. The $10.1 million principally consists of $9.6 million billed for undelivered services related to initial and extended service-type warranties and research services, as well as $0.5 million related to undelivered licenses of intellectual property for a diagnostics company.

We have classified the balance of capitalized costs to obtain a contract as a component of prepaid expenses and other current assets as of December 31, 2022 and will amortize the expense as a component of cost of goods sold and selling, general and administrative expense over the estimated life of the contract. We consider potential impairment in these amounts each period.

ASC 606 provides entities with certain practical expedients and accounting policy elections to minimize the cost and burden of adoption. We exclude from the transaction price any amounts collected from customers related to sales and other similar taxes. We have elected to account for the shipping and handling as an activity to fulfill the

promise to transfer the product, and therefore will not evaluate whether shipping and handling activities are promised services to its customers.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. We do not assess whether a significant financing component exists if the period between when we perform our obligations under the contract and when the customer pays is one year or less. None of our contracts contained a significant financing component for the years ended December 31, 2022 and 2021.

Grant Revenue

We recognize grant revenue as we perform services under the arrangement when the funding is committed. Revenues and related research and development expenses are presented gross in the consolidated statements of operations as we have determined we are the primary obligor under the arrangement relative to the research and development services.

Accounting for grants does not fall under ASC 606, as the grantor will not benefit directly from our expansion or product development. As there is no authoritative guidance under U.S. GAAP on accounting for grants to for-profit business entities, we have accounted for grants by analogy to IAS 20.

Our grants contain both monetary amounts granted related to assets and monetary amounts granted related to income, which are grants other than those related to assets. The grants related to assets are for the expansion and increase of manufacturing capacity. The grants related to income are for additional research and development, as well as other non-asset related scale up costs. We determined it was appropriate to account for each monetary grant amount under the appropriate accounting treatment outlined in IAS 20.

Under IAS 20, grants related to assets shall be presented in the consolidated balance sheets either by recognizing the grant as deferred income (which is recognized in the consolidated statements of operations on a systematic basis over the useful life of the asset), or by deducting the grant in calculating the carrying amount of the asset (which is recognized in the consolidated statements of operations over the life of the depreciable asset as a reduced depreciation expense). Both methods are acceptable under IAS 20. We have elected to record grants related to assets as a deduction in calculating the carrying value of the asset.

Under IAS 20, grants related to income are presented as part of the consolidated statements of operations, either separately or under a general heading. Both methods are acceptable under IAS 20. We have elected to record grants related to income separately on the consolidated statements of operations as grant revenue. The related expenses are recorded within operating expenses and not deducted.

On September 29, 2020, we entered into WP2 with the NIH under its RADx program. The contract, with a total award value of $18.2 million, accelerated the continued development, scale-up, and deployment of the novel SARS-CoV-2 antigen detection test using our Simoa technology. The contract provided funding to expand assay kit manufacturing capacity and commercial deployment readiness. Release of the $18.2 million of funding under WP2 was based on the achievement of certain milestones. Contract funding was subject to achievement of these pre-defined milestones and the contract period ran through September 2021, with one milestone extended to March 31, 2022. As of December 31, 2022, we received the full $18.2 million under WP2. During the year ended December 31, 2022, we recognized no grant revenue and incurred no research and development expense related to WP2. During the year ended December 31, 2021, we recognized $5.2 million in grant revenue and incurred $3.4 million in research and development expense related to WP2.

The following table summarizes the cumulative RADx activity as of December 31, 2022 and 2021 (in thousands):

	December 31, 2022	December 31, 2021
Total grant revenue from research and development activities	$ 9,576	$ 9,576
Total proceeds used for assets	8,624	8,104
Total recognized	$ 18,200	$ 17,680
Total recognized	$ 18,200	$ 17,680
Total amount accrued	—	—
Total cash received	$ 18,200	$ 17,680
Total proceeds received	$ 18,200	$ 17,680
Total proceeds reasonably assured	—	520
Total RADx Grant amount	$ 18,200	$ 18,200

ADDF

On March 24, 2022, we entered into a contract with the Alzheimer's Drug Discovery Foundation (ADDF) (the ADDF Grant). ADDF is a charitable venture philanthropy entity that has granted us funding in support of certain activities for the development of an in vitro diagnostic (IVD) test for early detection of Alzheimer's disease. The ADDF Grant, which has a total funding value of $2.3 million, restricts our use of the granted funds to be used solely for activities related to the Alzheimer's diagnostic test development project. Contract funding is subject to achievement of these pre-defined milestones and the contract period runs through June 2024. We are recognizing revenue over time as the related services are performed. As of December 31, 2022, we had received $1.3 million of the total funding value of $2.3 million under the ADDF Grant. During the year ended December 31, 2022, we recognized $0.6 million in grant revenue and incurred $0.6 million in research and development expense related to the ADDF Grant.

Stock-Based Compensation

We account for stock-based compensation awards in accordance with ASC 718, *Compensation—Stock Compensation* (ASC 718). ASC 718 requires all stock-based payments to employees and non-employees, including grants of stock options, to be recognized in the statement of operations based on their fair values. Stock-based compensation awards have historically consisted of stock options and restricted stock units.

We recognize forfeitures as they occur. We estimate the grant date fair value, and the resulting stock-based compensation expense, using a Black-Scholes option-pricing model. The grant date fair value of the stock-based awards for employees is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. The grant date fair value of stock-based awards for non-employees is recognized on a straight-line basis over the vesting period.

The fair value of stock options granted to employees and non-employees is estimated on the grant date using a Black-Scholes option-pricing model, based on the assumptions noted in the following table:

	Year Ended December 31,	
	2022	2021
Risk-free interest rate	1.4% - 4.1%	0.4% - 1.3%
Expected dividend yield	None	None
Expected term (in years)	5.0 - 5.8	6.0
Expected volatility	55.0% - 70.8%	49.2% - 55.6%
Weighted-average grant date fair value	$ 9.88	$ 29.96

Expected volatility was calculated based on proportional weighting of reported volatility data for a representative group of guideline publicly traded companies for which historical information was available, as well as our stock. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant, commensurate with the expected life assumption. We estimate the expected life of options granted to employees utilizing the simplified method which calculates the expected life of an option as the average of the time to vesting and contractual life of the options. The expected life is applied to the stock option grant group as a whole, as we do not expect substantially different exercise or post-vesting termination behavior among our employee population. We use the simplified method due to the lack of historical exercise data and the plain nature of the stock options. We use the remaining contractual term for the expected life of non-employee awards. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on common stock.

We determined the fair value of each share of common stock underlying share-based awards based on the closing price of our common stock as reported by Nasdaq on the date of grant.

The table below summarizes the stock-based compensation expense recognized in our statements of operations by classification (in thousands):

	Year Ended December 31,	
	2022	2021
Cost of product revenue	$ 608	$ 471
Cost of service and other revenue	819	403
Research and development	1,639	1,807
General and administrative	12,376	13,294
Total stock-based compensation	$ 15,442	$ 15,975

As of December 31, 2022, we had $33.9 million of total unrecognized stock-based compensation costs which we expect to recognize over a weighted-average period of 2.9 years.

Results of Operations

Comparison of the Years Ended December 31, 2022, and December 31, 2021 (dollars in thousands):

	Year Ended December 31,					
	2022		2021		Increase (Decrease)	
		% of revenue		% of revenue	Amount	%
Product revenue	$ 69,808	66 %	$ 81,062	73 %	$ (11,254)	(14)%
Service and other revenue	34,495	33 %	23,629	21 %	10,866	46 %
Collaboration revenue	649	0.5 %	648	1 %	1	0 %
Grant revenue	570	0.5 %	5,217	5 %	(4,647)	(89)%
Total revenue	105,522	100 %	110,556	100 %	(5,034)	(5)%
Cost of goods sold:						
Cost of product revenue	40,809	39 %	34,149	31 %	6,660	20 %
Cost of service and other revenue	17,907	17 %	14,679	13 %	3,228	22 %
Cost of collaboration and license revenue	—	— %	—	— %	—	— %
Total costs of goods sold, services, and licenses	58,716	56 %	48,828	44 %	9,888	20 %
Gross profit	46,806	44 %	61,728	56 %	(14,922)	(24)%
Operating expenses:						
Research and Development Expense	25,890	25 %	27,978	25 %	(2,088)	(7)%
Selling, general and administrative	91,995	87 %	92,336	84 %	(341)	(0)%
Other lease costs	1,278	1 %	—	— %	1,278	100 %
Restructuring	3,755	4 %	—	— %	3,755	100 %
Goodwill impairment	8,220	8 %	—	— %	8,220	100 %
Impairment expense	17,372	16 %	—	— %	17,372	100 %
Total operating expenses	148,510	141 %	120,314	109 %	28,196	23 %
Loss from operations	(101,704)	(96)%	(58,586)	(53)%	(43,118)	(74)%
Interest income (expense), net	5,131	5 %	(403)	— %	5,534	1,373 %
Other (expense) income, net	(62)	— %	1,265	1 %	(1,327)	(105)%
Loss before income taxes	(96,635)	(92)%	(57,724)	(52)%	(38,911)	(67)%
Income tax (expense) benefit	(65)	— %	36	— %	(101)	(281)%
Net loss	$ (96,700)	(92)%	$ (57,688)	(52)%	$ (39,012)	(68)%

Revenue

Revenue decreased by $5.0 million, or 5%, to $105.5 million for the year ended December 31, 2022 as compared to $110.6 million for the year ended December 31, 2021.

Product revenue decreased by $11.3 million, or 14%, to $69.8 million for the year ended December 31, 2022, as compared to $81.1 million for the year ended December 31, 2021. Product revenue consisted of sales of instruments totaling $25.0 million and sales of consumables and other products totaling $44.8 million for the year ended December 31, 2022. Product revenue consisted of sales of instruments totaling $26.0 million and sales of consumables and other products of $55.1 million for the year ended December 31, 2021. The decrease in product revenue was primarily due to reducing our production levels of consumables to ensure quality as we address the issues affecting our consumables.

Service and other revenue increased by $10.9 million, or 46%, to $34.5 million for the year ended December 31, 2022, as compared to $23.6 million for the year ended December 31, 2021. The increase in service and other revenue was primarily due to the revenue related to Lilly Collaboration Agreement recognized during the year-ended December 31, 2022.

We had $0.6 million and $0.6 million in collaboration revenue during the year ended December 31, 2022 and 2021, respectively, related to licensing technology and intellectual property.

We had grant revenue of $0.6 million related to the ADDF grant that was recognized during the year ended December 31, 2022, and grant revenue of $5.2 million related to our contract with WP2 was recognized during the year ended December 31, 2021.

Cost of Goods Sold, Services, and Licenses

Cost of product revenue increased by $6.7 million, or 20%, to $40.8 million for the year ended December 31, 2022, as compared to $34.1 million for the year ended December 31, 2021. The increase was primarily due to increased reserves for excess and discontinued products partially offset by lower volume.

Cost of service and other revenue increased by $3.2 million, or 22%, to $17.9 million for the year ended December 31, 2022, as compared to $14.7 million for the year ended December 31, 2021, primarily due to increased personnel costs from the build out of our field service organization as well as the increased efforts related to the Lilly Collaboration Agreement.

Total cost of goods sold, services, and licenses as a percentage of revenue increased to 56% of total revenue for the year ended December 31, 2022, from 44% for the year ended December 31, 2021, primarily due to increased reserves for excess and discontinued products, and changes in product mix, partially offset by decreased product revenues.

Research and Development Expense

Research and development expense decreased by $2.1 million, or 7%, to $25.9 million for the year ended December 31, 2022, as compared to $28.0 million for the year ended December 31, 2021. The decrease was mainly due to the reduction in headcount in connection with the implementation of the Restructuring Plan.

Selling, General and Administrative Expense

Selling, general and administrative expense decreased by $0.3 million, to $92.0 million for the year ended December 31, 2022 as compared to $92.3 million for the year ended December 31, 2021. This was primarily driven by the reduction in headcount in connection with the implementation of the Restructuring Plan, offset by the rent expense increase year over year due to the newly leased facilities in Bedford, Massachusetts. Included within selling, general and administrative expense are shipping and handling costs for product sales of $7.2 million and $6.9 million for the years ended December 31, 2022 and 2021, respectively.

Other Lease Costs

During the year ended December 31, 2022, we incurred other lease costs of $1.3 million. As part of the Restructuring Plan, we are not utilizing the office and laboratory space leased in Bedford, Massachusetts and are evaluating alternatives, including termination of the lease or sub-leasing the facilities. Other lease costs represent the depreciation expense of the right-of-use asset and the accretion of the lease facility for periods after the impairment and the determination that the facilities would not be utilized. There were no similar charges in the same period in 2021.

Restructuring, Goodwill Impairment, and Impairment Expense

During the year ended December 31, 2022, we incurred restructuring expense of $3.8 million, non-cash impairment expenses for long-lived assets of $17.4 million and non-cash impairment expenses for goodwill of $8.2 million. Included in restructuring expense were costs for severance and one-time termination benefits in connection with the elimination of 119 positions across the Company, associated legal fees and contract cancellation costs due to the implementation of the Restructuring Plan. Impairment expense of $17.4 million includes $16.3 million associated with the Bedford, Massachusetts facilities and $1.1 million associated with the impairment of software costs for projects that have been rationalized as part of the Restructuring Plan. As part of the Restructuring Plan, we are not utilizing the Bedford, Massachusetts facilities and are evaluating alternatives, including terminating the lease or sub-leasing the

facilities. The entire goodwill balance was written off during the year ended December 31, 2022, following the assessment of our interim goodwill impairment test. There were no similar charges in the same period in 2021.

Interest Income (Expense), Net

Interest income (expense), net increased by $5.5 million to $5.1 million of income for the year ended December 31, 2022, as compared to ($0.4) million of expense for the year ended December 31, 2021. This increase was due to the favorable impact of higher interest rates earned on cash and cash equivalents as well as the settlement of our notes payable in the year ended December 31, 2021.

Other (Expense) Income, Net

Other (expense) income, net decreased by $1.4 million to ($0.1) million of expense for the year ended December 31, 2022, as compared to $1.3 million of income for the year ended December 31, 2021. The decrease was primarily due to the recognition of a one-time employee retention tax credit of $2.2 million established under the Coronavirus Aid, Relief, and Economic Security Act in 2021.

Income Tax (Expense) Benefit, Net

Income tax (expense) benefit, net was less than ($0.1) million of expense for the year ended December 31, 2022, as compared to benefit of less than $0.1 million for the same period in 2021. The change was primarily due to the decrease in the tax benefit recorded on the operating results of our foreign subsidiaries.

Liquidity and Capital Resources

Since our inception, we have incurred annual net losses and negative cash flows from operations. We used $48.3 million and $47.9 million of cash for our operating activities for the years ended December 31, 2022 and 2021, respectively.

The impact to our operating cash flows of an increase in net loss of $39.0 million for the year ended December 31, 2022, was primarily offset due to one-time non-cash expenses (i.e., goodwill and long-lived assets impairment), improved collection of receivables, and lower levels of inventory. This resulted in no significant change in net cash used in operating activities during the years ended December 31, 2022, and 2021. As of December 31, 2022, we had an accumulated deficit of $402.2 million. As of December 2022, we had cash and cash equivalents of $338.7 million.

Sources of Liquidity

To date, we have financed our operations principally through equity offerings, borrowings from credit facilities and revenue from our commercial operations.

Equity Offerings

In February 2021, we raised approximately $270 million of net proceeds through an underwritten public offering of approximately 4.1 million shares of our common stock at a public offering price of $70.00 per share. There were no equity offerings during the year ended December 31, 2022.

Loan Facility with Hercules

On April 14, 2014, we executed a loan agreement with Hercules Capital, Inc. (Hercules), as subsequently amended most recently in April 2019. The interest rate on this term loan was variable based on a calculation of 8.0% plus the prime rate less 5.25%, with a minimum interest rate of 8.0%. Interest was to be paid monthly beginning the month following the borrowing date. Under the amended agreement, we were required to pay the loan principal in four equal installments starting July 1, 2021, with the final principal payment and end of term charge to be made on October 1, 2021. On October 1, 2021, we made the final principal payment, including end of term fees, of $2.0 million related to

the loan agreement. There were no outstanding balances under the loan facility at any time during the year ended December 31, 2022.

Cash Flows

The following table presents our cash flows for each period presented (in thousands):

	Year Ended December 31,	
	2022	2021
Net cash used in operating activities	$ (48,272)	$ (47,907)
Net cash used in investing activities	(11,206)	(6,338)
Net cash provided by financing activities	2,311	270,795
Net increase in cash and cash equivalents	$ (57,167)	$ 216,550

Net Cash Used in Operating Activities

We derive cash flows from operations primarily from the sale of our products and services. Our cash flows from operating activities are also significantly influenced by our use of cash for operating expenses to support the growth of our business. We have historically experienced negative cash flows from operating activities as we have developed our technology, expanded our business and built out our infrastructure and this may continue in the future.

Net cash used in operating activities was $48.3 million during the year ended December 31, 2022. Net cash used in operating activities primarily consisted of net loss of $96.7 million offset by non-cash charges of $15.4 million of stock-based compensation expense, $5.3 million of depreciation and amortization expense, $8.2 million of goodwill impairment and $17.4 million of impairment of long-lived assets. Net changes in operating assets and liabilities resulted in net cash inflows of $2.1 million, primarily due to a decrease in accounts receivable of $5.2 million, decrease in inventory of $5.4 million as well as an increase in deferred revenue of $2.6 million, offset by a decrease in payables of $5.4 million, decrease in compensation and payroll accruals of $4.1 million and an increase in prepaid expenses and other assets of $0.6 million.

Net cash used in operating activities was $47.9 million during the year ended December 31, 2021. Net cash used in operating activities primarily consisted of net loss of $57.7 million offset by non-cash charges of $16.0 million of stock based compensation expense and $4.9 million of depreciation and amortization expense. Cash used as a result of changes in operating assets and liabilities of $12.2 million was primarily due to an increase in inventory of $8.1 million and an increase in accounts receivable of $6.9 million, offset by an increase in accounts payable, accrued compensation and benefits and other accrued expenses of $3.5 million, all driven by growth and our investments in process improvements.

Net Cash Used in Investing Activities

Historically, our primary investing activities have consisted of capital expenditures for the purchase of capital equipment to support our expanding infrastructure and work force. We expect to continue to incur additional costs for capital expenditures related to these efforts in future periods.

On a net basis, we used $11.2 million of cash during the year ended December 31, 2022, consisting of $11.7 million for the purchase of property and equipment, offset by $0.5 million in grant proceeds related to assets acquired under RADx grant.

On a net basis, we used $6.3 million of cash during the year ended December 31, 2021, consisting of $13.6 million for the purchase of property and equipment, offset by $7.3 million in grant proceeds related to assets acquired under WP2.

Net Cash Provided by Financing Activities

Historically, we have financed our operations principally through equity offerings, borrowings from credit facilities and revenue from our commercial operations.

Financing activities provided $2.3 million of cash during the year ended December 31, 2022, consisting of $1.4 million in net proceeds from the exercise of stock options and $0.9 million in net proceeds from purchases under our Employee Stock Purchase Plan.

Financing activities provided $270.8 million of cash during the year ended December 31, 2021, primarily from $269.7 million in net proceeds from our underwritten public offering during the first quarter of 2021.

Capital Resources

We have not achieved profitability on an annual basis since our inception, and we expect to continue to incur net losses in the future. We also expect that our operating expenses will increase as we continue to increase our marketing efforts to drive adoption of our commercial products as well as our investment in improving the quality of our products and services. Our liquidity requirements have historically consisted, and we expect that they will continue to consist, of sales and marketing expenses, research and development expenses, working capital, debt service and general corporate expenses.

We believe cash generated from commercial sales along with our current cash and cash equivalents will be sufficient to meet our anticipated operating cash requirements for at least the next 12 months. In the future, we expect our operating and capital expenditures to increase as we increase headcount, expand our sales and marketing activities and grow our customer base. Our estimates of the period of time through which our financial resources will be adequate to support our operations and the costs to support research and development and our sales and marketing activities are forward-looking statements and involve risks and uncertainties and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in Item 1A, “Risk Factors” of this Annual Report on Form 10-K. We have based our estimates on assumptions that may prove to be wrong and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including:

- continued market acceptance of our products and services and the ability of our products to meet our customers’ expectations;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- the extent to which we achieve intended cost savings, revenue improvement and related benefits from our Restructuring Plan;
- the extent to which we are able to successfully complete our assay improvement program to enhance product quality;
- the cost of our research and development activities;
- our ability to enter into collaborations in the future, and the success of any such collaborations;
- potential opportunities to strategically acquire and integrate companies or technologies that may be complementary to our business;
- the cost and timing of potential regulatory clearances or approvals that may be required in the future for our products; and
- the effect of competing technological and market developments.

We cannot guarantee that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Future debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we do not have or are not

able to obtain sufficient funds, we may have to delay development or commercialization of our products. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations.

If the conditions for raising capital are favorable, we may seek to finance future cash needs through public or private equity or debt offerings or other financings.

Contractual Obligations, Commitments and Contingencies

Lease Obligations

We currently lease approximately 91,600 square feet of office, laboratory, and manufacturing space at our headquarters in Billerica, Massachusetts. The premises covered by this lease serve as our principal office and laboratory space. The initial term of the Billerica lease is eleven years and five months beginning on April 1, 2019, and we have the option to extend the lease for two additional five-year periods.

On January 28, 2022, we executed a lease for 85,800 square feet of office and laboratory space in Bedford, Massachusetts. The lease commencement date was February 1, 2022, when we gained access to the underlying facilities. The initial term of the lease's payment schedule is eight years and nine months beginning on May 1, 2022. We have the option to extend the lease for two additional five-year periods. As part of the Restructuring Plan, we decided not to utilize these facilities as part of our own operations. We are reviewing our alternatives with respect to this space. These alternatives may include the termination of the lease or the sub-lease of all or a portion of the leased facilities. Refer to Note 12 to the consolidated financial statements for further details related to the Bedford space.

In addition, our subsidiary, Uman, leases a total of approximately 6,500 square feet of office, laboratory, manufacturing and storage space in Umeå, Sweden through multiple leases that expire at various dates through June 30, 2025.

The following table summarizes our operating lease obligations (in thousands):

	As of December 31, 2022
2023	$ 6,707
2024	7,064
2025	7,228
2026	7,408
2027	7,641
thereafter	23,621
Total	$ 59,669

Backlog

We generally expect to ship all instrument and consumable orders in the same fiscal quarter in which they are received, with the exception of orders received near the end of a fiscal quarter. As a result, our backlog at the end of any fiscal quarter is typically insignificant.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to financial market risk, including foreign currency exchange risk and interest rate risk.

Concentration of Revenue and Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents and trade receivables. Cash equivalents consist primarily of cash deposits and short-term, highly liquid investments that are readily convertible into cash, such as government securities with original maturities of less than 90 days at the date of purchase. Deposits of cash held outside the United States totaled approximately $3.6 million and $3.4 million at December 31, 2022 and 2021, respectively.

We grant credit to customers in the ordinary course of business. Credit evaluations are performed on an ongoing basis to reduce credit risk, and no collateral is required from our customers. An allowance for credit loss is provided for those accounts receivable considered to be uncollectible based upon historical experience and credit evaluation. As of December 31, 2022, no customer individually accounted for more than 10% of our gross accounts receivable. As of December 31, 2021, one company represented 18% of our gross accounts receivable. Due to the nature of our quarterly revenue streams derived from royalty revenue, it is not unusual for our accounts receivable balances to include a few customers with large balances. There were no material losses recorded due to customers' non-payment for the years ended December 31, 2022, or 2021.

For the year ended December 31, 2022, only one company accounted for more than 10% of our total revenue at 13%. For the year ended December 31, 2021, no customers individually accounted for more than 10% of our total revenue.

Foreign Currency Exchange Risk

As we expand internationally our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. For the years ended December 31, 2022 and 2021, approximately 38% and 36%, respectively, of our total revenue was generated from customers located outside of North America. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States, with a portion of expenses incurred in Canada, Europe, Japan and China. Our results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates. Fluctuations in currency exchange rates could harm our business in the future. The effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables as of December 31, 2022 would not have been material. The effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables as of December 31, 2021 would not have been material.

To date, we have not entered into any material foreign currency hedging contracts although we may do so in the future.

Interest Rate Risk

We had cash and cash equivalents of $338.7 million as of December 31, 2022. These amounts were held primarily in cash on deposit with banks. Due to the short-term nature of these investments, we believe that we do not have any material exposure to changes in the fair value of our investment portfolio as a result of changes in interest rates. Declines in interest rates, however, will reduce future investment income. If overall interest rates had decreased by 10% during the years ended December 31, 2022 and 2021, our interest income would not have been materially affected. We do not hold or issue financial instruments for trading purposes.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K beginning on page F-1.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We have established disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and to ensure that such information is accumulated and communicated to management, including our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), to allow timely decisions regarding required disclosures. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2022. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of December 31, 2022, due to the material weaknesses described below in Management's Report on Internal Control over Financial Reporting.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as this term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022, based on the framework set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on our evaluation under the framework set forth in Internal Control-Integrated Framework, our management concluded that our internal control over financial reporting was not effective at the reasonable assurance level as of December 31, 2022, due to the material weaknesses described below.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Based on the evaluation described above, our management concluded that control deficiencies existed as of December 31, 2022, and that these control deficiencies constituted material weaknesses in our internal control over financial reporting. The material weaknesses related to the operating effectiveness of our internal control associated with (i) the accounting for inventory, including excess and obsolescence reserves, (ii) the accounting for salary and commissions expense, (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, and (iv) the accounting for property and equipment, net. The primary cause of these control deficiencies is that we did not maintain a sufficient number of qualified personnel with requisite expertise in key accounting and finance functions, including following the implementation of the Restructuring Plan in the second half of 2022. In addition, our reliance on a significant number of end user computing tools requires additional procedures to verify the completeness and accuracy of information used within our analyses.

There were no material misstatements as a result of the material weaknesses discussed above. If not remediated, or if we identify further material weaknesses in our internal control, our failure to establish and maintain effective

disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our consolidated financial statements or a failure to meet our reporting and financial obligations.

The Company's independent registered public accounting firm, Ernst & Young LLP, has also issued an audit report on the Company's internal control over financial reporting, which is included elsewhere in this Annual Report on Form 10-K.

Management's Plan to Remediate the Material Weaknesses

Management, with oversight from the Audit Committee of our Board of Directors, is taking steps to remediate the control deficiencies which resulted in the material weaknesses described above by implementing changes to our internal control over financial reporting. Our plans for remediation include, but are not limited to, the efforts summarized below, which have been or are in the process of being implemented:

- we have hired, and will continue to hire, additional personnel (including those with public company experience) who have the appropriate level of expertise in the areas of accounting, financial reporting, and internal controls commensurate with the volume and complexity of our reporting requirements;
- we have engaged accounting advisory consultants to provide additional depth and breadth in our period end close, technical accounting, and financial reporting capabilities until we have filled vacancies with qualified personnel;
- we will engage a third-party service provider to perform an assessment of our internal control design and related documentation;
- we have engaged a third-party consultant to assess our current enterprise resource planning system and identify opportunities to enhance our use of the system through automating certain controls and processes; and
- we have engaged an accounting advisory consultant to conduct additional trainings on a regular basis related to internal control over financial reporting to our team members including, but not limited to, finance and accounting personnel.

We are also developing a plan to manage, on an ongoing basis, the impact of personnel turnover in the areas of accounting and financial reporting by broadening the understanding and knowledge of a larger group of personnel who can thereby work to support our operations during periods of reduced staffing.

We expect to continue our efforts to remediate the material weaknesses as described above through fiscal year 2023. We believe that the implementation of the above steps will allow us to address the deficient controls within our internal control environment, which will facilitate the remediation of the material weaknesses. As we continue to evaluate and work to improve our internal control over financial reporting, we will take additional measures to address control deficiencies and we may modify certain of the remediation measures described above. Following our design and implementation of our remediation efforts, we will need to demonstrate their operating effectiveness. We will not be able to consider the material weaknesses remediated until the applicable remedial controls operate for a sufficient period of time and our management has concluded, through testing, that our controls are operating effectively.

Changes in Internal Control over Financial Reporting

Other than related to the changes outlined above to remediate the material weaknesses described above, there have been no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Quanterix Corporation

Opinion on Internal Control over Financial Reporting

We have audited Quanterix Corporation's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). In our opinion, because of the effect of the material weaknesses described below on the achievement of the objectives of the control criteria, Quanterix Corporation (the Company) has not maintained effective internal control over financial reporting as of December 31, 2022, based on the COSO criteria.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment. Management has identified material weaknesses in internal controls related to (i) the accounting for inventory, including excess and obsolescence reserves, (ii) the accounting for salary and commissions expense, (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, and (iv) the accounting for property and equipment, net.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2022, and December 31, 2021, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, and the related notes. These material weaknesses were considered in determining the nature, timing and extent of audit tests applied in our audit of the 2022 consolidated financial statements, and this report does not affect our report dated March 6, 2023, which expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded

as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 6, 2023

Item 9B. OTHER INFORMATION

Not applicable.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(1) *Financial Statements*

The consolidated financial statements are included beginning on page F-1 attached hereto and are filed as part of this Annual Report on Form 10-K.

(2) *Financial Statement Schedules*

Financial statement schedules have been omitted since they either are not required, not applicable, or the information is otherwise included.

(3) *Exhibits*

The following is a list of exhibits filed as part of this Annual Report on Form 10-K:

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
3.1	Amended and Restated Certificate of Incorporation		8-K	12/15/2017	001-38319
3.2	Restated Bylaws		8-K	12/15/2017	001-38319
4.1	Description of Securities		10-K	3/13/2020	001-38319
4.2	Form of Common Stock Certificate		S-1	11/9/2017	333-221475
10.1.1+	2007 Stock Option and Grant Plan, as amended		S-1	11/9/2017	333-221475
10.1.2+	Form of Incentive Stock Option Agreement under the 2007 Stock Option and Grant Plan, as amended		S-1	11/9/2017	333-221475
10.1.3+	Form of Non-qualified Stock Option Agreement under the 2007 Stock Option and Grant Plan, as amended		S-1	11/9/2017	333-221475
10.1.4+	Form of Restricted Stock Agreement under the 2007 Stock Option and Grant Plan, as amended		S-1	11/9/2017	333-221475
10.2.1+	2017 Employee, Director and Consultant Equity Incentive Plan		S-1/A	11/27/2017	333-221475
10.2.2+	Form of Stock Option Agreement under the 2017 Employee, Director and Consultant Equity Incentive Plan		S-1/A	11/27/2017	333-221475

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.2.3+	Form of Restricted Stock Agreement under the 2017 Employee, Director and Consultant Equity Incentive Plan		S-1/A	11/27/2017	333-221475
10.2.4+	Form of Restricted Stock Unit Agreement under the 2017 Employee, Director and Consultant Equity Incentive Plan		S-1/A	11/27/2017	333-221475
10.3.1+	Amended and Restated Employment Agreement, dated April 25, 2022, between the Registrant and E. Kevin Hrusovsky		8-K	4/29/2022	001-38319
10.3.2+	Separation Agreement, effective as of August 8, 2022, between the Registrant and E. Kevin Hrusovsky		8-K	8/8/2022	001-38319
10.4+	Employment Agreement, dated June 22, 2021, between the Registrant and Michael Doyle		8-K	6/28/2021	001-38319
10.5+	Amended and Restated Employment Agreement, dated April 25, 2022, between the Registrant and Dr. Masoud Toloue		8-K	4/29/2022	001-38319
10.6+	Employment Agreement, dated March 28, 2022, between the Registrant and Dan Pikora		8-K	9/8/2022	001-38319
10.7.1*	Exclusive License Agreement, dated June 18, 2007, between the Registrant and Tufts University, as amended on April 29, 2013		S-1	11/9/2017	333-221475
10.7.2*	Second Amendment, dated August 22, 2017, to the Exclusive License Agreement between the Registrant and Tufts University		S-1	11/9/2017	333-221475
10.7.3@	Third Amendment, dated September 25, 2020, to the Exclusive License Agreement between the Registrant and Tufts University		10-Q	11/6/2020	001-38319

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.8.1*	Supply and Manufacturing Agreement, dated September 14, 2011, between the Registrant and STRATEC Biomedical AG		S-1	11/9/2017	333-221475
10.8.2	First Amendment to Supply and Manufacturing Agreement, dated October 17, 2013, between the Registrant and STRATEC Biomedical AG		S-1	11/9/2017	333-221475
10.9.1*	STRATEC Development Services and Equity Participation Agreement, dated August 15, 2011, between the Registrant and STRATEC Biomedical Systems AG		S-1	11/9/2017	333-221475
10.9.2*	First Amendment to STRATEC Development Services and Equity Participation Agreement and Second Amendment to Supply and Manufacturing Agreement, dated November 18, 2016, between the Registrant and STRATEC Biomedical AG		S-1	11/9/2017	333-221475
10.10*	Manufacturing Services Agreement, dated November 23, 2016, between the Registrant and Paramit Corporation		S-1	11/9/2017	333-221475
10.11+	Form of Indemnification Agreement		S-1/A	11/27/2017	333-221475
10.12	Lease Agreement by and between SSI 900 Middlesex MA LP and the Registrant, dated October 2, 2018.		8-K	10/5/2018	001-38319
10.13	Lease Agreement by and between the Registrant and XChange Owner LLC, dated January 28, 2022.		8-K	1/31/2022	001-38319
10.14+	Amended and Restated 2018 Non-Employee Director Compensation Policy		10-K	3/1/2022	001-38319
21.1	Subsidiaries of Registrant		10-K	3/5/2021	001-38319
23.1	Consent of Ernst & Young LLP	X			

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101.INS	Inline XBRL Instance Document.	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X			
101.DEF	Inline XBRL Taxonomy Extension Definition.	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X			
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

+ Management contract or compensatory plan or arrangement.

* Confidential treatment has been granted for portions of this Exhibit. Redacted portions have been filed separately with the SEC.

@ Portions of this document (indicated by "[***]") have been omitted because such information is not material and is the type of information that the Registrant treats as private or confidential.

Item 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

QUANTERIX CORPORATION

Date: March 6, 2023

By: /s/ MASOUD TOLOUE, PH.D.
Masoud Toloue, Ph. D.
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ MASOUD TOLOUE, PH.D. Masoud Toloue, Ph. D.	President and Chief Executive Officer and Director (Principal Executive Officer)	March 6, 2023
/s/ MICHAEL A. DOYLE Michael A. Doyle	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 6, 2023
/s/ Martin D. Madaus, Ph.D. Martin D. Madaus, Ph.D.	Chairman	March 6, 2023
/s/ BRIAN J. BLASER Brian J. Blaser	Director	March 6, 2023
/s/ KEITH L. CRANDELL Keith L. Crandell	Director	March 6, 2023
/s/ KAREN A. FLYNN Karen A. Flynn	Director	March 6, 2023
/s/ SARAH E. HLAVINKA Sarah E. Hlavinka	Director	March 6, 2023
/s/ PAUL M. MEISTER Paul M. Meister	Director	March 6, 2023
/s/ LAURIE J. OLSON Laurie J. Olson	Director	March 6, 2023
/s/ DAVID R. WALT, PH.D. David R. Walt, Ph.D.	Director	March 6, 2023

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
QUANTERIX CORPORATION
Years ended December 31, 2022, 2021, and 2020

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Quanterix Corporation

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of Quanterix Corporation (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, cash flows and stockholders' equity for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated March 6, 2023 expressed an adverse opinion thereon.

Basis for Opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter
The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Excess Inventory

Description of the Matter	As of December 31, 2022, the Company had recognized inventory of $16.8 million. As discussed in Note 2 to the consolidated financial statements, the Company analyzes its inventory levels at each reporting date to identify inventory that is in excess of expected sales requirements. In the event that the Company identifies excess inventory, the Company recognizes a reduction in the carrying value of inventory. Auditing management's valuation of inventory involved judgement in evaluating management's analysis and significant assumptions related to projections of future demand which is dependent on market factors.

How We Addressed the Matter in Our Audit	To audit the Company's valuation of inventory, we performed audit procedures that included, among others, performing inquiries of management and testing the completeness and accuracy of the underlying data used supporting the Company's estimate. To evaluate the Company's estimate of future demand, we independently assessed the sensitivity and impact of reasonably possible changes in forecasted demand and the impact on the Company's calculation of excess inventory. We evaluated inventory levels compared to forecasted demand, historical sales and specific product considerations. We performed inquiries with appropriate non-financial personnel, including supply chain employees, regarding obsolete or discontinued inventory items and other factors to corroborate management's assertions regarding qualitative judgments about discontinued, slow moving and obsolete inventories. We also evaluated management's ability to accurately forecast demand by comparing actual demand to management's prior estimates.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2008.

Boston, Massachusetts
March 6, 2023

Quanterix Corporation
Consolidated Balance Sheets
(amounts in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 338,740	$ 396,465
Accounts receivable (less allowance for credit losses of $118 and $419 as of December 31, 2022 and December 31, 2021, respectively; including $89 and $200 due from related parties as of December 31, 2022 and December 31, 2021, respectively)	19,017	23,786
Inventory	16,786	22,190
Prepaid expenses and other current assets	6,860	6,514
Total current assets	381,403	448,955
Restricted cash	2,597	2,577
Property and equipment, net	20,162	17,960
Intangible assets, net	7,516	10,534
Goodwill	—	9,632
Right-of-use assets	21,223	11,491
Other non-current assets	1,298	378
Total assets	$ 434,199	$ 501,527
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable (including $0 and $42 to related parties as of December 31, 2022 and December 31, 2021, respectively)	$ 3,836	$ 9,209
Accrued compensation and benefits	10,658	13,252
Other accrued expenses	4,747	6,486
Deferred revenue (including $69 and $54 with related parties as of December 31, 2022 and December 31, 2021, respectively)	8,644	6,361
Short term lease liabilities	2,687	1,428
Other current liabilities	386	241
Total current liabilities	30,958	36,977
Deferred revenue, net of current portion	1,415	1,099
Long term lease liabilities	41,417	20,464
Other non-current liabilities	1,469	2,035
Total liabilities	75,259	60,575
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock, $0.001 par value:		
Authorized shares: 120,000,000 at December 31, 2022 and December 31, 2021, respectively; Issued and outstanding: 37,279,994 shares and 36,768,035 shares at December 31, 2022 and December 31, 2021, respectively	37	37
Additional paid-in capital	763,688	745,936
Accumulated other comprehensive income	(2,623)	441
Accumulated deficit	(402,162)	(305,462)
Total stockholders' equity	358,940	440,952
Total liabilities and stockholders' equity	$ 434,199	$ 501,527

The accompanying notes are an integral part of these financial statements.

Quanterix Corporation
Consolidated Statements of Operations
(amounts in thousands, except share and per share data)

	Years Ended December 31,		
	2022	2021	2020
Product revenue (including related party activity of $2,634, $505, and $580 for the years ended December 31, 2022, 2021, and 2020, respectively)	$ 69,808	$ 81,062	$ 44,017
Service and other revenue (including related party activity of $11, $114, and $202 for the years ended December 31, 2022, 2021, and 2020, respectively)	34,495	23,629	24,129
Collaboration revenue	649	648	11,809
Grant revenue	570	5,217	6,422
Total revenue	105,522	110,556	86,377
Costs of goods sold:			
Cost of product revenue (including related party activity of $154, $1,936, and $205 for the years ended December 31, 2022, 2021, and 2020 respectively)	40,809	34,149	25,950
Cost of service and other revenue (including related party activity of $87, $74, and $52 for the years ended December 31, 2022, 2021, and 2020 respectively)	17,907	14,679	11,245
Cost of collaboration and license revenue (including related party activity of $0, $0, and $1,000 for the years ended December 31, 2022, 2021, and 2020 respectively)	—	—	1,000
Total costs of goods sold, services, and licenses	58,716	48,828	38,195
Gross profit	46,806	61,728	48,182
Operating expenses:			
Research and Development Expense (including related party activity of $696, $565, and $235 for the years ended December 31, 2022, 2021, and 2020 respectively)	25,890	27,978	20,174
Selling, general and administrative (including related party activity of $41, $89, and $37 for the years ended December 31, 2022, 2021, and 2020 respectively)	91,995	92,336	59,592
Other lease costs	1,278	—	—
Restructuring	3,755	—	—
Goodwill impairment	8,220	—	—
Impairment expense	17,372	—	—
Total operating expenses	148,510	120,314	79,766
Loss from operations	(101,704)	(58,586)	(31,584)
Interest income (expense), net	5,131	(403)	(273)
Other (expense) income, net	(62)	1,265	(49)
Loss before income taxes	(96,635)	(57,724)	(31,906)
Income tax (expense) benefit	(65)	36	376
Net loss	$ (96,700)	$ (57,688)	$ (31,530)
Net loss per share, basic and diluted	$ (2.61)	$ (1.60)	$ (1.07)
Weighted-average common shares outstanding, basic and diluted	36,990,965	35,997,473	29,589,132

The accompanying notes are an integral part of these financial statements.

Quanterix Corporation
Consolidated Statements of Comprehensive Loss
(amounts in thousands)

	Years Ended December 31,		
	2022	2021	2020
Net loss	$ (96,700)	$ (57,688)	$ (31,530)
Other comprehensive loss:			
Foreign currency translation adjustment	(3,064)	(1,993)	2,587
Total other comprehensive loss	(3,064)	(1,993)	2,587
Comprehensive loss	$ (99,764)	$ (59,681)	$ (28,943)

The accompanying notes are an integral part of these financial statements.

Quanterix Corporation
Consolidated Statements of Cash Flows
(amounts in thousands)

	Year Ended December 31,		
	2022	2021	2020
Operating activities			
Net loss	$ (96,700)	$ (57,688)	$ (31,530)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	5,349	4,851	4,312
Inventory step-up amortization	—	275	722
Credit (income) loss expense on accounts receivable	(301)	213	493
Unrealized losses (gains) on foreign currency transactions	(219)	263	(20)
Non-cash lease expense	715	499	245
Stock-based compensation expense	15,442	15,975	10,099
Goodwill impairment	8,220	—	—
Impairment of long-lived assets	17,372	—	—
Non-cash interest expense	—	65	86
Deferred taxes	(226)	—	—
Loss on disposal of fixed assets	6	89	171
Changes in operating assets and liabilities:			
Accounts receivable	5,156	(6,853)	(6,733)
Prepaid expenses and other assets	(568)	(393)	(3,927)
Inventory	5,386	(8,090)	(5,119)
Other non-current assets	(909)	(2)	198
Accounts payable	(5,362)	2,414	649
Accrued compensation and benefits, other accrued expenses and other current liabilities	(3,976)	606	6,326
Operating lease liabilities	(266)	(1,230)	316
Other non-current liabilities	10	(363)	(488)
Deferred revenue	2,599	1,462	835
Net cash used in operating activities	(48,272)	(47,907)	(23,365)
Investing activities			
Purchases of property and equipment	(11,726)	(13,616)	(3,930)
Proceeds from RADx grant on assets purchased	520	7,278	3,304
Net cash used in investing activities	(11,206)	(6,338)	(626)
Financing activities			
Proceeds from stock options exercised	1,430	7,750	4,019
Sale of common stock in underwritten public offering, net	—	269,718	91,404
Proceeds from ESPP purchase	881	1,065	888
Payments on notes payable	—	(7,738)	(75)
Net cash provided by financing activities	2,311	270,795	96,236
Net increase in cash and cash equivalents	(57,167)	216,550	72,245
Effect of foreign currency exchange rate on cash	(538)	(92)	158
Cash, restricted cash, and cash equivalents at beginning of period	399,042	182,584	110,181
Cash, restricted cash, and cash equivalents at end of period	$ 341,337	$ 399,042	$ 182,584
Supplemental cash flow information			
Cash paid for interest	$ —	$ 389	$ 625
Cash paid for taxes	$ 684	$ —	$ —
Noncash transactions:			
Purchases of property and equipment included in accounts payable and other accrued expenses	$ 152	$ 229	$ 1,029
Right-of-use asset obtained in exchange for lease liabilities	$ 22,494	$ —	$ —
Reconciliation of cash, cash equivalents, and restricted cash:			
Cash and cash equivalents	$ 338,740	$ 396,465	$ 181,584
Restricted cash	$ 2,597	$ 2,577	$ 1,000
Total cash, cash equivalents, and restricted cash	$ 341,337	$ 399,042	$ 182,584

The accompanying notes are an integral part of these financial statements.

Quanterix Corporation
Consolidated Statements of Stockholders' Equity
(amounts in thousands, except share data)

	Common stock shares	Common stock value	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2019	**28,112,201**	**$ 28**	**$ 345,027**	**$ (153)**	**$ (216,244)**	**$ 128,658**
Issuance of capital shares:						
−Exercised stock options	407,687	1	4,018	—	—	4,019
−Restricted units converted	182,036	—	—	—	—	—
−ESPP stock purchase	45,846	—	888	—	—	888
Sale of common stock in underwritten public offering, net	3,048,774	3	91,401	—	—	91,404
Stock-based compensation expense	—	—	10,099	—	—	10,099
Cumulative translation adjustment	—	—	—	2,587	—	2,587
Net loss	—	—	—	—	(31,530)	(31,530)
Balance at December 31, 2020	**31,796,544**	**$ 32**	**$ 451,433**	**$ 2,434**	**$ (247,774)**	**$ 206,125**
Issuance of capital shares:						
−Exercised warrants	7,347	—	—	—	—	—
−Exercised stock options	516,792	1	7,749	—	—	7,750
−Restricted units converted	307,004	—	—	—	—	—
−ESPP stock purchase	29,037	—	1,065	—	—	1,065
−Issuance of common stock	4,169	—	—	—	—	—
Sale of common stock in underwritten public offering, net	4,107,142	4	269,714	—	—	269,718
Stock-based compensation expense	—	—	15,975	—	—	15,975
Cumulative translation adjustment	—	—	—	(1,993)	—	(1,993)
Net loss	—	—	—	—	(57,688)	(57,688)
Balance at December 31, 2021	**36,768,035**	**$ 37**	**$ 745,936**	**$ 441**	**$ (305,462)**	**$ 440,952**
Issuance of capital shares:						
−Exercised stock options	243,792	—	1,430	—	—	1,430
−Restricted units converted	199,938	—	(1)	—	—	(1)
−ESPP stock purchase	57,485	—	881	—	—	881
−Issuance of common stock	10,744	—	—	—	—	—
Stock-based compensation expense	—	—	15,442	—	—	15,442
Cumulative translation adjustment	—	—	—	(3,064)	—	(3,064)
Net loss	—	—	—	—	(96,700)	(96,700)
Balance at December 31, 2022	**37,279,994**	**$ 37**	**$ 763,688**	**$ (2,623)**	**$ (402,162)**	**$ 358,940**

The accompanying notes are an integral part of these financial statements.

Quanterix Corporation
Notes to Consolidated Financial Statements

1. Organization and operations

Quanterix Corporation (Nasdaq: QTRX) (the Company) is a life sciences company that has developed next generation, ultra-sensitive digital immunoassay platforms that advance precision health for life sciences research and diagnostics. The Company's platforms are based on its proprietary digital "Simoa" detection technology. The Company's Simoa bead-based and planar array platforms enable customers to reliably detect protein biomarkers in extremely low concentrations in blood, serum and other fluids that, in many cases, are undetectable using conventional, analog immunoassay technologies, and also allow researchers to define and validate the function of novel protein biomarkers that are only present in very low concentrations and have been discovered using technologies such as mass spectrometry. These capabilities provide the Company's customers with insight into the role of protein biomarkers in human health that has not been possible with other existing technologies and enable researchers to unlock unique insights into the continuum between health and disease. The Company is currently focusing on protein detection, but the Company's Simoa platforms have also demonstrated applicability across other testing applications, including detection of nucleic acids and small molecules.

The Company launched its first immunoassay platform, the Simoa HD-1, in 2014. The HD-1 is a fully automated immunoassay bead-based platform with multiplexing and custom assay capability, and related assay test kits and consumable materials. The Company launched a second bead-based immunoassay platform (SR-X) in the fourth quarter of 2017 with a more compact footprint than the Simoa HD-1 and less automation designed for lower volume requirements while still allowing multiplexing and custom assay capability. The Company initiated an early-access program for its third instrument (SP-X) on the new Simoa planar array platform in January 2019, with the full commercial launch commencing in April 2019. In July 2019, the Company launched the Simoa HD-X, an upgraded version of the Simoa HD-1 which replaces the HD-1. The HD-X has been designed to deliver significant productivity and operational efficiency improvements, as well as greater user flexibility. The Company began shipping and installing HD-X instruments at customer locations in the third quarter of 2019. The Company also performs research services on behalf of customers to apply the Simoa technology to specific customer needs. The Company's customers are primarily in the research use only market, which includes academic and governmental research institutions, the research and development laboratories of pharmaceutical manufacturers, contract research organizations, and specialty research laboratories.

The Company's wholly owned subsidiary UmanDiagnostics AB (Uman), a Swedish company located in Umeå, Sweden, supplies neurofilament light (Nf-L) antibodies and ELISA kits, which are widely recognized by researchers and biopharmaceutical and diagnostics companies world-wide as the premier solution for the detection of Nf-L to advance the development of therapeutics and diagnostics for neurodegenerative conditions.

Underwritten public offerings

On August 6, 2020, the Company entered into an underwriting agreement with SVB Leerink LLC and Cowen and Company, LLC (Cowen), as representatives of the several underwriters, relating to an underwritten public offering of approximately 3.0 million shares of the Company's common stock, par value $0.001 per share. The underwritten public offering resulted in gross proceeds of $97.6 million. The Company incurred $6.2 million in issuance costs associated with the underwritten public offering, resulting in net proceeds to the Company of $91.4 million.

On February 3, 2021, the Company entered into an underwriting agreement with Goldman Sachs & Co. LLC, Leerink, and Cowen, as representatives of the several underwriters, relating to an underwritten public offering of approximately 4.1 million shares of the Company's common stock, par value $0.001 per share. The underwritten public offering resulted in gross proceeds of $287.5 million. The Company incurred $17.8 million in issuance costs associated with the underwritten public offering, resulting in net proceeds to the Company of $269.7 million.

Liquidity

The Company has recognized annual losses from operations since inception and has an accumulated deficit of $402.2 million as of December 31, 2022. The Company incurred net losses of $96.7 million, $57.7 million, and $31.5 million for the years ended December 31, 2022, 2021, and 2020, respectively. The Company had $338.7 million and $396.5 million of unrestricted cash and cash equivalents for the years ended December 31, 2022 and 2021, respectively. The Company expects that its cash and cash equivalents, as of December 31, 2022, will be sufficient to fund its operations for a period of at least one year from the date the consolidated financial statements are issued. There can be no assurances, however, that no additional funding will be required or that additional funding will be available on terms acceptable to the Company, or at all.

2. Significant accounting policies

Principles of consolidation

The consolidated financial statements have been prepared in accordance with U.S. GAAP and include the accounts of Quanterix Corporation, and its wholly-owned subsidiaries. All material intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. In making those estimates and assumptions, the Company bases its estimates on historical experience and on various other assumptions believed to be reasonable. The Company’s significant estimates included in the preparation of the consolidated financial statements are related to revenue recognition and valuation of inventory. Actual results could differ from those estimates.

Reclassifications

Certain amounts in the prior years’ consolidated financial statements have been reclassified to conform to the current year’s presentation.

Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker, the Company’s Chief Executive Officer, in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision-maker reviews the Company's operations and manages its business as a single operating segment.

Cost of revenue

Cost of goods sold for products consists of HD-X, HD-1, and SR-X instrument costs from the manufacturer and related reagents and other consumables. Cost of goods sold for SP-X consists of costs based on the internal assembly of this item. Raw material part costs; inbound freight, shipping and handling costs associated with purchased goods; contract manufacturer costs; personnel costs; royalties; overhead and other direct costs related to those sales are classified as cost of goods sold for products.

Cost of service and other revenue consists of raw materials, personnel costs, royalties as well as overhead and other direct costs associated with operating the Accelerator Laboratory on behalf of customers, in addition to costs related to warranties and other costs of servicing equipment at customer sites.

Cost of license revenue consists of license fees that are the direct results of cash payments received related to license agreements.

Research and development expenses

Research and development expenses, including personnel costs, allocated facility costs, lab supplies, outside services, contract laboratory costs are charged to research and development expense as incurred. The Company accounts for nonrefundable advance payments for goods and services that will be used in future research and development activities as expense when the service has been performed or when the goods have been received. Expenses incurred related to grant funded activities are recorded in research and development expense.

Selling, general, and administrative expenses

Selling, general and administrative expenses consist primarily of personnel costs for the Company's sales and marketing, finance, legal, human resources and general management, costs associated with shipping and handling for product sales, other general and administrative costs, as well as professional services costs, such as marketing, advertising, legal and accounting services in addition to allocated overhead costs that include facility and other overhead costs.

The classification of shipping and handling costs for product sales as selling, general, and administrative expenses varies from company to company with some companies recording these as selling, general and administrative expenses and others recording such expenses within costs of goods sold for products. To the extent the classification of these shipping and handling costs differs from the reporting approach used by other companies, the Company's gross margins may not be comparable with those reported by such other companies. Shipping and handling costs for product sales included within selling, general and administrative expenses were $7.2 million, $6.9 million and $4.8 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Net loss per share

Basic net loss per common share attributable to common stockholders is calculated by dividing the loss attributable to common stockholders by the weighted-average number of common shares. For purposes of the diluted net loss per share calculations, unvested restricted common stock, restricted stock units, common stock options, and warrants are considered to be potentially dilutive securities, but are excluded from the diluted net loss per share because their effect would be anti-dilutive and therefore basic and diluted net loss per share were the same for all periods presented.

Cash and cash equivalents

Cash and cash equivalents consist of cash deposits and short-term, highly liquid investments that are readily convertible into cash, with original maturities of three months or less. Cash equivalents are carried at fair value based on quoted prices for identical assets. Cash and cash equivalents consist of the following (in thousands):

	As of December 31,	
	2022	2021
Cash	$ 32,643	$ 64,372
Money market funds invested in U.S. Treasury obligations	306,097	332,093
Total cash and cash equivalents	$ 338,740	$ 396,465

Restricted cash and deposits

Restricted cash primarily represents collateral for a letter of credit issued as security for the lease for the Company's headquarters in Billerica, Massachusetts, and additional space in Bedford, Massachusetts, and to secure the

Company's corporate credit card program. The restricted cash is long term in nature as the Company will not have access to the funds until more than one year from December 31, 2022.

Inventory

Inventory is stated at the lower of cost or market on a first-in, first-out (FIFO) basis. The Company analyzes its inventory levels on each reporting date and writes down inventory that is expected to expire prior to being sold and inventory in excess of expected sales requirements. In the event that the Company identifies these conditions exist in its inventory, the carrying value is reduced to its estimated net realizable value.

Property and equipment

Property and equipment, including leasehold improvements, are stated at cost and are depreciated, or amortized in the case of leasehold improvements, over their estimated useful lives using the straight-line method. Expenditures for maintenance and repairs are charged to expense as incurred, whereas major betterments are capitalized as additions to property and equipment. The Company reviews its property and equipment whenever events or changes in circumstances indicate that the carrying value of certain assets might not be recoverable and recognizes an impairment loss when it is probable that an asset's realizable value is less than the carrying value. The Company recorded impairment expenses during the year-end December 31, 2022. Refer to Note 7 for additional details.

Depreciation is calculated based upon the following estimated useful lives of the assets:

Laboratory and manufacturing equipment	Five years
Computers and software	Three years
Office furniture and equipment	Seven years
Leasehold improvements	Shorter of the useful life of the asset or the remaining term of the lease

Leases

The Company accounts for leases in accordance with ASC Topic 842, *Leases* (ASC 842), which was adopted on January 1, 2020. ASC 842 requires a lessee to recognize assets and liabilities on the balance sheet for most leases. Lessees are differentiated between finance leases and operating leases, and classification impacts expense recognition. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use (ROU) assets and short-term and long-term lease liabilities, as applicable. The Company does not recognize leases on the balance sheet with a term of twelve months or less. The Company's leases consist of office and lab space and office equipment. All of the Company's leases are classified as operating, and options to renew a lease are only included in the lease term to the extent those options are reasonably certain to be exercised. Additionally, the Company does not separate lease and non-lease components for all leases.

Operating lease liabilities and their corresponding ROU assets are initially recorded based on the present value of lease payments over the expected remaining lease term. The rate implicit in lease contracts is typically not readily determinable and, as a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments, for a similar term, in a similar economic environment. To estimate its incremental borrowing rate, a credit rating applicable to the Company is estimated using a synthetic credit rating analysis since the Company does not currently have a rating agency-based credit rating.

Software development costs

The Company develops and modifies software related to the operation of some of its instruments. Software development costs are expensed as incurred until the point the Company establishes technological feasibility. Based on

the Company's product development process, technological feasibility is established upon the completion of a working model. The Company does not incur material costs between the completion of the working model and the point at which the product is ready for release. Therefore, software development costs are charged to the statement of operations as incurred as research and development expense.

Fair value of financial instruments

ASC Topic 820, *Fair Value Measurement* (ASC 820), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 inputs are inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly; and

Level 3 inputs are unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amount reflected on the balance sheets for cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximated their fair values, due to the short-term nature of these instruments.

Fair value measurements are as follows (in thousands):

December 31, 2022	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Financial assets				
Cash equivalents - money market funds	$ 306,097	$ 306,097	$ —	$ —

December 31, 2021	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Financial assets				
Cash equivalents - money market funds	$ 332,093	$ 332,093	$ —	$ —

Warranties

The Company provides a one-year warranty and maintenance service related to its instruments and sells extended warranty contracts for additional periods. The Company defers revenue associated with these services and recognizes them on a pro-rata basis over the period of service.

Income taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's consolidated financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on differences between the consolidated financial statement carrying amounts and the tax bases of the assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance against deferred tax assets is recorded if, based on the weight of the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740 *Income Taxes* (ASC 740). When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2022 and 2021, the Company did not have any significant uncertain tax positions.

Credit, product, and supplier concentrations and off-balance-sheet risk

The Company has no significant off-balance-sheet risk, such as foreign exchange contracts, option contracts, or other hedging arrangements. Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash and cash equivalents and a cost method investment. The Company places its cash and cash equivalents principally in depository accounts with a bank.

The Company is also subject to supply chain risks related to the outsourcing of the manufacturing of its instruments. Although there are a limited number of manufacturers for instruments of this type, the Company believes that other suppliers could provide similar products on comparable terms. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which would adversely affect operating results. In addition to outsourcing the manufacturing of its instruments, the Company also purchases antibodies through a number of different suppliers. Although a disruption in service from any one of its antibody suppliers is possible, the Company believes that it would be able to find an adequate supply from alternative suppliers.

Customers outside the United States represented 41% and 39% of the Company's gross trade accounts receivable balance as of December 31, 2022, and 2021, respectively. For the year ended December 31, 2022, one customer of approximately $13.7 million revenue accounted for 13% of the Company's total revenue. For the year ended December 31, 2021, no customers individually accounted for more than 10% of the Company's total revenue.

Stock-based compensation

The Company accounts for stock-based compensation awards in accordance with ASC 718, *Compensation—Stock Compensation* (ASC 718). The Company generally recognizes stock-based payments to employees and non-employees based on their grant date fair values. Stock-based compensation awards have historically consisted of stock

options and restricted stock units. Stock-based compensation costs for employees are recognized as expense over the requisite service period, which is generally the vesting period of the respective awards. Stock-based compensation costs for non-employees are recognized as expense over the vesting period on a straight-line basis. There were no material non-employee awards outstanding during the years ended December 31, 2022, 2021, and 2020.

The Company recognizes forfeitures as they occur. The Company estimates the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model.

The fair value of stock options granted to employees and non-employees is estimated on the grant date using the Black-Scholes option-pricing model, based on the assumptions noted in the following table:

	Year Ended December 31,		
	2022	2021	2020
Risk-free interest rate	1.4% - 4.1%	0.4% - 1.3%	0.4% - 1.7%
Expected dividend yield	None	None	None
Expected term (in years)	5.0 - 5.8	6.0	6.0
Expected volatility	55.0% - 70.8%	49.2% - 55.6%	43.9% - 49.2%
Weighted-average grant date fair value	$ 9.88	$ 29.96	$ 12.66

The Company uses its historical volatility and implied volatility as a basis to estimate expected volatility in the Company's valuation of stock options. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant, commensurate with the expected term assumption. The Company estimates the expected term of options granted to employees utilizing the simplified method which calculates the expected term of an option as the average of the time to vesting and contractual life of the options. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. The Company used the simplified method due to the lack of historical exercise data and the plain nature of the stock options. The Company uses the remaining contractual term for the expected term of non-employee awards. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on common stock.

Recent accounting pronouncements

Adopted

In June 2016, the Financial Accounting Standards Board (FASB) established Topic 326*, Financial Instruments — Credit Losses: Measurement of Credit Losses on Financial Instruments* (ASC 326) by issuing ASU No. 2016-13 (ASU 2016-13), which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. The Company early adopted ASU 2016-13 on January 1, 2021 using the modified retrospective approach. The Company's consolidated financial statements for prior-year periods have not been revised and are reflective of the credit loss requirements which were in effect for that period. The adoption of ASU 2016-13 did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* (ASU 2018-15). This ASU addresses the accounting for implementation, setup and other upfront costs paid by a customer in a cloud computing or hosting arrangement. The guidance aligns the accounting treatment of these costs incurred in a hosting arrangement treated as a service contract with the requirements for capitalization and amortization costs to develop or obtain internal-use software. The Company adopted ASU 2018-15 on January 1, 2021 using the prospective method. The adoption of ASU 2018-15 did not have a material impact on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes* (ASU 2019-12), which is intended to simplify various areas related to ASC 740, *Income Taxes* (ASC 740). ASU 2019-

12 removes certain exceptions for performing intra period tax allocations and calculating income taxes in interim periods. The guidance also simplifies the accounting for transactions that result in a step-up in the tax basis of goodwill and the effect of enacted changes in tax laws or rates in interim periods. The Company early adopted ASU 2019-12 on January 1, 2021. The adoption of ASU 2019-12 did not have a material impact on the Company's consolidated financial statements.

3. Revenue

The Company recognizes revenue when a customer obtains control of a promised good or service. The amount of revenue recognized reflects consideration that the Company expects to be entitled to receive in exchange for these goods and services, incentives and taxes collected from customers that are subsequently remitted to governmental authorities.

Customers

The Company's customers primarily consist of entities engaged in the life sciences research market that pursue the discovery and development of new drugs for a variety of neurologic, cardiovascular, oncologic and other protein biomarkers associated with diseases. The Company's customer base includes several of the largest biopharmaceutical companies, academic research organizations and distributors who serve certain geographic markets.

Product revenue

The Company's products are composed of analyzer instruments, assay kits and other consumables such as reagents. Products are sold directly to biopharmaceutical and academic research organizations or are sold through distributors in EMEA and Asia Pacific regions. The sales of instruments are generally accompanied by an initial year of implied service-type warranties and may be bundled with assays and other consumables and may also include other items such as training and installation of the instrument and/or an extended service warranty. Revenues from the sale of products are recognized at a point in time when the Company transfers control of the product to the customer, which is generally upon installation for instruments sold to direct customers, and based upon shipping terms for assay kits and other consumables. Revenue for instruments sold to distributors is generally recognized based upon shipping terms (either upon shipment or delivery).

Service and other revenue

Service revenues are composed of contract research services, initial implied one-year service-type warranties, extended services contracts and other services such as training. Contract research services are provided through the Company's Accelerator Laboratory and generally consist of fixed fee contracts. Revenues from contract research services are recognized at a point in time when the Company completes and delivers its research report on each individually completed study, or over time if the contractual provisions allow for the collection of transaction consideration for costs incurred plus a reasonable margin through the period of performance of the services. Revenues from service-type warranties are recognized ratably over the contract service period. For contract research services recognized over time, the Company uses the output method to measure the progress toward the complete satisfaction of the performance obligations. Revenues from other services are immaterial.

During the first quarter of 2022, the Company entered into a Master Collaboration Agreement with Eli Lilly and Company (Lilly) establishing a framework for future projects focused on the development of Simoa immunoassays (the Lilly Collaboration Agreement). The Company also entered into a Statement of Work under the Lilly Collaboration Agreement to perform assay research and development services within the field of Alzheimer's disease. In connection with the Lilly Collaboration Agreement, the Company received a non-refundable up-front payment of $5.0 million during the first quarter of 2022, and under the Statement of Work received $1.5 million per calendar quarter during 2022, beginning with the first quarter of 2022. The revenue has been recognized over a one-year period. The Lilly Collaboration Agreement automatically renews on a quarterly basis unless Lilly provides 100 days' termination notice.

Concurrent with the execution of the Lilly Collaboration Agreement, the Company entered into a Technology License Agreement (the Lilly License) under which Lilly granted to the Company a non-exclusive license to Lilly's proprietary P-tau217 antibody technology for potential near-term use in research use only products and services and future in vitro diagnostics applications within the field of Alzheimer's disease. In consideration of the license, the Company paid an upfront fee, is required to make milestone payments based on the achievement of predetermined regulatory and commercial events, and will pay a royalty on net sales of licensed products.

The Company concluded that the Lilly Collaboration Agreement (including the Statement of Work) and the Lilly License represented a single contract with a customer and we are accounting for the agreements as service revenue recognized over time as the services are delivered. The transaction price for the Lilly Collaboration Agreement is $10.9 million. Contingent amounts due to Lilly, under the Lilly License, represent variable consideration payable to a customer and will be recognized as reductions to service revenue up to the amount of the transaction price recognized, when probable. The Company is utilizing an input method to measure the delivery of services by calculating costs incurred at each period end relative to total costs expected to be incurred.

During the year ended December 31, 2022, the Company recognized approximately $10.9 million of revenue from the Lilly Collaboration Agreement.

Collaboration and license revenue

The Company may enter into agreements to license the intellectual property and know-how associated with its instruments and certain antibodies in exchange for license fees and future royalties (as described below). The license agreements provide the licensee with a right to use the intellectual property with the license fee revenues recognized at a point in time as the underlying license is considered functional intellectual property.

Payment terms

The Company's payment terms vary by the type and location of the customer and the products or services offered. Payment from customers is generally required in a term ranging from 30 to 45 days from date of shipment or satisfaction of the performance obligation. The Company does not provide financing arrangements to its customers.

Disaggregated revenue

When disaggregating revenue, the Company considered all of the economic factors that may affect its revenues. The following tables disaggregate the Company's revenue from contracts with customers by revenue type (in thousands):

	Year Ended December 31, 2022			
(in thousands)	**North America**	**EMEA**	**Asia Pacific**	**Total**
Product revenues:				
Instruments	$ 9,254	8,362	7,388	$ 25,004
Consumable and other products	25,894	14,514	4,396	44,804
Total	$ 35,148	$ 22,876	$ 11,784	$ 69,808
Service and other revenues:				
Service-type warranties	$ 5,581	$ 2,779	$ 480	$ 8,840
Research services	22,493	1,013	147	23,653
Other services	1,144	722	136	2,002
Total	$ 29,218	$ 4,514	$ 763	$ 34,495
Collaboration and license revenue:				
Collaboration and license revenue	$ 274	$ 323	$ 52	$ 649

(in thousands)	Year Ended December 31, 2021 North America	EMEA	Asia Pacific	Total
Product revenues:				
Instruments	$ 12,138	$ 8,178	$ 5,657	$ 25,973
Consumable and other products	34,997	16,122	3,970	55,089
Total	$ 47,135	$ 24,300	$ 9,627	$ 81,062
Service and other revenues:				
Service-type warranties	$ 4,334	$ 2,039	$ 255	$ 6,628
Research services	12,101	2,600	124	14,825
Other services	1,372	695	109	2,176
Total	$ 17,807	$ 5,334	$ 488	$ 23,629
Collaboration and license revenue:				
Collaboration and license revenue	$ 360	$ 288	$ —	$ 648

(in thousands)	Year Ended December 31, 2020 North America	EMEA	Asia Pacific	Total
Product revenues:				
Instruments	$ 8,680	$ 4,332	$ 3,594	$ 16,606
Consumable and other products	14,305	10,854	2,252	27,411
Total	$ 22,985	$ 15,186	$ 5,846	$ 44,017
Service and other revenues:				
Service-type warranties	$ 3,171	$ 1,543	$ 207	$ 4,921
Research services	15,011	2,225	737	17,973
Other services	700	435	100	1,235
Total	$ 18,882	$ 4,203	$ 1,044	$ 24,129
Collaboration and license revenue:				
Collaboration and license revenue	$ 11,685	$ 124	$ —	$ 11,809

The Company's contracts with customers may include promises to transfer multiple products and services to a customer. The Company combines any performance obligations that are immaterial with one or more other performance obligations that are material to the contract. For arrangements with multiple performance obligations, the Company allocates the contract transaction price, including discounts, to each performance obligation based on its relative standalone selling price. Judgment is required to determine the standalone selling price for each distinct performance obligation. The Company determines standalone selling prices based on prices charged to customers in observable transactions and uses a range of amounts to estimate standalone selling prices for each performance obligation. The Company may have more than one range of standalone selling price for certain products and services based on the pricing for different customer classes.

Variable consideration in the Company's contracts primarily relates to (i) sales- and usage-based royalties related to the license of intellectual property in collaboration and license contracts and (ii) certain non-fixed fee research services contracts. Accounting Standard Codification (ASC) Topic 606, *Revenue from Contracts with Customers* (ASC 606) provides for an exception to estimating the variable consideration for sales- and usage-based royalties related to the license of intellectual property, such that the sales- and usage-based royalty will be recognized in the period the underlying transaction occurs. The Company recognizes revenue from sales- and usage-based royalty revenue at the later of when the sale or usage occurs and the satisfaction or partial satisfaction of the performance obligation to which the royalty has been allocated.

Changes in deferred revenue from contracts with customers were as follows (in thousands):

	Year Ended December 31, 2022
Balance at December 31, 2021	$ 7,460
Deferral of revenue	11,444
Recognition of deferred revenue	(8,845)
Balance at December 31, 2022	$ 10,059

The aggregate amount of transaction price that is allocated to performance obligations that have not yet been satisfied or that are partially satisfied as of December 31, 2022 is $10.1 million. Of the performance obligations not yet satisfied or that are partially satisfied, $8.6 million is expected to be recognized as revenue in the next 12 months, with the remainder to be recognized within the 24 months thereafter. The $10.1 million principally consists of amounts billed for undelivered services related to initial and extended service-type warranties and research services, as well as $0.5 million related to undelivered licenses of intellectual property for a diagnostics company. For further discussion, refer to Note 5.

Costs to obtain a contract

The Company's sales commissions are generally based on bookings of the Company. The Company has determined that certain commissions paid under its sales incentive programs meet the requirements to be capitalized as they are incremental and would not have occurred absent a customer contract. The change in the balance of costs to obtain a contract are as follows (in thousands):

	2022
Balance at January 1	$ 440
Deferral of costs to obtain a contract	1,387
Recognition of costs to obtain a contract	(1,450)
Balance at December 31	$ 377

The Company has classified the balance of capitalized costs to obtain a contract as a component of prepaid expenses and other current assets and will subsequently amortize the expense as a component of cost of goods sold and selling, general, and administrative expense over the estimated life of the contract. The Company considers potential impairment in these amounts each period.

ASC 606 provides entities with certain practical expedients and accounting policy elections to minimize the cost and burden of adoption.

The Company does not disclose the value of unsatisfied performance obligations for (i) contracts with original expected length of one year or less and (ii) contracts for which revenue is recognized at the amount to which the Company has the right to invoice for services performed.

The Company will exclude from its transaction price any amounts collected from customers related to sales and other similar taxes.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. The Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of December 31, 2022, and 2021, respectively.

The Company has elected to account for the shipping and handling as an activity to fulfill the promise to transfer the product, and therefore will not evaluate whether shipping and handling activities are promised services to its customers.

Grant revenue

The Company recognizes grant revenue as the Company performs services under the arrangement when the funding is committed. Revenues and related research and development expenses are presented gross in the consolidated statements of operations as the Company has determined it is the primary obligor under the arrangement relative to the research and development services.

Accounting for grants does not fall under ASC 606, as the grantor will not benefit directly from the Company's expansion or product development. As there is no authoritative guidance under U.S. GAAP on accounting for grants to for profit business entities from government entities, the Company has accounted for grants obtained with the National Institute of Health (NIH) under its Rapid Acceleration of Diagnostics (RADx) program by analogy to International Accounting Standards Topic 20, *Accounting for Government Grants and Disclosure of Government Assistance* (IAS 20) The Company accounts for grants from the Alzheimer's Drug Discovery Foundation (ADDF) under ASC Topic 958, *Not for-Profit Entities* (ASC 958).

Under IAS 20, grants related to assets shall be presented in the consolidated balance sheets either by recognizing the grant as deferred income (which is recognized in the consolidated statements of operations on a systematic basis over the useful life of the asset), or by deducting the grant in calculating the carrying amount of the asset (which is recognized in the consolidated statements of operations over the life of the depreciable asset as a reduced depreciation expense). Both methods are acceptable under IAS 20. The Company has elected to record grants related to assets as a deduction in calculating the carrying value of the asset.

Under IAS 20, grants related to income are presented as part of the consolidated statements of operations, either separately or under a general heading. Both methods are acceptable under IAS 20. The Company has elected to record grants related to income separately on the consolidated statements of operations as grant revenue. The related expenses are recorded within operating expenses.

Under ASC 958, grants related to income are presented as part of the consolidated statements of operations, either separately or under a general heading. Both methods are acceptable under ASC 958. The Company has elected to record grants related to income separately on the consolidated statements of operations as grant revenue. The related expenses are recorded within operating expenses.

RADx grant

On September 29, 2020, the Company entered into WP2 with the NIH under its RADx program. The contract, which had a total award value of $18.2 million, accelerated the continued development, scale-up, and deployment of the novel SARS-CoV-2 antigen detection test using the Company's Simoa technology. The contract provided funding to expand assay kit manufacturing capacity and commercial deployment readiness. Release of the $18.2 million of funding under WP2 was based on the achievement of certain milestones. Contract funding was subject to achievement of these pre-defined milestones and the contract period ran through September 2021, with one milestone extended to March 31, 2022. The Company has received the full $18.2 million under WP2. During the year ended December 31, 2022, the Company recognized no grant revenue and incurred no research and development expense related to WP2. During the year ended December 31, 2021, the Company recognized $5.2 million in grant revenue and incurred $3.4 million in research and development expense related to WP2. During the year ended December 31, 2020, the Company recognized $4.4 million in grant revenue and incurred $2.6 million in research and development expense related to WP2.

The RADx Grant contains both monetary amounts granted related to assets and monetary amounts granted related to income, which are grants other than those related to assets. The grants related to assets are for the expansion and increase of manufacturing capacity. The grants related to income are for additional research and development, as well as other non-asset related scale up costs.

The following table summarizes the cumulative activity under the RADx Grant (in thousands):

	December 31, 2022	December 31, 2021	December 31, 2020
Total grant revenue from research and development activities	$ 9,576	$ 9,576	$ 4,362
Total proceeds used for assets	8,624	8,104	826
Total deferred proceeds for assets	—	—	2,478
Total deferred grant revenue	—	—	304
Total recognized	$ 18,200	$ 17,680	$ 7,970
Total recognized	$ 18,200	$ 17,680	$ 7,970
Total amount accrued	—	—	(2,968)
Total cash received	$ 18,200	$ 17,680	$ 5,002
Total proceeds received	$ 18,200	$ 17,680	$ 5,002
Total proceeds reasonably assured	—	520	13,198
Total RADx Grant amount	$ 18,200	$ 18,200	$ 18,200

ADDF

On March 24, 2022, the Company entered into a contract with the Alzheimer's Drug Discovery Foundation (ADDF) (the ADDF Grant). ADDF is a charitable venture philanthropy entity that has granted the Company funding in support of certain activities for the development of an in vitro diagnostic (IVD) test for early detection of Alzheimer's disease. The ADDF Grant, which has a total funding value of $2.3 million, restricts the Company's use of the granted funds to be used solely for activities related to the Alzheimer's diagnostic test development project. Contract funding is subject to achievement of these pre-defined milestones and the contract period runs through June 2024. The Company recognizes revenue over time as the related services are performed. As of December 31, 2022, the Company had received $1.3 million of the total funding value of $2.3 million under the ADDF Grant. During the year ended December 31, 2022, the Company recognized $0.6 million in grant revenue and incurred $0.6 million in research and development expense related to the ADDF Grant. No such activities occurred in the years ended December 31, 2021 and 2020.

4. Allowance for credit losses

The Company is exposed to credit losses primarily through sales of products and services. The Company's expected loss allowance methodology for accounts receivable is developed using historical collection experience, current and future economic and market conditions, and a review of the current status of customers' trade accounts receivable. Due to the short-term nature of such receivables, the estimated accounts receivable that may not be collected is based on aging of the accounts receivable balances.

Customers are assessed for credit worthiness upfront through a credit review, which includes assessment based on the Company's analysis of customers' financial statements when a credit rating is not available. The Company evaluates contract terms and conditions, country, and political risk, and may require prepayment to mitigate risk of loss. Specific allowance amounts are established to record the appropriate provision for customers that have a higher probability of default. The Company monitors changes to the receivables balance on a timely basis, and balances are written off as they are determined to be uncollectable after all collection efforts have been exhausted.

Activity related to the allowance for credit losses was as follows (in thousands):

	2022	2021	2020
Balance at January 1	$ 419	$ 370	$ 162
Provision charges	752	213	493
Deductions	(1,053)	(164)	(285)
Balance at December 31	$ 118	$ 419	$ 370

5. Collaboration and license arrangements

The Company has entered into certain licenses with other companies for use of the Company's technology. These licenses have royalty components which the Company earns and recognizes as collaboration and license revenue throughout the year. As of December 31, 2022 and 2021, the Company had $0.5 million of deferred revenue related to ongoing negotiations with a diagnostics company.

Abbott Laboratories

On September 29, 2020, the Company entered into a Non-Exclusive License Agreement (the Abbott License Agreement) with Abbott. Pursuant to the terms of the Abbott License Agreement, the Company granted Abbott a non-exclusive, worldwide, royalty-bearing license, without the right to sublicense, under the Company's bead-based single molecule detection patents (Licensed Patents) in the field of *in vitro* diagnostics. Abbott has paid the Company an initial license fee of $10.0 million in connection with the execution of the Abbott License Agreement, which was recognized as license revenue for the year ended December 31, 2020. Abbott has also agreed to pay the Company milestone fees subject to the achievement by Abbott of certain development, regulatory and commercialization milestones and low single-digit royalties on net sales of licensed products.

The Abbott License Agreement includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature. The Abbot License Agreement became effective upon signing and will continue until expiration of the last-to-expire Licensed Patent, or the agreement is earlier terminated. Under the terms of the Abbott License Agreement, the Company and Abbott each have the right to terminate the agreement for uncured material breach by, or insolvency of, the other party. Abbott may also terminate the Abbott License Agreement at any time without cause upon 60 days' notice.

During the years ended December 31, 2022 and 2021, the Company recognized no revenue, respectively, within collaboration and license revenue related to the initial license fee under the Abbott License Agreement.

6. Inventory

Inventory consists of the following (in thousands):

	As of December 31,	
	2022	2021
Raw materials	$ 5,509	$ 7,892
Work in process	3,362	4,923
Finished goods	7,915	9,375
Total	$ 16,786	$ 22,190

Inventory comprises commercial instruments, assays, and the materials required to manufacture assays.

7. Property and equipment

Property and equipment consists of the following (in thousands):

	As of December 31,	
	2022	2021
Laboratory and manufacturing equipment	$ 11,806	$ 9,742
Office furniture and equipment	1,798	1,617
Computers and software	3,831	3,893
Leasehold improvements	13,688	10,413
Total cost	$ 31,123	$ 25,665
Less: accumulated depreciation	(10,961)	(7,705)
Property and equipment, net	$ 20,162	$ 17,960

The Company incurred depreciation expense of $3.5 million, $2.8 million and $2.2 million for the years ended December 31, 2022, 2021, and 2020, respectively. The Company has instruments included in laboratory and manufacturing equipment, which are used internally by the Company. As of December 31, 2022, the laboratory and manufacturing equipment balance includes $7.5 million of cost and $3.2 million of accumulated depreciation related to these instruments. As of December 31, 2021, the laboratory and manufacturing equipment balance includes $3.9 million of cost and $1.5 million of accumulated depreciation related to these instruments.

For the year ended December 31, 2022, the Company recorded $4.3 million of impairment expense to leasehold improvements and other assets associated with the Bedford, Massachusetts leased office and laboratory space not being utilized by the Company. The Company decided not to utilize the space as part of the Restructuring Plan and intends to sublease the vacant space to recover a portion of the total cost. The Company's decision to not utilize, and sublease, the leased asset triggered an impairment event. The impairment testing deemed all assets associated with the leased assets as one asset group. The impairment analysis evaluated the present value of net cash flows under the original lease and the estimated cash flows under the sublease to identify the impairment amount. The impairment assessment considered all industry and economic factors such as rental rates, interest rates and recent real estate activities to estimate the net cash flows analysis and impairment amount.

The Company recorded $1.1 million of impairment expense to Computers and software for the year ended December 31, 2022. A change in the scope of the intended use of these assets was considered to be the triggering event for the impairment assessment and expense.

No such impairment expenses were recognized for the years ended December 31, 2021 and 2020.

8. Other accrued expenses

Other accrued expenses consist of the following (in thousands):

	As of December 31,	
	2022	2021
Royalties	$ 815	$ 1,250
Professional and outside services	1,409	2,126
Tax liabilities	172	430
Other	2,351	2,680
Total accrued expenses	$ 4,747	$ 6,486

9. Income taxes

The following table presents the components of loss before income taxes (in thousands):

	Year Ended December 31,		
	2022	2021	2020
United States	$ (89,590)	$ (56,554)	$ (29,896)
Foreign	(7,045)	(1,170)	(2,010)
Total loss before income taxes	$ (96,635)	$ (57,724)	$ (31,906)

The following table summarizes income tax (expense) benefit (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Current:			
United States			
Federal	$ —	$ —	$ —
State	(77)	(30)	(13)
Foreign	(368)	(342)	(102)
Total current income tax provision	(445)	(372)	(115)
Deferred			
United States			
Federal	10	5	(8)
State	13	(6)	(3)
Foreign	357	409	502
Total deferred income tax benefit	380	408	491
Total income tax (expense) benefit	$ (65)	$ 36	$ 376

A reconciliation of the federal statutory income tax rate to the effective tax rate is as follows:

	Year Ended December 31,		
	2022	2021	2020
Federal statutory income tax rate	21.0 %	21.0 %	21.0 %
Foreign tax rate differential	— %	— %	0.30 %
State taxes, net of federal benefit	2.7 %	6.5 %	2.5 %
Tax credits	1.4 %	2.0 %	1.6 %
Share-based compensation	(2.5)%	7.4 %	5.2 %
Permanent items	(0.3)%	(1.8)%	(0.4)%
Deferred tax rate change	— %	0.2 %	0.3 %
Change in valuation allowance	(20.8)%	(34.8)%	(29.7)%
Impairment of goodwill	(1.7)%	— %	— %
Other	0.0 %	(0.4)%	0.4 %
Effective income tax rate	(0.2)%	0.1 %	1.2 %

The effective income tax rate differs from the U.S. federal statutory rate of 21.0% primarily as a result of the valuation allowance maintained against the Company's net deferred tax assets.

Deferred tax assets and liabilities reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities were as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 78,191	$ 67,543
Tax credits	7,407	6,113
Deferred revenue	2,385	1,862
Amortization	847	962
Stock-based compensation	2,773	3,138
Inventory	1,507	686
Capitalized R&D Costs	5,680	—
Lease liability	10,856	5,464
Other deferred tax assets	1,370	2,340
Total deferred tax assets	111,016	88,108
Less: valuation allowances	(103,243)	(83,121)
Net deferred tax assets	7,773	4,987
Deferred tax liabilities:		
Right-of-Use Assets	(5,219)	(2,867)
Depreciation	(2,244)	(1,752)
Amortization acquired intangibles	(1,570)	(2,208)
Goodwill	—	(66)
Other deferred tax liabilities	(209)	(129)
Net deferred tax (liability) asset	$ (1,469)	$ (2,035)

The Company's change in its valuation allowance account with respect to the deferred tax asset is as follows (in thousands):

	2022	2021
Balance, beginning of year	$ 83,121	$ 63,609
Change in valuation allowance	20,122	19,512
Balance, end of year	$ 103,243	$ 83,121

The valuation allowance increased during the year ended December 31, 2022 primarily as a result of the U.S. operating losses incurred and research and development tax credit carryforwards generated during the year.

In determining the need for a valuation allowance, the Company has given consideration to the cumulative book income and loss positions of each of its entities as well as its worldwide cumulative book loss position. The Company has assessed, on a jurisdictional basis, the available means of recovering deferred tax assets, including the ability to carryback net operating losses (NOLs), the existence of reversing taxable temporary differences, the availability of tax planning strategies, and forecasted future taxable income. At December 31, 2022, the Company maintains a full valuation allowance against its worldwide net deferred tax assets.

As of December 31, 2022, the Company had U.S. federal NOLs of approximately $309.7 million. U.S. federal NOLs generated through December 31, 2017 of approximately $108.5 million expire at various dates through 2037, and U.S. federal NOLs generated in the tax years beginning after December 31, 2017 of approximately $201.2 million do not expire. As of December 31, 2022, the Company had $207.4 million of state NOLs, approximately $197.4 million expire at various dates through 2042, and certain state NOLs of approximately $10.0 million do not expire. As of December 31, 2022, the Company had U.S. federal tax credit carryforwards of approximately $5.8 million that expire at various dates through 2042. As of December 31, 2022, the Company had U.S. state tax credit carryforwards of approximately $2.0 million that expire at various dates through 2037.

Under Sections 382 and 383 of the U.S. Internal Revenue Code, if a corporation undergoes an ownership change, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its post-change income and taxes may be limited. In general, an ownership change generally occurs if there is a cumulative change in its ownership by 5% stockholders that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under U.S. state tax laws. Under the Tax Cuts and Jobs Act of 2017 (TCJA), the use of federal NOLs arising in taxable years beginning after December 31, 2017 is limited to 80% of current year taxable income and NOLs arising in taxable years ending after December 31, 2017 may not be carried back (though any such NOLs may be carried forward indefinitely).

The Company may have experienced an ownership change in the past and may experience ownership changes in the future as a result of future transactions in its share capital, some of which may be outside of the control of the Company. As a result, if the Company earns net taxable income, its ability to use its pre-change NOLs, or other pre-change tax attributes, to offset U.S. federal and state taxable income and taxes may be subject to significant limitations.

The Company accounts for uncertain tax positions using a more likely than not threshold for recognizing uncertain tax positions. The evaluation of uncertain tax positions is based on factors that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates uncertain tax positions on an ongoing basis and adjusts the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. The Company accounts for interest and penalties related to uncertain tax positions as a component of its benefit (provision) for income taxes. For the years ended December 31, 2022, 2021, and 2020, the Company had no tax reserves accrued for uncertain tax positions and there were no accrued interest or penalties in the consolidated statements of operations.

The Company is subject to taxation in the United States as well as the Netherlands, Sweden, and China. At December 31, 2022, the Company is generally no longer subject to examination by taxing authorities in the United States for years prior to 2019. However, NOLs and tax credits in the United States may be subject to adjustments by taxing authorities in future years in which they are utilized. The Company's foreign subsidiaries remain open to examination by taxing authorities from 2013 onward.

As of December 31, 2022, the Company's foreign subsidiaries had immaterial undistributed earnings and the tax payable on the earnings that are indefinitely reinvested would be immaterial.

10. Stock-Based Compensation

Stock-based compensation

Stock-based compensation expense for all stock awards consists of the following (in thousands):

	December 31,		
	2022	2021	2020
Cost of product revenue	$ 608	$ 471	$ 189
Cost of service and other revenue	819	403	311
Research and development	1,639	1,807	1,129
Selling, general, and administrative	12,376	13,294	8,470
Total stock-based compensation	$ 15,442	$ 15,975	$ 10,099

At December 31, 2022, there was $33.9 million of total unrecognized compensation cost related to unvested stock options and restricted stock units which is expected to be recognized over the remaining weighted-average vesting period of 2.9 years.

Stock-based compensation plans

In June 2007, the Company adopted the 2007 Stock Option and Grant Plan (the 2007 Plan), under which it could grant incentive stock options, non-qualified options, restricted stock, and stock grants. In connection with the completion of the Company's IPO, the Company terminated the 2007 Plan. As of December 31, 2022, 207,464 shares were outstanding under the 2007 Plan, and no shares are available for future grant under the 2007 Plan.

In December 2017, the Company adopted the 2017 Employee, Director and Consultant Equity Incentive Plan (the 2017 Plan), under which it may grant incentive stock options, non-qualified stock options, restricted stock, and other stock-based awards. As of December 31, 2017, the 2017 Plan allowed for the issuance of up to 1,042,314 shares of common stock plus up to 2,490,290 shares of common stock represented by awards granted under the 2007 Plan that are forfeited, expired, or are cancelled without delivery of shares or which result in the forfeiture of shares of common stock back to the Company on or after the date the 2017 Plan became effective. As of December 31, 2022, 3,168,278 shares were outstanding and there were 1,847,643 shares available for grant under the 2017 Plan.

In addition, the 2017 Plan contains an "evergreen" provision, which allows for an annual increase in the number of shares of common stock available for issuance under the 2017 Plan on the first day of each fiscal year during the period beginning in fiscal year 2019 and ending in fiscal year 2027. The annual increase in the number of shares shall be equal to the lowest of: (i) 4% of the number of shares of common stock outstanding as of such date and (ii) an amount determined by the Company's Board of Directors or Compensation Committee. On January 3, 2023, the number of shares of common stock available for issuance under the 2017 plan was increased by 1,488,696 shares in accordance with the 2017 Plan's evergreen provision.

In December 2017, the Company adopted the 2017 Employee Stock Purchase Plan (the 2017 ESPP). As of December 31, 2019, the 2017 ESPP allowed for the issuance of up to 612,572 shares of common stock. As of December 31, 2022, 1,447,467 shares were available for grant under the 2017 ESPP.

In addition, the 2017 ESPP contains an "evergreen" provision, which allows for an increase on the first day of each fiscal year beginning with fiscal year 2018. The increase in the number of shares shall be equal to the lowest of: (i) 1% of the number of shares of common stock outstanding on the last day of the immediately preceding fiscal year and (ii) an amount determined by the Company's Board of Directors or Compensation Committee. On January 3, 2023, the number of shares of common stock available for issuance under the 2017 ESPP was increased by 372,174 shares in accordance with the 2017 ESPP's evergreen provision.

The 2017 ESPP provides for six-month option periods commencing on March 1 and ending August 31 and commencing September 1 and ending February 28 of each calendar year.

Stock options

Under the 2017 Plan, stock options may not be granted with exercise prices of less than fair market value on the date of the grant. Options generally vest ratably over a four-year period with 25% vesting on the first anniversary and the remaining 75% vesting ratably on a monthly basis over the remaining three years. These options expire ten years after the grant date. Option activity is as follows:

	Options	Weighted-average exercise price	Remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2021	2,204,813	$ 25.36	6.8	$ 44,813
Granted	1,507,452	$ 18.07		
Exercised	(243,792)	$ 5.10		
Cancelled	(1,280,825)	$ 28.63		
Outstanding at December 31, 2022	2,187,648	$ 20.69	8.1	4,273
Exercisable at December 31, 2022	820,868	$ 22.92	5.8	1,566
Vested and expected to vest at December 31, 2022	2,187,648	$ 20.69	8.1	4,273

Restricted stock units

Restricted stock units (RSUs) represent the right to receive shares of common stock upon meeting specified vesting requirements. A summary of RSU activity is as follows:

	Shares	Weighted-average grant date fair value per share	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Unvested RSUs as of December 31, 2021	529,871	$ 49.32	9.7	$ 22,467
Granted	1,273,807	$ 18.32		
Vested	(200,078)	$ 48.93		
Cancelled	(415,506)	$ 34.94		
Unvested RSUs as of December 31, 2022	1,188,094	21.18	9.6	$ 16,455
Expected to convert at December 31, 2022	1,188,094	$ 21.18		$ 16,455

11. Earnings (Loss) Per Share

The following table presents the computation of basic and diluted earnings per share:

	Year Ended December 31,		
	2022	2021	2020
	(in thousands, except share and per share data)		
Numerator:			
Net loss attributable to Quanterix Corporation	($ 96,700)	($ 57,688)	($ 31,530)
Denominator:			
Weighted average shares of common stock outstanding, basic and diluted	36,990,965	35,997,473	29,589,132
Net loss per share attributable to Quanterix Corporation, basic and diluted	($ 2.61)	($ 1.60)	($ 1.07)

In periods when the Company is in a net loss position, dilutive securities are excluded from the computation of diluted earnings per share because their inclusion would have an anti-dilutive effect. Thus, basic net loss per share is the same as diluted net loss per share. The following common share equivalents have been excluded from the calculation of diluted net loss per share:

	Year Ended December 31,		
	2022	2021	2020
Unvested restricted common stock and restricted stock units	701,707	531,473	518,387
Outstanding stock options	446,180	2,304,543	2,494,045
Outstanding common stock warrants	—	—	10,000

12. Leases

Bedford Lease

On January 28, 2022, the Company executed a lease for 85,800 square feet of office and laboratory space in Bedford, Massachusetts. The lease commencement date was February 1, 2022, when the Company gained access to the underlying facilities. The Company has negotiated a tenant improvement allowance with the landlord which will offset a portion of the Company's construction costs. The Company has assessed whether improvements made to the premises are landlord-owned or company-owned, with payments made by the Company for landlord-owned assets accounted for as lease incentives. The initial term of the lease's payment schedule is eight years and nine months beginning on May 1, 2022. The Company has the option to extend the lease for two additional five-year periods.

In applying the ASC 842 transition guidance, the Bedford Lease has been assessed as an operating lease and the Company recorded ROU assets of $18.2 million and lease liability of $23.7 million on the effective date. The difference between the ROU and the lease liability was driven by the lease obligation incentive of $5.5 million.

As part of the Restructuring Plan, the Company decided not to utilize these facilities as part of its own operations and intends to sublease the vacant space to recover a portion of the total cost. The Company's decision to not utilize, and sublease, the leased asset triggered an impairment event. The impairment testing deemed all assets associated with the leased assets as one asset group. The impairment analysis evaluated the present value of net cash flows under the original lease and the estimated cash flows under the sublease to identify the impairment amount. The impairment assessment considered all industry and economic factors such as rental rates, interest rates and recent real estate activities to estimate the net cash flows analysis and impairment amount.

For the year ended December 31, 2022, the Company recorded an impairment of $12.0 million to the right-of-use assets related to the Bedford facilities.

No such impairment expenses were recognized for the years ended December 31, 2021 and 2020.

Summary of all lease costs recognized under ASC 842

Total operating lease costs were $8.9 million, which includes $3.4 million of short term and variable lease costs for the year ended December 31, 2022. Total operating lease costs were $5.4 million and $4.8 million for the years ended December 31, 2021 and 2020, respectively. The fixed lease costs were $5.5 million, $5.4 million and $4.8 million for the years ended December 31, 2022, 2021 and 2020, respectively. Short-term lease costs and variable lease costs incurred by the Company for the years ended December 31, 2021 and 2020 were considered immaterial.

Refer to table below for additional information related to operating leases under ASC 842:

	Year Ended December 31,	
Operating leases (in thousands)	**2022**	**2021**
Supplemental balance sheet information:		
Weighted average remaining lease term (years)	7.8	8.6
Weighted average discount rate	7.83%	9.73%
Supplemental cash flow information:		
Operating cash flows used for operating leases	$ 6,539	$ 3,388

Future minimum commitments under ASC 842 under the Company's operating leases in effect at December 31, 2022 were as follows:

Maturity of lease liabilities (in thousands)	**As of December 31, 2022**
2023	$ 6,707
2024	7,064
2025	7,228
2026	7,408
2027	7,641
thereafter	23,621
Total lease payments	$ 59,669
Less: imputed interest and lease incentive reimbursements	15,565
Total operating lease liabilities	$ 44,104

13. Commitments and contingencies

Purchase Commitments

Stratec

During the year ended December 31, 2022, the Company entered into a supply agreement (the Stratec Supply Agreement) with Stratec Consumables GmBH (Stratec) to order discs used in manufacturing the Simoa HD-X instrument. As part of the Stratec Supply Agreement, the Company agreed to purchase a total of 375,000 discs to be shipped at various points starting in 2022 and continuing through 2024 at an agreed purchase price per disc. In 2022, under the Stratec Supply Agreement, Stratec shipped 75,000 discs to the Company. The Company recorded cost of product revenue related to this shipment of $0.5 million for the year ended December 31, 2022. No such activities existed for the years ended December 31, 2021 and 2020. Additionally, per the Stratec Supply Agreement, during the years ended December 31, 2023 and 2024, Stratec is required to ship 220,000 and 80,000 discs, respectively, to the Company. In the years ending December 31, 2023 and 2024, the Company expects to record cost of product revenue of $1.6 million and $0.6 million, respectively, related to those shipments. As of December 31, 2022, the Company also has $0.9 million of open purchase orders with Stratec.

Other Purchase Commitments

The Company purchases substantial amounts of raw materials for manufacturing operations under annual and multi-year agreements, some of which have minimum quantity requirements. Additionally, the Company enters into annual agreements for other parts of its operations. The Company has total purchase commitments for the year ended December 31, 2022, of $3.1 million, most of which the Company expects to incur in the year ending December 31, 2023.

License Agreements

Tufts University

In June 2007, the Company entered into a license agreement (the License Agreement) for certain intellectual property with Tufts University (Tufts). Tufts is a related party to the Company due to Tufts' equity ownership in the Company and because a board member of the Company's Board of Directors was affiliated with Tufts. The License Agreement, which was subsequently amended, is exclusive and sub-licensable, and will continue in effect on a country by country basis as long as there is a valid claim of a licensed patent in a country. The Company is committed to pay license and maintenance fees, prior to commercialization, in addition to low single digit royalties on direct sales and services and a royalty on sublicense income. During the years ended December 31, 2022, 2021, and 2020, the Company recorded royalty expense of $1.4 million, $1.6 million and $1.1 million, respectively, related to Tufts. This royalty expense is recorded in cost of product revenue on the consolidated statements of operations. During the year ended December 31, 2020, the Company incurred $1.0 million in cost of collaboration and license revenue owed to Tufts related to sublicensing certain technology and intellectual property to Abbott Laboratories (Abbott), refer to Note 5 for additional details.

Legal contingencies

The Company is subject to claims in the ordinary course of business; however, the Company is not currently a party to any pending or threatened litigation, the outcome of which would be expected to have a material adverse effect on its financial condition or the results of its operations. The Company accrues for contingent liabilities to the extent that the liability is probable and estimable.

14. Restructuring and Other Charges

Following a strategic review and assessment of the Company's operations and cost structure, on August 8, 2022, the Company announced a plan of restructuring and strategic re-alignment (the Restructuring Plan). As part of the Restructuring Plan, the Company began an assay redevelopment program with the ultimate objective of improving its ability to manufacture and deliver high-quality assays at scale. In accordance with the Restructuring Plan, the Company implemented a workforce reduction, which was substantially completed by the end of the third quarter of 2022. The Company recorded charges during the year ended December 31, 2022, consisting of one-time termination benefits for employee severance, benefits and related costs, all of which were cash expenditures.

The following shows the number of positions by function and by location eliminated in connection with the Restructuring Plan:

	North America	EMEA	Asia Pacific	Total
Cost of goods sold	21	—	—	21
Research and development	34	1	—	35
Selling, general and administrative	50	9	4	63
Total headcount	105	10	4	119

As part of the Restructuring Plan, the Company also performed an assessment of impairment for long-lived assets, including right-of-use assets, and recorded an impairment charge of $17.4 million. The impairment expense includes $16.3 million associated with the right-of-use and property and equipment at the Bedford facilities and $1.1 million for software costs related to projects that have been rationalized as part of the Restructuring Plan. Refer to Note 7 and Note 12 for further information.

The following table presents the restructuring reserve and provision activity for the year ended December 31, 2022 (in thousands):

	Severance and Employee Benefit Costs	Other Restructuring Charges	Total
Balance at January 1, 2022	$ —	$ —	$ —
Charges	3,634	121	3,755
Cash payments	(3,288)	(121)	(3,409)
Foreign exchange	(18)	—	(18)
Balance at December 31, 2022	$ 328	$ —	$ 328

No such restructuring activities existed for the years ended December 31, 2021 and 2020.

15. Notes payable

Loan agreement

On April 14, 2014, the Company executed a loan agreement with a lender, as subsequently amended. As of December 31, 2021, there were no additional amounts available to borrow under the debt facility. The interest rate on the term loan was variable based on the greater of 8% or 8% plus the prime rate less 5.25%. Interest was paid monthly beginning the month following the borrowing date. At loan inception and in connection with the amendments, the Company issued the lender warrants to purchase shares of stock. The loan agreement also contained prepayment penalties and an end of term charge. Fees incurred upon execution of the agreements, and the fair value of warrants on

the date of grant were accounted for as a reduction in the book value of debt and accreted through interest expense, using the effective interest rate method, over the term of the debt. Under the amended agreement, the Company was required to pay the loan principal in four equal installments starting July 1, 2021, with the final payment and end of term charge to be made on October 1, 2021. On October 1, 2021, the Company made the final principal payment, including end of term fees, of $2.0 million related to the loan agreement.

The Company has not executed any subsequent loan agreements and there were no outstanding loan balances during the year ended December 31, 2022.

16. Employee benefit plans

The Company sponsors a 401(k) savings plan for employees. The Company may make discretionary contributions for each 401(k) plan year. During the years ended December 31, 2022, 2021, and 2020, the Company made contributions of $1.2 million, $1.1 million, and $0.7 million, respectively.

17. Goodwill and intangible assets

During the third quarter of 2022, the Company identified certain indicators of impairment, including the significant decline in the Company's stock price, actions taken under the Restructuring Plan and the reduction of forecasted sales and profitability. As a result, the Company performed an interim goodwill impairment test. It was determined that the Company's goodwill was impaired as the carrying amount of the Company's sole reporting unit exceeded the estimated fair value. The Company concluded that the entire goodwill balance was impaired and recognized a non-cash impairment charge during the third quarter of 2022.

The changes in the carrying amount of goodwill are as follows (in thousands):

	Goodwill
Balance as of December 31, 2021	$ 9,632
Impairment losses	(8,220)
Foreign exchange adjustments	(1,412)
Balance as of December 31, 2022	$ —

Acquired intangible assets, principally originating from the acquisition of Uman, consist of the following (dollars in thousands):

		December 31, 2022				
	Estimated Useful Life (in years)	Gross Carrying Value	Accumulated Amortization	Cumulative Translation Adjustment	Net Carrying Value	Weighted Average Life Remaining (in years)
Know-how	8.5	$ 13,000	$ (4,763)	$ (1,433)	$ 6,804	5.0
Developed technology	7	1,650	(1,458)	—	192	2.1
Customer relationships	8.5 - 10	1,360	(938)	(12)	410	5.1
Non-compete agreements	5.5	340	(193)	(37)	110	2.0
Trade names	3	50	(50)	—	—	—
Total		$ 16,400	$ (7,402)	$ (1,482)	$ 7,516	

	Estimated Useful Life (in years)	December 31, 2021 Gross Carrying Value	Accumulated Amortization	Cumulative Translation Adjustment	Net Carrying Value	Weighted Average Life Remaining (in years)
Know-how	8.5	$ 13,000	$ (3,825)	$ 241	$ 9,416	6.0
Developed technology	7	1,650	(1,277)	—	373	3.1
Customer relationships	8.5 - 10	1,360	(792)	2	570	6.1
Non-compete agreements	5.5	340	(170)	5	175	3.0
Trade names	3	50	(50)	—	-	—
Total		$ 16,400	$ (6,114)	$ 248	$ 10,534	

The Company recorded amortization expense of $1.8 million, $2.0 million, and $2.1 million for the years ended December 31, 2022, 2021, and 2020, respectively. Amortization of developed technology is recorded within research and development expenses, amortization of customer relationships is recorded within selling, general, and administrative expenses, amortization of trade names is recorded within selling, general, and administrative expenses, amortization of non-compete agreements is recorded within selling, general, and administrative expenses, and amortization of know-how is recorded within cost of goods sold.

Future estimated amortization expense of acquired intangible assets as of December 31, 2022 is as follows (amounts in thousands):

	As of December 31, 2022
2023	$ 1,665
2024	1,584
2025	1,447
2026	1,420
2027	1,398
Thereafter	2
Total amortization expense	$ 7,516

18. Related party transactions

As described in Note 13, in June 2007, the Company entered into a license agreement for certain intellectual property with Tufts. Tufts is a related party to the Company due to Tufts' equity ownership in the Company and because one of the Company's directors was affiliated with Tufts. During the years ended December 31, 2022, 2021, and 2020, the Company recorded royalty expense of $1.4 million, $1.6 million and $1.1 million, respectively, related to Tufts. This royalty expense is recorded in cost of product revenue on the consolidated statements of operations. During the year ended December 31, 2020, the Company also incurred $1.0 million in cost of collaboration and license revenue owed to Tufts related to sublicensing certain technology and intellectual property to Abbott, refer to 5 for additional details.

One of the Company's directors is affiliated with Harvard University and Mass General Brigham. Revenue recorded from sales to Harvard University and its affiliates and to Mass General Brigham and its affiliates totaled $0.7 million, $0.2 million, $0.1 million for the years ended December 31, 2022, 2021, and 2020 respectively. The Company recorded cost of goods sold of $0.1 million for the year ended December 31, 2022 related to Harvard University and its affiliates and to Mass General Brigham and its affiliates, with immaterial cost of goods sold recorded for years ended December 31, 2021 and 2020. The Company also incurred research and development expenses of $0.6 million with Harvard University and its affiliates for the year ended December 31, 2022, with immaterial research and development expenses incurred for years ended December 31, 2021 and 2020. The Company had $0.1 million and $0.2 million in accounts receivable from Harvard University and its affiliates and Mass General Brigham and its affiliates at December 31, 2022 and 2021, respectively. Deferred revenue from Harvard University and its affiliates and Mass General Brigham and its affiliates was $0.1 million at both December 31, 2022 and 2021.

On May 26, 2022, the Company entered into an agreement (the UltraDx Agreement) with UltraDx Limited (UltraDx), a new company formed by ARCH Venture Partners (ARCH). Under the UltraDx Agreement, the Company

will supply HD-X instruments (both fully assembled and disassembled) as well as assays and assay components to UltraDx, and UltraDx has the non-exclusive right to seek Chinese regulatory approval of and to commercialize the HD-X instrument and related assays in the Chinese neurological in vitro diagnostic market. The Company has determined that UltraDx is a related party because one of the Company's directors is affiliated with ARCH and UltraDx. Under the terms of the UltraDx Agreement, the Company shipped a total of ten fully assembled and disassembled HD-X instruments to UltraDx on June 30, 2022 at a purchase price of approximately $1.9 million. The Company recognized revenue on these shipments upon receipt of payment during the year ended December 31, 2022. No such activities occurred in the years ended December 31, 2021 and 2020.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No.333-223771) pertaining to the 2007 Stock Option and Grant Plan, as amended, the 2017 Employee Stock Purchase Plan, and 2017 Employee, Director, and Consultant Equity Incentive Plan;

(2) Registration Statement (Form S-8 No. 333-231373) pertaining to the 2017 Employee Stock Purchase Plan, and 2017 Employee, Director and Consultant Equity Incentive Plan;

(3) Registration Statement (Form S-8 No. 333-240420) pertaining to the 2017 Employee Stock Purchase Plan, and 2017 Employee, Director and Consultant Equity Incentive Plan;

(4) Registration Statement (Form S-8 No. 333-256032) pertaining to the 2017 Employee Stock Purchase Plan, and 2017 Employee, Director and Consultant Equity Incentive Plan; and

(5) Registration Statement (Form S-8 No. 333-264836) pertaining to the 2017 Employee Stock Purchase Plan, and 2017 Employee, Director and Consultant Equity Incentive Plan;

of our reports dated March 6, 2023, with respect to the consolidated financial statements of Quanterix Corporation and the effectiveness of internal control over financial reporting of Quanterix Corporation included in this Annual Report (Form 10-K) of Quanterix Corporation for the year ended December 31, 2022.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 6, 2023

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Masoud Toloue, certify that:

1. I have reviewed this annual report on Form 10-K of Quanterix Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 6, 2023

/s/ MASOUD TOLOUE
Masoud Toloue, Ph.D.
President and Chief Executive Officer (principal executive officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Michael Doyle, certify that:

1. I have reviewed this annual report on Form 10-K of Quanterix Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 6, 2023

/s/ MICHAEL A. DOYLE
Michael A. Doyle
Chief Financial Officer
(principal financial officer and principal accounting officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Quanterix Corporation, a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2022 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 6, 2023

/s/ MASOUD TOLOUE
Masoud Toloue, Ph.D.
President and Chief Executive Officer

Dated: March 6, 2023

/s/ MICHAEL A. DOYLE
Michael A. Doyle
Chief Financial Officer