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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, 2021

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. ☒

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, 2021), 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 $2.1 billion.

As of February 23, 2022, the registrant had 36,847,340 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2022 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, 2021, 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 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, you can identify forward-looking statements 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;
- 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;
- our ability to develop additional assays, including multiplexed assays;
- 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 companion diagnostics and its adoption by healthcare professionals;
- the impact of our Simoa technology on proteomic research;
- the usefulness of the data generated by our Simoa technology in the life science research, diagnostic and precision health screening 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.

You 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.

You 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. This Annual Report on Form 10-K also contains estimates and other statistical data from a custom market research report by an independent third-party research firm, which was commissioned by us and was issued in January 2021, referred to herein as the Third-Party Research Report. 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 you 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 Analyzer”, “HD-1 Analyzer” 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 precision health for 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 ELISA technology, which has been the industry standard for protein detection for over 40 years. Furthermore, we believe the HD-X is the most sensitive commercially available automated multiplex protein detection platform. 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 at least 10,000 are known to be secreted in blood. 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 approximately 1,600 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 1,120 customers across our end markets and includes 22 of the 25 largest biopharmaceutical companies.

Our Products and Services

Our proprietary Simoa technology is based on traditional enzyme-linked immunosorbent assay (ELISA) technology, which has been the most widely used method of detection of proteins for over 40 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. This ability is the key to our bead-based technology's unprecedented sensitivity. In addition, in January 2018, we acquired Aushon BioSystems, Inc. (Aushon) and its proprietary sensitive planar array detection technology. Leveraging our proprietary sophisticated Simoa image analysis and data analysis algorithms, we further refined this planar array technology to provide the same Simoa sensitivity 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 80 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 120 biomarkers ranging from 1-10 analytes per assay in the areas of immunology and oncology research. We intend to continue to increase the number of Simoa biomarker assays across our platforms. 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 1,700 projects for approximately 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 significant 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.

In view of the COVID-19 pandemic, in 2020 we adjusted our operations to expand capacity in our Accelerator Laboratory to support customers whose operations have been disrupted and to sustain clinical trials. We also 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 began developing a SARS- CoV-2 semi-quantitative IgG assay and a SARS-CoV-2 antigen detection assay and prototyping a high-definition multiplex SARS-CoV-2 serology assay. In December 2020, the United States Food and Drug Administration (FDA) issued an Emergency Use Authorization (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, each of which is run on our HD-X instrument. 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. We are exploring extending the test to home-based sample collection and pooling to enable larger scale testing.

In August 2019, we completed the acquisition of UmanDiagnostics AB (Uman), a company located in Umeå, Sweden, that supplies neurofilament light (Nf-L) antibodies and Nf-L ELISA kits. Uman’s Nf-L antibodies 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. Since we commercially launched the first assay that could reliably measure Nf-L in blood using Uman’s antibodies and our Simoa technology in 2017, Nf-L has seen dramatic growth as a neurological biomarker. This innovation allowed research, previously limited primarily to cerebrospinal fluid (CSF), to expand significantly and has led many of the world’s foremost neurology researchers and clinicians to conclude that Nf-L may be one of the most clinically relevant

brain biomarkers available today. Despite significant efforts by us and others to identify or develop an alternative source of antibodies, we believe the Uman Nf-L antibodies remain the best-in-class for highly sensitive and specific Nf-L detection in serum or plasma. The superiority of the Uman antibodies is evidenced by the fact that, to date over 600 publications relating to the detection of Nf-L in serum or plasma have used the Uman antibodies. The Uman acquisition secured the Nf-L antibody supply critical to our industry-leading ultrasensitive Simoa Nf-L assays and services, provided us with additional revenue opportunities via the sale of the Nf-L antibodies and Nf-L ELISA kits, and positioned us to capitalize on significant growth opportunities with Nf-L applications in Alzheimer's disease, multiple sclerosis, and other neurodegenerative conditions.

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 other select markets. In addition, we sell Uman's Nf-L antibodies and Nf-L 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 Market Opportunities

Our commercial strategy is to pursue the application of our Simoa technology to the life science research/drug trial, diagnostics and precision health screening markets.

Life Science Research/Drug Trial Markets

Our initial target market is the large and growing life science research and drug trial markets, which we sometimes refer to collectively as the translational market. We have chosen these markets to target initially because we believe there is 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. 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.

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. 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. 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.

According to estimates in the Third-Party Research Report, as we further expand our focus in these markets on other areas, such as immunology, oncology and other therapeutic areas, coupled with the growing adoption of decentralized clinical trials, the life science research/drug trial addressable market is expected to expand to as much as $12 billion.

Diagnostics

The diagnostic market represents a significant future commercial opportunity for our Simoa technology as well. We believe existing biomarker diagnostics, as well as invasive, expensive and inconvenient diagnostic methods, including spinal tap, diagnostic imaging and biopsy, can be improved by Simoa's sensitivity to enable earlier detection of diseases and injuries. Simoa technology also has significant potential in the emerging field of companion diagnostics. Drug developers can use companion diagnostics to stratify patients and select only those patients for whom a drug is expected to be most effective and safe.

In view of the COVID-19 pandemic, as an initial foray into the diagnostics market, in 2020 we began developing a SARS- CoV-2 semi-quantitative IgG assay and a SARS-CoV-2 antigen detection assay and prototyping a high-definition multiplex SARS-CoV-2 serology assay. We currently have EUAs for our Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test and our Simoa SARS-CoV-2 N Protein Antigen Test, each of which is run on our HD-X instrument. In addition, in 2021, our pTau-181 assay was granted Breakthrough Device Designation from the U.S. FDA as an aid in the diagnosis of Alzheimer's disease. We believe this gives us an opportunity to further advance a potential Alzheimer's disease diagnostic test either alone or with a partner.

There has also been significant interest from third parties to use our technology to develop applications for the diagnostic market, such as our licensing and supply arrangement with Siemens Healthineers (Siemens) for access to our Nf-L antibodies, which will allow Siemens to begin developing blood-based Nf-L clinical tests for future commercialization, as well as our 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.

Precision Health Screening

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, enabling a "precision health" revolution.

Simoa products sold or used in the diagnostics and precision health screening markets will be subject to regulation by the FDA or comparable international agencies, including requirements for regulatory clearance or approval of such products before they can be marketed. To date, other than our EUAs for our COVID assays, we have not received or applied for regulatory approvals for Simoa products. See "Risk Factors—Risks Related to Governmental Regulation and Diagnostic Product Reimbursement" and "—Government Regulation" for a more detailed discussion regarding the regulatory approvals that may be required.

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. We believe that sensitivity is so important that we have published an approach to increase the sensitivity of our Simoa technology – in some cases as much as 100-fold - and we intend to launch a beta program using this more sensitive technology in our Accelerator Laboratory by the end of 2022.

- ***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 40 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 approximately 1,600 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 1,120 customers includes some of the world's leading academic and government research institutions as well as 22 of the 25 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.

- ***Highly attractive business model that leverages growing installed base of instruments.*** Our installed instrument base increased by 32% in 2021 to 708 instruments as of December 31, 2021. 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 consumables and other product revenue increased by $27.7 million to $55.1 million in 2021 from $27.4 million in 2020 and $25.6 million in 2019. Consumables and other product revenue represented approximately 50% of our total revenue in 2021.

- ***Our highly experienced senior management team.*** We are led by a dedicated and highly experienced senior management team with significant industry experience and proven ability to develop novel solutions. Each of the members of our senior management has more than 20 years of relevant 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/drug trial markets in the near-term, and the diagnostics and precision health screening markets in the long-term.*** 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 on these markets because we believe there is reduced regulatory and reimbursement risk for us in these markets. However, we also 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. We have had two EUAs approved for our COVID assays. In addition, in 2021 our pTau-181 assay was granted Breakthrough Device designation from the FDA as an aid in diagnostic evaluation of Alzheimer's disease, and we are currently aiming to launch our first laboratory developed test in 2023. In the precision health screening market, we believe that Simoa technology has the potential to someday be used to monitor biomarker levels of seemingly healthy, asymptomatic people, and potentially to signal and provide earlier detection and monitoring of the onset of disease.

- ***Leverage the growing importance of Nf-L and other neurological biomarkers to advance the development of therapeutics and diagnostics for neurodegenerative conditions.*** The importance of Nf-L and other neurological biomarkers, such as 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 CSF, to expand significantly. To capitalize on the growing importance of Nf-L, in mid-2019, we acquired Uman and its proprietary Nf-L antibodies, which we believe are the best-in-class for highly sensitive and specific Nf-L detection in serum or plasma. In addition, other neuro biomarkers, such as pTau-217 and pTau-181, have shown increasing relevance in neurological research and drug development. 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. 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.

- ***Grow into new markets organically with our customers and through strategic collaborations.*** Our customers have access to a large breadth of diverse markets, spanning research and clinical settings. As these customers continue to gain experience with our proprietary Simoa technology and further appreciate its potential, we believe moving into diagnostics and ultimately precision health is a natural extension of some of the work that our customers are doing today in the research market. For example, use of Simoa technology by pharmaceutical companies to measure biomarkers in clinical trials potentially could lead to a companion diagnostic, and ultimately a precision health test that could monitor and identify early disease. We believe this progression with our customers will help us move into new markets organically in a cost-effective manner, while also retaining significant upside. In addition, we have entered into, and will continue to explore, partnerships that will help us access these markets. For example, following our acquisition of Uman, we entered into a licensing and supply arrangement with Siemens Healthineers for access to Uman's proprietary Nf-L antibodies, which will allow Siemens to begin developing blood-based Nf-L clinical tests for future commercialization. Additionally, in September 2020, we granted Abbott Laboratories a non-exclusive license under our bead-based single molecule detection patents for IVD use.

- ***Grow through strategic acquisitions.*** We intend to strategically acquire businesses and technologies to expand our operations and strengthen our market position. For example, in January 2018, we acquired Aushon and its proprietary sensitive planar array detection technology, which led to the development of our SP-X instrument. In mid-2019, we also acquired Uman, securing the Nf-L antibody supply critical to our industry leading ultrasensitive Simoa Nf-L assays and services and positioning us to capitalize on the

growing significance of Nf-L as a neurological biomarker. We expect that acquisitions will continue to be an important part of our strategy to increase scale, and we intend to pursue acquisitions to expand product offerings, strengthen domestic or international distribution, add technologies, and/or provide access to complementary or strategic growth areas.

- ***Leverage the PPH ecosystem.*** Powering Precision Health (PPH) is a non-profit organization founded in 2016 by our Chief Executive Officer, Kevin Hrusovsky. PPH aims to gather many of the world's top innovators, scientists, physicians, medical professionals, patient advocates, government officials, regulators and investors to discuss the critical issues and opportunities related to advancing precision medicine in key disease areas including neurology, oncology, cardiology, inflammation and infectious disease. Quanterix is uniquely positioned to leverage this PPH ecosystem to gather and synthesize key insights and information, to collaborate on important research, to deepen our credibility and expand our business opportunities in the proteomics space, and to raise awareness of the technological innovations, such as Simoa, that are powering the latest breakthroughs in medical research and precision health.

Industry Background

We intend to pursue the application of our Simoa technology to the life science research/drug trial, diagnostics and precision health screening markets. Our initial commercial strategy targets the large and growing life science research/drug trial markets, and we believe that the diagnostic market and the precision health screening market represent significant future commercial opportunities for Simoa. According to estimates in the Third-Party Research Report, we believe the aggregate commercial opportunity across these markets has the potential to expand to over $100 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 at least 10,000 are known to be secreted in blood, and fewer than 1,300 of which can 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. Currently, across our platforms, we commercialize assays that address approximately 154 protein biomarkers secreted or released in blood and CSF.

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 understand precisely the nuanced continuum between health and disease. Genes may indicate the risk of developing a certain disease later in life, but they are not able to account for the impact of environmental factors and lifestyle, such as diet and exercise, or provide insight into what is happening in a patient's body in real time. For example, identical twins have the same genotype, but may develop different diseases over the course of their lifetime, largely due to environmental factors.

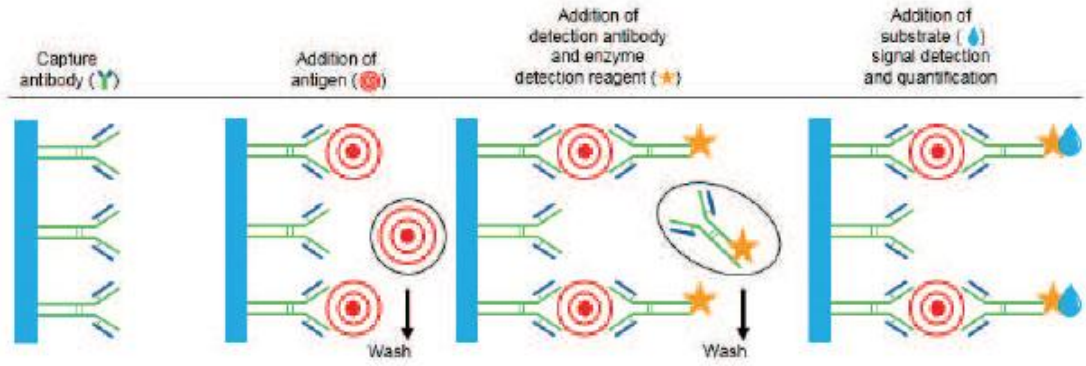
Much like the sequencing of the human genome with the Human Genome Project and the development of both PCR and next generation sequencing technologies to detect nucleic acids, both of which accelerated biomedical genomic research, we believe the ability to study more of the proteome enabled by our more 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 40 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 at least 10,000 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 restrict 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.

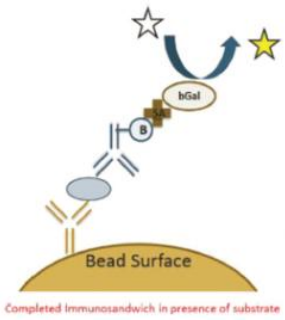
Simoa Bead-Based Technology

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:

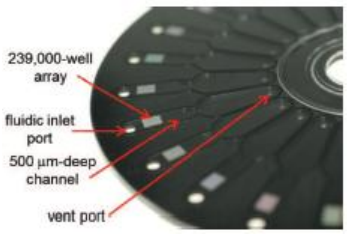
Simoa Bead-Based Analytic Process

Sample Preparation of ELISA Sandwich



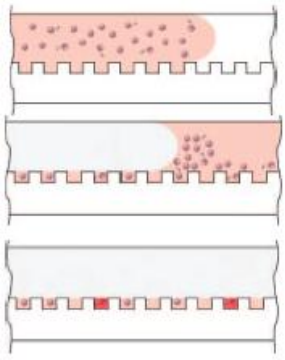
Simoa bead-based technology uses beads coated with capture antibodies that bind specifically to the protein being measured. After an enzyme-linked detection antibody binds to the protein, the enzyme substrate is added (as depicted by the white star in the graphic on the left). The enzyme associated with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



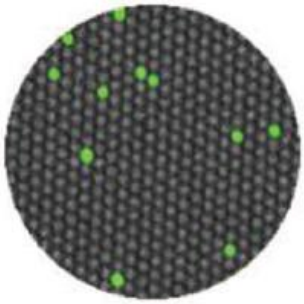
This mixture of beads and enzyme substrate is then injected into our proprietary Simoa disk, which contains 24 arrays of microwells arranged radially. Each 3 × 4 millimeter array contains approximately 239,000 microwells, each of which is large enough to accommodate only a single bead.

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.

Our Simoa bead-based technology offers unprecedented protein detection sensitivity and enables detection of low abundance and previously undetectable biomarkers. 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 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

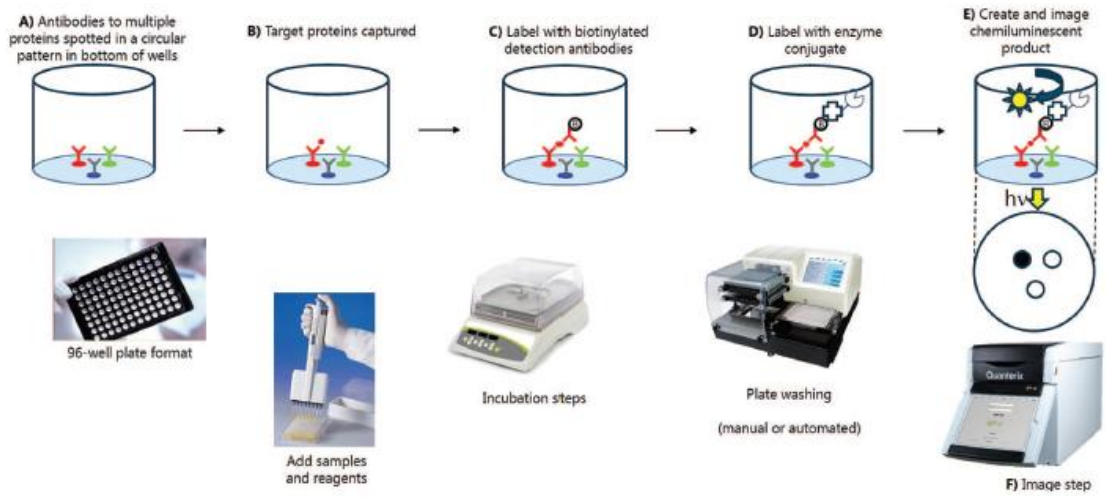
achieved with our Simoa bead-based technology by using beads labeled with different fluorescent dyes specific to the biomarker being analyzed. After the assay is run, the array of microwells is imaged across the wavelengths of the different labeled beads. The results are measured for each protein captured by each of the different beads. In 2017, we commercially launched a Simoa neurology 4-plex assay (Nf-L, 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, Nf-L) 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, 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 above a 6-plex 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 two 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.

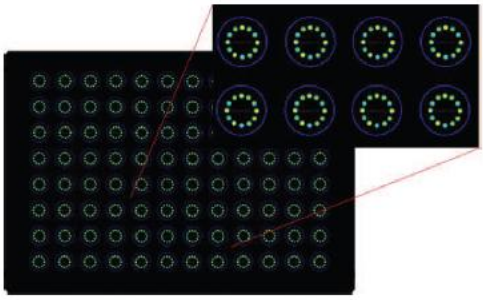
C) A mixture of biotinylated detection antibodies are added to the plate to form the antibody sandwich. Excess detection antibodies are removed by washing.

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.

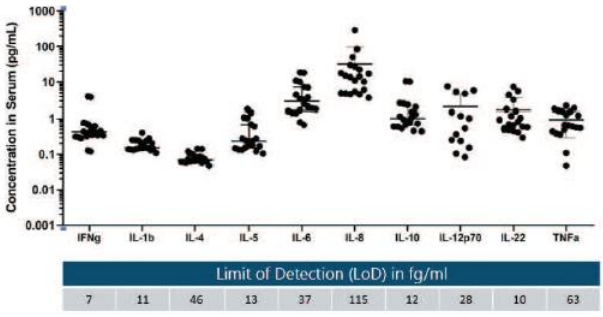
E) A high-sensitivity chemiluminescent substate reagent is added to each well. The enzyme associated with the enzyme linked detection antibody then reacts with the enzyme substrate causing the enzyme substrate to emit light.

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 SP-X 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/drug trial, diagnostics and precision health screening markets.

Life Science Research/Drug Trial Markets

Our initial target market is the large and growing life science research and drug trial markets, which we sometimes refer to collectively as the translational market. 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. 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.

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.

According to estimates in the Third-Party Research Report, as we further expand our life science research focus in other areas of immunology, oncology and other therapeutic areas, coupled with growing adoption of decentralized clinical trials, the life science research/drug trial addressable market is expected to expand to as much as $12 billion.

Diagnostics

The diagnostic market represents a significant future 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 companion diagnostics. A companion 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 companion diagnostics to stratify patients and select only those patients for whom a drug is expected to be most effective and safe. Companion diagnostics 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 companion diagnostics to stratify patients in clinical trials and for treatment, but Simoa's sensitivity can also enable the development of companion diagnostics 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.

In view of the COVID-19 pandemic, as an initial foray into the diagnostics market, in 2020 we began developing a SARS- CoV-2 semi-quantitative IgG assay and a SARS-CoV-2 antigen detection assay and prototyping a high-definition multiplex SARS-CoV-2 serology assay. 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, each of which is run on our HD-X instrument. 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. We are exploring extending the test to home-based sample collection and pooling to enable larger scale testing.

In 2021, our pTau-181 assay was granted Breakthrough Device designation from the FDA as an aid in the diagnosis of Alzheimer's disease. We believe this gives us an opportunity to further advance a potential Alzheimer's disease diagnostic test either alone or with a partner.

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 Nf-L antibodies, which will allow Siemens to begin developing blood-based Nf-L clinical 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.

Precision Health Screening

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, enabling a "precision health" revolution.

We believe there is the potential for a number of neurological, cardiovascular, oncologic and other protein biomarkers associated with disease to be measured with a simple blood draw on a regular, ongoing basis as part of a patient's routine health screening, and for those results to be compared periodically with baseline measurements to predict or detect the early onset of disease, prior to the appearance of symptoms.

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. In particular, we have focused on neurology and oncology, as well as COVID, 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 cerebrospinal fluid (CSF), has the potential to rapidly advance neurology research and drug development, and transform the way brain diseases and injuries are diagnosed and treated. To our knowledge, the brain is the only organ in the body for which there is not currently 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 an MRI scan of the brain 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 are so low that they are undetectable by conventional, analog immunoassay technologies.

To date, there have been over 1,000 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, dementia, Parkinson's disease, and traumatic brain injury, or TBI. The goal of this research is to eventually develop accurate diagnostic tools, predictive health screens and, ultimately, more effective treatments. The importance of Nf-L and other neurological biomarkers, such as pTau-181 and pTau-217, has increased significantly 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.

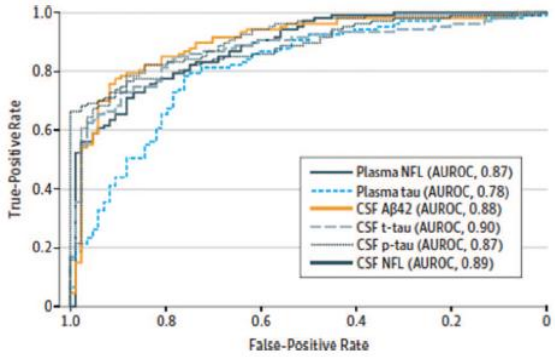
Dementia is a collective name for brain syndromes that affect memory, thinking, behavior and emotion. According to *Alzheimer's Disease International*, as of 2021, there were more than 55 million people worldwide living with dementia, a figure expected to increase to over 139 million by 2050, and the 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 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. These results highlight the potential role for emerging biomarker measurements in the detection of Alzheimer's disease pathology even earlier in the disease continuum, when patients are asymptomatic and not yet exhibiting brain pathology in PET imaging studies.

In 2017, researchers using Simoa technology published a paper in *JAMA Neurology* demonstrating that a simple blood test for Nf-L exhibited the same level of diagnostic accuracy for diagnosing Alzheimer's disease as currently established CSF biomarkers. The study was a major study of almost 600 patients from the Alzheimer's Disease Neuroimaging Initiative. The graph below depicts the diagnostic accuracy of plasma Simoa Nf-L measurements compared with traditional CSF biomarkers. The diagnostic accuracy of the plasma Simoa Nf-L results approached 90%, in line with the CSF biomarkers on the same patients.

Diagnostic Accuracy



In addition, Simoa plasma Nf-L values were associated with cognitive deficits and neuroimaging hallmarks of Alzheimer's disease at baseline and during follow-up. High plasma Nf-L correlated with poor cognition and Alzheimer's disease-related brain atrophy and with brain hypometabolism (lower neural energy). These data suggest a simple Simoa blood test for Nf-L may have clinical utility as a noninvasive biomarker in Alzheimer's disease.

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. We believe this gives us an opportunity to further advance a potential Alzheimer's disease diagnostic test either alone or with a partner. 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.

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 million people over the age of 18 live with a diagnosis of MS.

Evidence of the potential clinical utility of Nf-L as a biomarker in multiple sclerosis is progressing rapidly, and Simoa's role in that progression has been significant. In 2021, Simoa technology supported 31 scientific presentations at the 37th 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 2020, Simoa supported 42 presentations at ECTRIMS, and at ECTRIMS in 2019, there were nearly 50 presentations in which our Simoa Nf-L 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 Nf-L as measured using our Simoa Nf-L 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 Nf-L, 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 Nf-L levels and increased proportion of patients reaching healthy donor range for Nf-L in both relapsing multiple sclerosis and primary progressive multiple sclerosis. Roche believes that this data helps advance the understanding of Nf-L 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 Nf-L, as measured by the Simoa Nf-L 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 Nf-L 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 Nf-L, a biomarker of neuroaxonal degeneration, increased only after EBV seroconversion, suggesting that EBV played a role in nerve cell damage.

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 Nf-L, 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 recent 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. Eventually, we believe it may be possible to develop a mobile screen enabling clinicians to quickly and accurately determine whether it is safe for concussed athletes to return to play.

In 2016, Fast Company named Quanterix one of the "World's Most Innovative Companies" for our work in concussion detection. We also were awarded two competitive grants from the NFL-GE Head Health Challenge to advance this work in the detection and quantification of mild TBI.

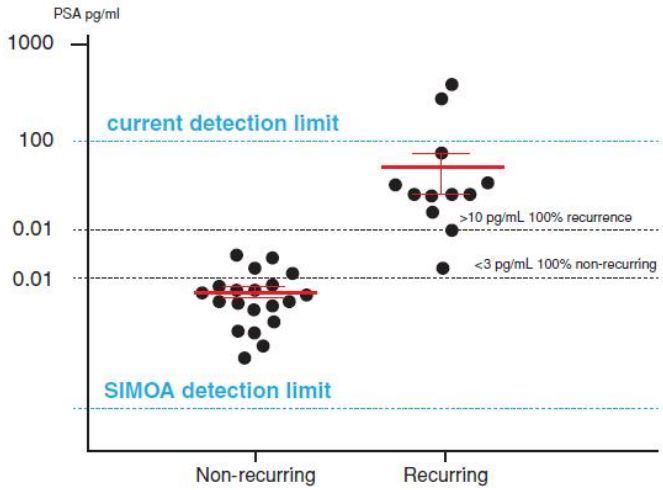
Oncology

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.

Simoa technology was used in an unpublished scientific study that indicates it may be possible to eventually replace routine mammograms with a very sensitive, more accurate, low cost, non-invasive blood test. In this retrospective study, researchers found that Simoa assays resulted in significantly fewer false positives and false negatives than mammography. Inaccurate mammography can result in unnecessary stress, additional health care costs from follow up diagnostic mammograms, unnecessary biopsies and increased lifetime exposure to radiation. Researchers are also developing ultrasensitive assays for lung and pancreatic cancer biomarkers using Simoa technology, potentially replacing the need for imaging and biopsy. We believe our Simoa technology has the potential to lead to rapid, cost effective, accurate blood-based health screens, further enabling the liquid biopsy market.

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 set of over 100 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.



COVID-19

In view of the COVID-19 pandemic, in 2020 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 began developing a SARS-CoV-2 semi-quantitative IgG assay and a SARS-CoV-2 antigen detection assay and prototyping a high-definition multiplex SARS-CoV-2 serology assay.

In December 2020, the FDA issued an EUA for our Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test that is run on our HD-X instrument. This test targets antibodies that are directed against the region of the novel coronavirus known as the spike protein. The spike protein contains multiple subunits which together mediate entry of the virus into human cells, and for this reason, many candidate and authorized COVID-19 vaccines are designed to elicit an antibody response to the spike protein. Accordingly, we believe that this test may be useful for measuring the antibody response to vaccine therapy. The assay may also be used for measurement of IgG antibodies in patients suspected of previous infection or recent SARS-CoV-2 exposure. The test provides a numerical result representing the concentration of antibodies from 0.21 to 250 mg/mL. In clinical studies, the test demonstrated a 100% positive percent agreement (sensitivity) and 99.2% negative percent agreement (specificity) 15 or more days following a positive PCR test.

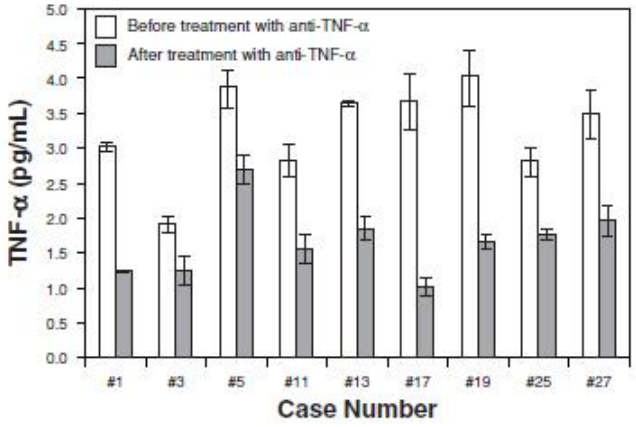
In January 2021, the FDA issued an EUA for our Simoa SARS-CoV-2 N Protein Antigen Test that is also run on our HD-X instrument. This test detects the presence of the SARS-CoV-2 virus nucleocapsid protein (or N protein) which is known to be elevated in respiratory fluids during the initial acute phase of the infection. We believe that direct detection of antigen proteins from the virus may be a more meaningful measure of infection status than detection of RNA by rRT-PCR because genetic material can linger even after the virus has left the body, resulting in increased risk of false positives. In clinical studies, this test demonstrated a sensitivity of 97.7% and specificity of 100% up to 14 days following onset of symptoms. Under the current EUA, the test is intended for use with nasopharyngeal (NP) samples in individuals suspected of COVID-19 infection by their healthcare providers. 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. We are exploring extending the test to home-based sample collection and pooling to enable larger scale testing.

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.

Cardiology

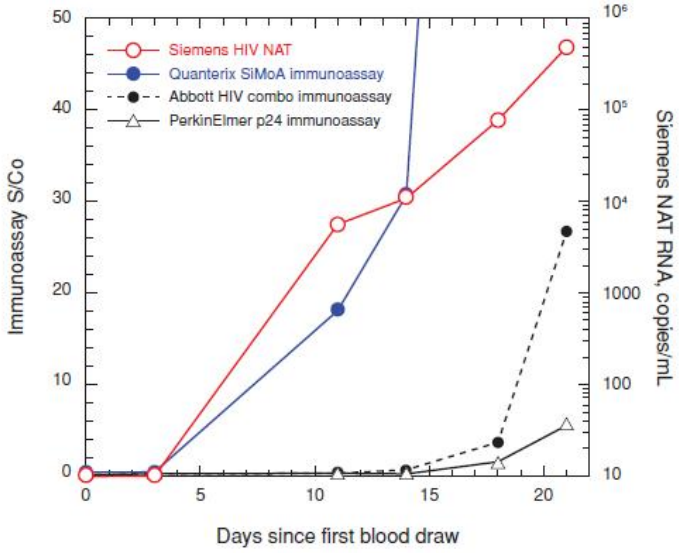
Heart disease and related cardiovascular ailments remain the leading cause of death in the United States, contributing to nearly 1 in 4 deaths in the United States, according to the CDC. A significant need remains for early prediction of heart attacks and other cardiac events. Simoa's highly sensitive digital measurement capabilities have the potential to be used to predict early cardiac disease.

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.

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 6-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 • same sensitivity, dynamic range and homebrew capabilities as HD-X • multiplexing capability: SR-X currently has up to 6-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 80 single-plex and multi-plex bead-based assay kits includes assays for biomarkers in the areas of neurology, infectious disease, immunology and oncology • Two EUA approved SARS-CoV-2 assays • menu of Simoa planar array reagent kits includes approximately 120 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
Nf-L antibodies and Nf-L ELISA kits 	• sold through our wholly-owned subsidiary, Uman, which we acquired in 2019 • Nf-L capture/detection antibodies with unparalleled sensitivity and specificity • Nf-L ELISA kits for CSF (CE-certified in Europe; RUO outside of Europe) • Nf-L ELISA kits for serum (RUO) • licensing and supply arrangement with Siemens Healthineers that will allow Siemens to begin developing blood-based Nf-L clinical tests for future commercialization
Services 	• contract research services provided through our Accelerator Laboratory • over 1,700 projects completed to date • extended warranty and service contracts • CLIA-certified lab available

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., 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 2021, approximately 68% 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 for multiplex chemiluminescent immunoassay measurement, which we refined by leveraging our proprietary sophisticated Simoa image analysis and data analysis algorithms to provide the same Simoa sensitivity 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 80 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 120 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.

Nf-L Antibodies and Nf-L ELISA Kits

In August 2019, we completed our acquisition of Uman. Uman supplies Nf-L antibodies and ELISA kits for Nf-L detection. Uman's Nf-L antibodies are widely recognized by researchers and biopharmaceutical and diagnostics companies worldwide as the premier solution for the detection of Nf-L to advance the development of therapeutics and diagnostics for neurodegenerative conditions. Through Uman we sell proprietary Nf-L capture and detection antibodies, as well as two Nf-L ELISA kits for CSF, one of which is CE-certified in Europe, and one RUO Nf-L 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.

To date, we have completed over 1,700 projects for approximately 400 customers from all over the world using our Simoa platforms, including over 150 projects for clinical studies. In addition to being an important source of revenue, we have also found the Accelerator Laboratory to be a significant 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 believe that sensitivity is so important that we have published an approach to increase the sensitivity of our Simoa technology – in some cases as much as 100-fold, and we intend to launch a beta program using this more sensitive technology in our Accelerator Laboratory by the end of 2022. We are also focused on expanding our assay menu to extend the scope of applications for our platform and grow our customer base. 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 Nf-L antibodies and Nf-L 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 ourselves. 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, 2021, we had 135 full-time people employed 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 intend to significantly 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 plan to expand 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 systems are relatively new to the life science marketplace and 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 system 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

Our manufacturing strategy has two components: to outsource the Simoa bead-based instrument development and manufacturing with industry leaders, and to internally 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. See "—Key Agreements—Development Agreement and Supply Agreement with STRATEC" for a description of our agreement with STRATEC. 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—Paramit Manufacturing Services Agreement" for a description of our agreement with 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 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 have increased the shelf life of the vast majority of our bead-based assays from six months 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.

Nf-L antibodies and Nf-L ELISA Kits

The storage of Uman's proprietary Nf-L 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 Nf-L 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 Nf-L 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 diluent and wash solution), an ELISA 96-well plate coated with a capture antibody, detector antibody, streptavidine conjugate, substrate (TMB) and stop reagent. The kit components are labeled (either "RUO" or "CE") and assembled. The final ELISA kit product is subject to quality control which include testing of human CSF 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.

Key Agreements

Development Agreement and Supply Agreement with STRATEC

In August 2011, we entered into a Strategic Development Services and Equity Participation Agreement (the STRATEC Development Agreement) with STRATEC, pursuant to which STRATEC undertook the development of the Simoa HD instrument. Under the STRATEC Development Agreement, we were required to pay a fee and issue to STRATEC warrants to purchase our equity securities, all of which have been exercised as of December 31, 2017. These fees and warrants were subject to a milestone based payment schedule. The STRATEC Development Agreement was amended in November 2016. The Amendment reduced our obligation to satisfy a minimum purchase commitment under the STRATEC Supply Agreement described below. Additionally, the parties agreed on additional development services for an additional fee, which is payable when the additional development is completed. This fee includes the final milestone payment that was associated with the final milestone due under the terms of the STRATEC Development Agreement. The services were completed in and the final milestone payment was paid in the fourth quarter of 2019. The STRATEC Development Agreement may be terminated on the insolvency of a party, for an uncured material breach, or, by us, on a change of control of our company (subject to certain obligations to compensate STRATEC on such termination) or if we and STRATEC are unable to agree on pricing of the instrument, within certain parameters.

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, provided that neither party may terminate the STRATEC Supply Agreement prior to the later of the seven year anniversary of the acceptance of the first prototype instrument and the purchase of the minimum number of instruments which we were committed to procure. 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 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. 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 has 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.

Non-Exclusive License Agreement with Abbott Laboratories

In September 2020, we entered into a Non-Exclusive License Agreement with Abbott. Pursuant to the terms of the License Agreement, we granted Abbott a non-exclusive, worldwide, royalty-bearing license, without the right to sublicense, under our bead-based single molecule detection patents in the field of IVD. Abbott paid us an initial license fee of $10.0 million in connection with the execution of the License Agreement. Abbott has also agreed to pay us 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 License Agreement includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature. The 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 License Agreement, each party has the right to terminate the agreement for uncured material breach by, or insolvency of, the other party. Abbott may also terminate the License Agreement at any time without cause upon sixty (60) days' notice.

Contracts with the NIH under RADx

In September 2020, we entered into the Rapid Acceleration of Diagnostics (RADx) workplan 2 award (WP2) with the National Institute of Health (NIH) under the RADx program. This contract, which has a total award value of up to $18.2 million, is intended to accelerate the continued development, scale-up and deployment of our novel SARS-CoV-2 antigen test. Initial early feasibility of this test was funded in part through the RADx workplan 1 award (WP1) we were granted in June 2020. WP2 supports clinical validation of the test in support of the EUA submissions with the FDA, and provides funding to expand assay kit manufacturing capacity and commercial deployment readiness. Contract funding was subject to achievement of pre-defined milestones and the contract period ran through September 2021, with one milestone extended to March 31, 2022. As of December 31, 2021, we had received $17.7 million out of the full $18.2 million under WP2.

Competition

We compete with both established and development-stage life science companies that design, manufacture and market instruments for protein discovery, detection, nucleic acid detection and additional applications. For example, companies such as Bio-Techne, Luminex, MesoScale Discovery, Gyros, Nanostring, O-Link, SEER, Somalogic, MilliporeSigma, Bio-Rad Laboratories, Thermo Fisher Scientific, and others, have products for protein discovery or detection 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, Myriad RBM, 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 and precision health screening, 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, diagnostic and precision health screening 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 2017 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 February 1, 2022, we had exclusively licensed 18 patents and two patent applications from Tufts. These patents and patent applications include nine 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 electro-optical systems including an array and a plurality of electrodes. This patent family includes one granted U.S. patent. The standard patent expiration date for the U.S. patent in this family is February 14, 2023.

A fourth 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 the U.S. patent in this family is May 29, 2039.

As of February 1, 2022, we owned 27 issued U.S. patents and 17 pending U.S. patent applications, six granted European patents and three pending European patent applications, six granted Japanese patents, four granted Chinese patents and one pending Chinese patent application, three granted Canadian patents and one pending Canadian patent application, two registered Hong Kong patent applications, and one Patent Cooperation Treaty 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, two granted Japanese patents, one granted Chinese patent and one pending Chinese patent applications, one registered Hong Kong patent application and one pending patent application in each of Europe and Canada. The standard patent expiration date for any U.S. patents that may issue from 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 Patent Cooperation Treaty patent application. If we pursue protection by filing any national stage applications, the standard patent expiration date for any patents that may issue from this family will be in 2041.

We own or co-own ten 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. These families include one granted U.S. patent 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 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 2017, we acquired their patent portfolio for our planar array technology. As of February 1, 2022, the acquired patent portfolio includes at least ten issued U.S. patents and one pending U.S. patent application, one granted Canadian patent, one granted European patent (nationalized and active in eight countries) and one pending European patent application, and one registered Hong Kong patent.

We have licensed additional patents and patent applications from third parties.

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

Other than the COVID assays for which we have received EUAs, 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 and Medicaid Services (CMS). Although most products intended for RUO are not currently subject to clearance or approval by the FDA, RUO products are subject to FDA's premarket review requirements if they are determined to be intended for use for clinical rather than research purposes. Consequently, our products (other than the COVID assays for which we have received EUAs) are labeled "For Research Use Only."

On November 25, 2013, the FDA 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" (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 IUO, 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 510(k) clearance, 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 is a statement of the FDA's thinking with respect to certain RUOs and IUOs in 2013 and 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. We also are not promoting or using our products in the development or promotion of laboratory developed test (LDT) services. When we develop products for clinical use, we will do so in accordance with FDA requirements applicable to those products at that time. Separately, when we become aware that accredited or licensed clinical laboratories may be using our RUO products either for research or clinical uses, such as part of LDT services, in accordance with the regulations that apply to clinical laboratories, we will continue to review the labeling and promotion of our products for consistency with the RUO/IUO Guidance.

When our products are marketed for clinical diagnostic use, our products will be regulated by the FDA as medical devices. 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 products 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. Class III devices, which have the highest level of risk associated with them, are subject to general controls and premarket 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 a Class II device. Class III devices may not be commercialized until a premarket approval application (PMA) is submitted to and approved by the FDA.

510(k) Clearance Pathway

To obtain 510(k) clearance, a sponsor must submit to the FDA a premarket notification demonstrating that the device is substantially equivalent (SE), to a device legally marketed in the U.S. for which a PMA was not required. The FDA is supposed to make a SE determination within 90 days of 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.

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. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure.

This procedure 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 application. 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.

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 the safety and effectiveness of the device 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.

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 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 clearances or 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.

On January 31, 2020, the Secretary of HHS issued a declaration of a public health emergency related to COVID-19. On February 4, 2020, HHS determined that COVID-19 represents a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and, subsequently, declared on March 24, 2020, that circumstances exist to justify the authorization of emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 pandemic, subject to the terms of any authorization as issued by the FDA. On February 29, 2020, the FDA issued an immediately in effect guidance with policy specific to development of IVD tests during the COVID-19 public health emergency. This guidance was updated on March 16, 2020, May 4, 2020, and May 11, 2020.

Clinical Trials

Clinical trials are usually required to support a PMA and are sometimes required for a 510(k). 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 application (IDE) and obtains approval of the IDE from the FDA. These clinical trials are also subject to the review, approval and oversight of an institutional review board (IRB) at each clinical trial site. 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 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.

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 and potential Medicare reimbursement through the Medicare Coverage of Innovative Technology payment pathway. 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 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 510(k) clearance or PMA approvals of new devices; withdrawal of 510(k) clearance or PMA approvals; and civil or criminal prosecution.

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

Since our acquisition of Aushon in January 2018, 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 clinical trials and basic research). 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 health assessment and for the diagnosis, prevention, or treatment of disease. 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 if performing testing in any category for which proficiency testing is required. If a laboratory fails to achieve a passing score on a proficiency test, then it loses its right to perform testing.

As a condition of CLIA certification, laboratories are subject to survey and inspection every other year, in addition to being subject to additional random inspections. The biennial survey is conducted by the Centers for Medicare & Medicaid Services (“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 nearly all complex laboratories for the last few decades as LDTs, which are subject to CMS oversight through its enforcement of CLIA. The FDA also has claimed that it has regulatory authority over LDTs, 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. During 2010, the FDA publicly 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. In September 2014, the FDA announced its framework and timetable for implementing this guidance. On November 18, 2016, the FDA announced it would not release final guidance at that time and instead would continue to work with stakeholders, the new administration and Congress to determine the right approach. On January 3, 2017, the FDA released a discussion paper outlining a possible risk-based approach for FDA and CMS oversight of LDTs. Later in 2017, the FDA indicated that Congress should enact legislation to address improved oversight of diagnostics, including LTDs, rather than the FDA addressing the issue through administrative proposals. We cannot predict the ultimate timing or form of any such guidance or regulation or their potential impact. If adopted, such a regulatory

approach by the FDA may lead to an increased regulatory burden, including additional costs and delays in introducing new tests. While the ultimate impact of the FDA's 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, Florida, 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.

If, in the future, we perform clinical diagnostic testing, we would also become 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, the European Union (the EU) recently published new regulations that will result in greater regulation of medical devices and IVDs. This new IVD regulation (new IVD Regulation) is significantly different from the European directive for In vitro diagnostic products (IVD Directive) that it replaces in that it will ensure that the new requirements apply uniformly and on the same schedule across the member states, include a risk-based classification system and increase the requirements for conformity assessment.

The CE registration for Uman's Nf-L ELISA assay kit 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. Under the new IVD Regulation, the requirements increase and involve assessment by a notified body for class B, C and D products. Uman's Nf-L ELISA assay kit is classified as class B product and must fully implement the new 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 meet the new technical requirements is on-going. An internal GAP-analysis is to be performed and work to eliminate the GAPs performed. When completed, the available technical documentation will be assessed by an external consultant. When all requirements are met, a notified body will be contacted, and the certification initiated.

Other Governmental Regulation

Data Privacy and Security Laws and Regulations

As a business with a global footprint, compliance with evolving regulations and standards in data privacy and cybersecurity 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 the Health Insurance Portability and Accountability Act of 1996 (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. The U.S. Department of Health and Human Services (HHS) (through the Office of Civil Rights) has direct enforcement authority against Covered Entities and Business Associates with regard to both the Security and Privacy Rules, including civil and criminal liability. 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 cost 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 laws and regulations related to the protection of the environment, the health and safety of employees and the handling, transportation 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. 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, 2021, we had 460 full-time employees, of which 135 work in sales, sales support, field service, and marketing, 125 work in engineering and research and development, 125 work in manufacturing and operations and 75 work in general and administration. Of our 460 full-time employees, 407 were located in the United States and 53 were located in twelve 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 including Alzheimer's, cancer and COVID-19. We invest in creating a diverse, inclusive and safe work environment where our employees can deliver their workplace best every day. Historically, we have experienced a turnover rate that is comparable to industry average.

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, including 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, 2021, approximately 42% of our employees were women and approximately 30% were non-white. We are focused on the engagement and empowerment of our employees through the demonstration of our foundational values, which we refer to as AT&T3: Accountability, Trust, Teamwork and Transparency.

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. In response to the COVID-19 pandemic, we have implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, and which comply with government regulations. This includes allowing our employees to work remotely as appropriate, while implementing significant safety measures designed to protect the health of all those working in and entering our facilities.

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. You can also review our electronically filed reports and other information that we file with the SEC 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 you should consider with respect to our business and prospects. This summary is not complete and the risks summarized below are not the only risks we face. You 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, causing the value of our common stock to decline substantially.
- If our products fail to achieve and sustain sufficient market acceptance, our revenue will be adversely affected.
- Sales of our assay for the neurological biomarker Nf-L and other neurological assays 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.
- Epidemic diseases, such as COVID-19 and its variants, could negatively affect various aspects of our business, make it more difficult to meet our obligations to our customers, and result in reduced demand from our customers, which could have a material adverse effect on our business, financial condition, results of operations, or cash flows.
- Our long-term results depend upon our ability to improve existing products and introduce and market new products successfully.
- Undetected errors or defects in our products could harm our reputation, decrease market acceptance of our products or expose us to product liability claims.

- 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 expect to generate a substantial portion of our revenue internationally in the future and can become further 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 instruments 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 may not be able to find replacements or immediately transition to alternative suppliers, which could have a material adverse effect on our business, financial condition, results of operations and reputation.

- If the FDA determines that our products are 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 are subject to extensive regulatory requirements in connection with the EUAs that we have received from the FDA for our COVID-19 antibody and antigen tests. If we fail to comply with these requirements, or if the FDA otherwise determines that the conditions no longer warrant such authorization, we will be unable to market these products pursuant to this authorization and our business may be harmed.

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

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

- If we or any of our partners are sued for infringing intellectual property rights of third parties, it 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 materially, negatively affect 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 $57.7 million, $31.5 million, and $40.8 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, we had an accumulated deficit of $305.5 million. We

cannot predict if we will achieve sustained profitability in the near future or at all. We expect that our losses will continue at least through the next 24 months as we plan to continue to invest significant funds toward expansion of our commercial organization and the development of our technology. In addition, as a public company, we incur significant legal, accounting, and other expenses that we would not incur as a private company. These expenses make it harder for us to achieve and sustain future profitability. 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, causing the value of our common stock to decline substantially.

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. You 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 substantially.

If we are unable to maintain adequate revenue growth or do not successfully manage such growth, our business and growth prospects will be harmed.

We have experienced significant revenue growth in a short period of time. We may not achieve similar growth rates in future periods. Investors should not rely on our operating results for any prior periods as an indication of our future operating performance. To effectively manage our anticipated future growth, we must continue to maintain and enhance our financial, accounting, manufacturing, customer support and sales administration systems, processes and controls. Failure to effectively manage our anticipated growth could lead us to over-invest or under-invest in development, operational, and administrative infrastructure; result in weaknesses in our infrastructure, systems, or controls; give rise to operational mistakes, losses, loss of customers, productivity or business opportunities; and result in loss of employees and reduced productivity of remaining employees.

Our continued growth could require significant capital expenditures and might divert financial resources from other projects such as the development of new products and services. As we commercialize additional products , we may need to incorporate new equipment, implement new technology systems, or hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining product quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products, and could damage our reputation and the prospects for our business.

If our management is unable to effectively manage our anticipated growth, our expenses may increase more than expected, our revenue could decline or grow more slowly than expected and we may be unable to implement our business strategy. In addition, the quality of our products and services may suffer, which could negatively affect our reputation and harm our ability to retain and attract customers.

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, 2021, 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;

- potential opportunities to strategically acquire companies or technologies that may be complementary to our business;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- the cost of our research and development activities;
- our ability to enter into collaborations in the future, and the success of any such collaborations;
- 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 assure you 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 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.

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

As of December 31, 2021, we had federal net operating loss (NOLs) carryforwards to offset future taxable income of approximately $267.2 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, we may be limited as to the amount that can be utilized each year 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.

U.S. taxation of international business activities or the adoption of tax reform policies could materially impact our future financial position and results of operations.

Limitations on the ability of taxpayers to claim and utilize foreign tax credits and the deferral of certain tax deductions until earnings outside of the United States are repatriated to the United States, as well as changes to U.S. tax laws that may be enacted in the future, could impact the tax treatment of future foreign earnings. Should the scale of our international business activities expand, any changes in the U.S. taxation of such activities could increase our worldwide effective tax rate and harm our future financial position and results of operations.

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 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 the results of 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 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 increase our revenue would be adversely affected.

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

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

- our ability to attract, retain and manage the sales, marketing and service personnel necessary to expand market acceptance for our Simoa technology platforms;
- the time and cost of maintaining and growing a specialized sales, marketing and service force; 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 assay for the neurological biomarker Nf-L and other neurological assays 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, Nf-L in particular, 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.

Epidemic diseases, such as COVID-19 and its variants, could negatively affect various aspects of our business, make it more difficult to meet our obligations to our customers, and result in reduced demand from our customers, 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. 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, a significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our products and likely impact our operating results.

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.

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 potential future technology. 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 assure you 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 expect to continue to use a substantial amount of capital for product research and development. 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.

Undetected errors or defects in our products could harm our reputation, decrease market acceptance of our products or expose us to product liability claims.

Our Simoa products may contain undetected errors or defects when first introduced or as new versions or new products are released. 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.

Although we do not, and cannot currently, promote the use of our products, or services based on our products, for diagnostic purposes, if our customers develop or use them for diagnostic purposes, someone could file 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 assure you 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 in vitro diagnostics, or 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, such as our license agreement with Abbott, if our partners do not prioritize and commit sufficient resources to develop and sell products based on our Simoa technology, they 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, Czech Republic, India, Hong Kong, Israel, Japan, New Zealand, Qatar, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan, and 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 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 expect to generate a substantial portion of our revenue internationally in the future and can become further 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, 2021, 2020, and 2019, approximately 36%, 31% and 41%, 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. We have limited experience operating internationally and 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, such as the tension in Russia and Ukraine, 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 their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. 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 these distributors could be deemed to be our agents, and 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 agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar antibribery 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. We have limited experience in complying with these laws and in developing procedures to monitor compliance with these laws by our agents. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you 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 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, we would experience additional costs, delays and difficulties in doing so as a result of identifying and entering into an agreement with a new supplier as well as preparing such new supplier to meet the logistical requirements associated with manufacturing our units, 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 our SP-X instrument, and may not be able to find replacements or immediately transition to alternative suppliers, 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 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 them. 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;
- substantial intellectual property portfolios;
- larger and more established customer bases and relationships; and
- better established, larger scale, and lower cost manufacturing capabilities.

We cannot assure you 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 assure you 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.

Risks Related to Government Regulation and Diagnostic Product Reimbursement

If the FDA determines that our products are 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 have 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, other than our COVID assays for which we have received EUAs, our products are labeled as “Research Use Only” and are not intended for diagnostic uses. While we have focused initially on the life sciences research market and RUO products only, our future strategy includes expanding our product line to encompass products that are intended to be used for the diagnosis of disease, either alone or in collaboration with third parties. 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 automatically classified into Class III, 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 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.

High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, 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, Quality Systems Regulations (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. 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 designed, manufactured and offered as services by high complexity clinical laboratories and used within a single laboratory. The FDA maintains that LDTs are medical devices and has for the most part exercised enforcement discretion for most LDTs. 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 and holding a number of public hearings and workshops, no final guidance has been issued. However, if 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.

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. As a result, the imposition of foreign requirements may also have a material adverse effect on the commercial viability of our operations.

We are subject to extensive regulatory requirements in connection with the EUAs that we have received from the FDA for our COVID-19 antibody and antigen tests. If we fail to comply with these requirements, or if the FDA otherwise determines that the conditions no longer warrant such authorization, we will be unable to market these products pursuant to this authorization and our business may be harmed.

We have received EUAs from the FDA authorizing us to market our Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test and our Simoa SARS-CoV-2 N Protein Antigen Test, each of which is run on our HD-X instrument. These EUAs allow us to market and sell these products without the need to obtain premarket clearance or approval under the FDA's standard review pathways for the duration of the COVID-19 public health emergency. The FDA has also established certain conditions which must be met in order to maintain authorization under these EUAs. The requirements can be unclear and are subject to change.

The FDA has the authority to issue an EUA during a public health emergency if it determines, based on the totality of the scientific evidence, that it is reasonable to believe that the product may be effective, that the known and potential benefits of a product outweigh the known and potential risks, that there is no adequate, approved and available alternative, and if certain other regulatory criteria are met. These standards for marketing authorization are lower than if the FDA had reviewed these tests under its traditional marketing authorization pathways, and we cannot assure you that our tests would be cleared or approved under those more extensive clearance and approval standards. Moreover, the FDA's policies regarding EUAs can change unexpectedly, and the FDA may revoke an EUA when it determines that the underlying health emergency no longer exists or warrants such authorization or if problems are identified with the authorized product. We cannot predict how long our authorizations will remain in place. FDA policies regarding diagnostic tests, therapies and other products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. Changes to FDA regulations or requirements could require changes to our authorized tests, necessitate additional measures or make it impractical or impossible for us to market our tests at all.

In addition, even though we have received these EUAs, these tests may not gain broad market acceptance among customers, including physicians, healthcare payors, users and others in the medical community. The commercial success of our COVID-19 tests will initially be dependent upon physicians and healthcare providers adopting our test kits, which will be informed, in part, by the convenience and accuracy of our tests. Furthermore, the COVID-19 diagnostic testing market is susceptible to rapid technological developments and we may not be able to match new technological advances, which might render our COVID-19 test kits uncompetitive or obsolete. If we are unable to match technological improvements in competitive products or effectively respond to the needs of our customers and users, the demand for our COVID-19 test kits could be reduced.

The termination of the emergency conditions under which EUAs are permitted, the rescission of an EUA, the failure of our tests to gain market acceptance or our inability to match advances in competing products could adversely impact our business.

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 classifications of recalls be reported to 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. 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, the EU recently published new regulations that will result in greater regulation of medical devices and IVDs. The new IVD regulation (new IVD Regulation) is significantly different from the European directive for In vitro diagnostic products (IVD Directive) that it replaces in that it will ensure that the new requirements apply uniformly and on the same schedule across the member states, include a risk-based classification system and increase the requirements for conformity assessment. The CE registration for Uman's Nf-L ELISA assay kit for CSF 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. Under the new IVD Regulation, the requirements increase and involve assessment by a notified body for class B, C and D products. Uman's Nf-L ELISA assay kit for CSF is classified as class B product and must fully implement the new 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 meet the new technical requirements is on-going. An internal GAP-analysis is to be performed and work to eliminate the GAPs performed.

In order to continue to sell our products in Europe, we must maintain our CE marks and continue to comply with certain EU directives and, in the future with the new IVD Regulation. Our failure to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the 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 European Union, such as the departure of the United Kingdom (Brexit), 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 operations.

The operation of our Clinical Laboratory Improvement Amendments (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 disease. 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, consultants, and collaborators to conduct such studies if needed. 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 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 the Centers for Medicare and Medicaid Services (CMS). Private payors often follow CMS 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 payments. Reimbursement may impact the demand for those tests. If reimbursement is not available or is available only to limited levels, 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 commercialize any products based on our technology and affect the prices that may be obtained.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the ACA, became law. 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. Both Congress and former President Trump expressed their intention to repeal or repeal and replace the ACA, and 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 impact 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. The expansion in government's effect on the United States healthcare industry 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. We have installed, and expect to expand, a number of enterprise software systems that 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. In addition to the aforementioned business systems, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, network design, and automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including manufacturing operations, quality control, customer service support, and general administrative activities.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses, and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, 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. 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.

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

In the ordinary course of our business, we collect and store sensitive data, 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, 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. 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.

The failure to maintain our current enterprise resource planning system (ERP) could adversely impact our business and results of operations.

If our ERP system does not continue to operate as intended, the effectiveness of our internal controls over financial reporting could be adversely affected or our ability to assess those controls adequately could be delayed. Significant delays in documenting, reviewing, and testing our internal control could cause us to fail to comply with our SEC reporting obligations related to our management's assessment of our internal control over financial reporting.

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 (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, or 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 the Health Insurance Portability and Accountability Act of 1996 (HIPAA), establish privacy and security standards that limit the use and disclosure of individually identifiable health information (known as “protected health information”) and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether 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, the Health Information Technology for Economic and Clinical Health Act (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 or State Attorneys General. Such a notice could harm our reputation and our ability to compete.

In addition, the European Parliament and the Council of the European Union adopted the GDPR in 2016 to replace the current 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 European Union. 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 European Union 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 such as reviewing our security procedures and entering into data processing agreements with relevant contractors, we cannot assure you that our efforts to remain in compliance 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 and damage our reputation, 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 safety.

Our operations are subject to complex and stringent environmental, health, safety and other governmental laws and regulations that both public officials and private individuals may seek to enforce. Our activities that are subject to these regulations include, among other things, our use of hazardous materials and the generation, transportation 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, it may reduce our ability to maintain any technological or competitive advantage over our competitors and potential competitors, 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.

We cannot assure investors that any of our currently pending or future patent applications will 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, we cannot assure investors that other parties will not challenge any patents granted to us or that courts or regulatory agencies will hold our patents to be valid or enforceable. We cannot guarantee investors that we will 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. 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:

- royalty payments;

- milestone payments;
- annual maintenance fees;
- 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's 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, 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 to 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, it 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 materially, negatively affect 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, particularly 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.

The America Invents Act (the AIA) was signed into law on September 16, 2011, and many of the substantive changes became effective on March 16, 2013. An important change introduced by the AIA is that, 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 after that date but 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 will require 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

We expect that our stock price may 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, 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 for 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 your sole source of gain for the foreseeable future. Consequently, in the foreseeable future, you 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—Class I, Class II, and Class III—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.

We incur increased costs and devote substantial management time as a result of operating as a public company.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and The Nasdaq Global Market. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations substantially increase our legal and financial compliance costs and make some activities more time-consuming and costly. These costs increase our net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

In addition, as a public company we incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting and to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve timely compliance with Section 404, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. The process of obtaining the attestation report from our independent registered public accounting firm is costly and requires the devotion of significant management attention and resources. We have been required to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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. 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 premises covered by these leases 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. The initial term of the Bedford lease is eight years and nine months beginning on the earlier of our occupancy, or May 1, 2022. We believe that these office, laboratory, and manufacturing spaces will be sufficient to meet our needs for the foreseeable future.

In addition, our subsidiary, Uman, leases a total of approximately 6,500 square feet of office, laboratory, manufacturing and storage space in Umeå, Sweden. These leases expire at various dates through February 28, 2023.

Item 3. LEGAL PROCEEDINGS

We are not currently a 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 23, 2022, there were approximately 23 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, 2021.

Issuer Purchases of Equity Securities

Not applicable.

Item 6. RESERVED

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. In addition to historical consolidated financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. See "Special Note Regarding Forward-Looking Statements." Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in "Risk Factors." Results of operations for the fiscal year ended December 31, 2019 can be referenced on our 2020 Annual Report on Form 10-K filed with the SEC on March 5, 2021.

Overview

We are a life sciences company that has developed next generation, ultra-sensitive digital immunoassay platforms that advance precision health for 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 believe that consumables revenue should be subject to less period-to-period fluctuation than our instrument sales revenue, and will become an increasingly important contributor to our overall revenue.

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 2021, approximately 68% of the HD instrument installed base was HD-X instruments.

On January 30, 2018, we acquired Aushon for $3.2 million in cash, with an additional payment of $0.8 million made in July 2018, six months after the acquisition date. With the acquisition of Aushon, we acquired a CLIA certified laboratory, as well as Aushon's proprietary sensitive planar array detection technology. Leveraging our proprietary sophisticated Simoa image analysis and data analysis algorithms, we further refined this planar array technology to develop the SP-X instrument to provide the same Simoa sensitivity found in our Simoa bead-based platform. We initiated an early-access program for the SP-X instrument in January 2019, with the full commercial launch commenced in April 2019.

On August 1, 2019, we completed our acquisition of Uman for an aggregate purchase price of $21.2 million, comprised of (i) $15.7 million in cash plus (ii) 191,152 shares of our common stock (representing $5.5 million based on the closing prices of our common stock on the Nasdaq Global Market on July 1, 2019 and August 1, 2019, the dates of issuance). Uman 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 1,700 projects for approximately 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 other 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.

On September 29, 2020, we entered the Abbott License Agreement with Abbott. Pursuant to the terms of the Abbott License Agreement, we granted Abbott a non-exclusive, worldwide, royalty-bearing license, without the right to sublicense, under our bead-based single molecule detection patents in the field of IVD. Abbott paid 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 us 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.

We are subject to ongoing uncertainty concerning the COVID-19 pandemic, including its length and severity and its effect on our business. During the first and second quarters of 2020, we implemented a resiliency plan focused on the health and safety of our employees and maintaining continuity of our operations. We saw an impact on instrument revenue due to limitations on our ability to access certain customer sites and complete instrument installations, as well as an impact on consumables revenue from interruptions in certain customer laboratories through the first quarter of 2021. As customers began returning to normal operations in the second quarter of 2021, we have seen less of an impact related to COVID-19 related shutdowns. However, we expect COVID-19 related challenges to continue for the foreseeable future and potentially increase if variants result in new shutdowns.

In view of the COVID-19 pandemic, in 2020, we adjusted our operations to expand capacity in our Accelerator Laboratory to support customers whose operations have been disrupted and to sustain clinical trials. We also 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 began developing a SARS-CoV-2 semi-quantitative IgG assay and a SARS-CoV-2 antigen detection assay, and prototyping a high-definition multiplex SARS-CoV-2 serology assay. 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, each of which is run on our HD-X instrument. 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. We are exploring extending the test to home-based sample collection and pooling to enable larger scale testing.

In September 2020, we entered into WP2 with the NIH under the RADx program. This contract, which has a total award value of up to $18.2 million, is intended to accelerate the continued development, scale-up and deployment of our novel SARS-CoV-2 antigen test. Initial early feasibility of this test was funded in part through the RADx WP1 award we were granted in June 2020. WP2 supports clinical validation of the test in support of the EUA submissions with the FDA, and provides funding to expand assay kit manufacturing capacity and commercial deployment readiness. Contract funding was subject to the achievement of pre-defined milestones and the contract period ran through September 2021, with one milestone extended to March 31, 2022. As of December 31, 2021, we had received $17.7 million out of the full $18.2 million under WP2.

The COVID-19 situation remains dynamic, and there remains significant uncertainty as to the length and severity of the pandemic, the actions that may be taken by government authorities, the impact to the business of our customers and suppliers, the long-term economic implications and other factors identified in “Part I, Item 1A, Risk Factors” of this Annual Report on Form 10-K. We will continue to evaluate the nature and extent of the impact to our business, financial condition, and operating results.

As of December 31, 2021, we had cash and cash equivalents of $396.5 million. Since inception, we have incurred annual net losses. Our net loss was $57.7 million, $31.5 million, and $40.8 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, we had an accumulated deficit of $305.5 million and stockholders' equity of $441.0 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 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 continue to grow our employee headcount;
- enter into collaboration arrangements, if any, or in-license other products and technologies;
- add operational, financial and management information systems; and
- continue to incur increased costs as a result of operating as a public company.

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, HD-1, 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. Cost of goods sold for SP-X consists of costs based on the internal assembly of this item. Raw material part costs, associated freight, shipping and handling costs, contract manufacturer costs, salaries, personnel costs, royalties, stock-based compensation, 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 salaries and other personnel costs, royalties, stock-based compensation and facility 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 salaries and other personnel costs, stock-based compensation, 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. 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 salaries and other personnel costs, and stock-based compensation for our sales and marketing, finance, legal, human resources and general management, as well as professional services, such as legal and accounting services. We expect selling, general and administrative expenses to increase in future periods as the number of sales, technical support and marketing and administrative personnel grows and we continue to introduce new products, broaden our customer base and grow our business. We also expect to incur additional public company expenses, including expenses related to compliance with the rules and regulations of the SEC and the Nasdaq Stock Market, additional insurance expenses, and expenses related to investor relations activities and other administrative and professional services.

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” (Note 2) in the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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. Revenues from other services are immaterial.

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 revenues from a sales- or usage based royalties 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 considered 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, 2021			
(in thousands)	**NA**	**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
Total	$ 360	$ 288	$ —	$ 648

(in thousands)	Year Ended December 31, 2020 NA	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
Total	$ 11,685	$ 124	$ —	$ 11,809

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, 2021, 2020 and 2019 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, 2021 is $7.5 million. Of the performance obligations not yet satisfied or that are partially satisfied, $6.4 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 $7.5 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.

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, 2021 and classified 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, 2021, 2020, and 2019.

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 June 22, 2020, we entered into WP1 under the NIH's RADx program to assess the feasibility of a novel SARS-CoV-2 antigen detection test using our Simoa technology. During the year ended December 31, 2020 we recognized $2.0 million of grant revenue and incurred $1.0 million in research and development expense related to WP1. WP1 was completed as of December 31, 2020.

On September 29, 2020, we entered into WP2 with the NIH under its RADx program. The contract, which has a total award value of $18.2 million, accelerates the continued development, scale-up, and deployment of the novel SARS-CoV-2 antigen detection test using our Simoa technology. The contract provides funding to expand assay kit manufacturing capacity and commercial deployment readiness. Release of the $18.2 million of funding under WP2 is 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, 2021, we had received $17.7 million out of the full $18.2 million under 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. During the year ended December 31, 2020, we recognized $4.4 million in grant revenue and incurred $2.6 million in research and development expense related to WP2.

The following table summarizes the cumulative activity under WP2 as of December 31, 2021 and 2020 (in thousands):

	December 31, 2021	December 31, 2020
Total grant revenue from research and development activities	$ 9,576	$ 4,362
Total proceeds used for assets	8,104	826
Total deferred proceeds for assets	—	2,478
Total deferred grant revenue	—	304
Total recognized	$ 17,680	$ 7,970
Total recognized	$ 17,680	$ 7,970
Total amount accrued	—	(2,968)
Total cash received	$ 17,680	$ 5,002
Total proceeds received	$ 17,680	$ 5,002
Total proceeds reasonably assured	520	13,198
Total WP2 grant amount	$ 18,200	$ 18,200

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, including grants of employee 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. Prior to the adoption of Accounting Standards Update (ASU) No. 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07), the measurement date for non-employee awards was generally the date the services were completed, resulting in financial reporting period adjustments to stock-based compensation during the vesting period for changes in the fair value of the awards. We adopted ASU 2018-07 on January 1, 2020. After the adoption of ASU 2018-07, the measurement date for non-employee awards is the date of grant without changes in the fair value of the award. 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, 2021, 2020, and 2019.

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 is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

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,	
	2021	2020
Risk-free interest rate	0.4% - 1.3%	0.4% - 1.7%
Expected dividend yield	None	None
Expected term (in years)	6.0	6.0
Expected volatility	49.2% - 55.6%	43.9% - 49.2%
Weighted-average grant date fair value	$ 29.96	$ 12.66

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,	
	2021	2020
Cost of product revenue	$ 471	$ 189
Cost of service and other revenue	403	311
Research and development	1,807	1,129
General and administrative	13,294	8,470
Total stock-based compensation	$ 15,975	$ 10,099

As of December 31, 2021, we had $35.8 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, 2021 and December 31, 2020 (dollars in thousands):

	Year Ended December 31,					
	2021		2020		Increase (Decrease)	
		% of revenue		% of revenue	Amount	%
Product revenue	$ 81,062	73 %	$ 44,017	52 %	$ 37,045	84 %
Service and other revenue	23,629	21 %	24,129	28 %	(500)	(2)%
Collaboration and license revenue	648	1 %	11,809	14 %	(11,161)	(95)%
Grant revenue	5,217	5 %	6,422	6 %	(1,205)	(19)%
Total revenue	110,556	100 %	86,377	100 %	24,179	28 %
Cost of goods sold:						
Cost of product revenue	34,149	31 %	25,950	30 %	8,199	32 %
Cost of service revenue	14,679	13 %	11,245	13 %	3,434	31 %
Cost of collaboration and license revenue	—	— %	1,000	1 %	(1,000)	(100)%
Total costs of goods sold, services, and licenses	48,828	44 %	38,195	44 %	10,633	28 %
Gross profit	61,728	56 %	48,182	56 %	13,546	28 %
Operating expenses:						
Research and development	27,978	25 %	20,174	23 %	7,804	39 %
Selling, general, and administrative	92,336	84 %	59,592	69 %	32,744	55 %
Total operating expenses	120,314	109 %	79,766	92 %	40,548	51 %
Loss from operations	(58,586)	(53)%	(31,584)	(37)%	(27,002)	(85)%
Interest expense, net	(403)	— %	(273)	(0)%	(130)	(48)%
Other income (expense), net	1,265	1 %	(49)	— %	1,314	2,682 %
Loss before income taxes	(57,724)	(52)%	(31,906)	(37)%	(25,818)	(81)%
Income tax benefit	36	— %	376	— %	(340)	(90)%
Net loss	$ (57,688)	(52)%	$ (31,530)	(37)%	$ (26,158)	(83)%

Revenue

Revenue increased by $24.2 million, or 28%, to $110.6 million for the year ended December 31, 2021 as compared to $86.4 million for the year ended December 31, 2020. Product revenue increased 84% to $81.1 million for the year ended December 31, 2021, as compared to $44.0 million in the same period in 2020. Product revenue consisted of sales of instruments totaling $26.0 million and sales of consumables and other products totaling $55.1 million for the year ended December 31, 2021. Product revenue consisted of sales of instruments totaling $16.6 million and sales of consumables and other products of $27.4 million for the year ended December 31, 2020. The increase in product revenue was primarily due to the increased ability to install instruments as customer sites reopened from COVID-19 related shutdowns that impacted results in the same period in 2020. In addition, as the installed base of instruments increased year over year, consumable sales increased. The decrease in service and other revenue of $0.5 million was primarily due to our open headcount within our services personnel. We had $0.6 million and $11.8 million in collaboration and license revenue during the year ended December 31, 2021 and 2020, respectively, related to licensing technology and intellectual property. We had $11.2 million in collaboration and license revenue during the year ended December 31, 2020, primarily related to entering into the Abbott License Agreement. Grant revenue of $5.2 million and $6.4 million consisted of revenue related to WP2 recognized during the year ended December 31, 2021, and revenue related to WP2 and WP1 recognized during the year ended December 31, 2020, respectively.

Cost of Goods Sold, Services, and Licenses

Cost of product revenue increased by $8.2 million, or 32%, to $34.1 million for the year ended December 31, 2021 as compared to $26.0 million for the year ended December 31, 2020. The increase was primarily due to our increase in volume of our product revenue. Cost of service revenue increased by $3.4 million, or 31%, to $14.7 million for the year ended December 31, 2021, as compared to $11.2 million for the year ended December 31, 2020, primarily due to increased personnel costs from the build out of our field service organization. Cost of collaboration and license revenue of $1.0 million for the year ended December 31, 2020 resulted from the licensing of certain technology and intellectual property to Abbott. Overall cost of goods sold and services as a percentage of revenue was consistent at 44% of total revenue for the years ended December 31, 2021 and 2020, respectively.

Research and Development Expense

Research and development expense increased by $7.8 million, or 39%, to $28.0 million for the year ended December 31, 2021, as compared to $20.2 million for the year ended December 31, 2020. The increase was primarily due to increased headcount as we build our organization to support growth and invest in process improvements.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by $32.7 million, or 55%, to $92.3 million for the year ended December 31, 2021 as compared to $59.6 million for the year ended December 31, 2020. The increase was primarily due to higher personnel costs from increased headcount and other spending increases in various departments as we build out our organization to support growth and invest in process improvements.

Interest Expense

Interest expense, net decreased by $0.1 million for the year ended December 31, 2021 as compared to the same period in 2020, primarily due to the unfavorable impact of interest rates on our cash equivalents for the year ended December 31, 2021, as compared to the year ended December 31, 2020.

Other Income (Expense), Net

Other income (expense), net increased by $1.3 million for the year ended December 31, 2021 as compared to the same period in 2020, primarily due to other income of $2.1 million related to an employee retention tax credit established under the Coronavirus Aid, Relief and Economic Securities Act, offset by other expense due to unfavorable foreign currency exchange rates during the year ended December 31, 2021.

Income Tax Benefit

Income tax benefit was less than $0.1 million for the year ended December 31, 2021, as compared to $0.4 million tax for the same period in 2020. The change is 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 $47.9 million, $23.4 million and $26.2 million of cash for our operating activities for the years ended December 31, 2021, 2020, and 2019, respectively. The significant increase in our cash used for operating activities for the year ended December 31, 2021, as compared to December 31, 2020, was principally driven by our increased net loss for the 2021 period. As of December 31, 2021, we had an accumulated deficit of $305.5 million. As of December 2021, we had cash and cash equivalents of $396.5 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

On March 19, 2019, we entered into a Sales Agreement for an “at-the-market offering” arrangement with Cowen and Company, LLC (Cowen), which allowed us to issue and sell shares of common stock pursuant to a shelf registration statement for total gross sales proceeds of up to $50.0 million from time to time through Cowen, acting as our agent. During the year ended December 31, 2019, we sold an aggregate of 2,186,163 shares of common stock pursuant to this agreement resulting in $49.7 million in gross proceeds and $48.0 million in net proceeds. On August 6, 2020, we delivered written notice to Cowen to terminate the Sales Agreement, which termination the parties agreed to make immediately effective.

On August 8, 2019, we entered into an underwriting agreement with J.P. Morgan Securities LLC and SVB Leerink LLC, or Leerink, as representatives of the several underwriters, relating to an underwritten public offering of 2,732,673 shares of common stock at a public offering price of $25.25 per share. We received $69.0 million in gross proceeds and $64.5 million in net proceeds.

On August 6, 2020, we entered into an underwriting agreement with Leerink and Cowen, as representatives of the several underwriters, relating to an underwritten public offering of 3,048,774 shares of common stock at a public offering price of $32.00 per share. We received $97.6 million in gross proceeds and $91.4 million in net proceeds.

On February 3, 2021, we 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 4,107,142 shares of common stock at a public offering price of $70.00 per share. We received $287.5 million in gross proceeds and approximately $269.7 million in net proceeds.

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% plus the prime rate less 5.25%, with a minimum interest rate of 8%. 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. As of December 31, 2021, there were no additional amounts available to borrow under the loan facility.

Uman Acquisition

In August 2019, we completed the acquisition of Uman, in which we paid $15.7 million in cash to the shareholders of Uman. We funded this payment through our existing cash balances. In addition, we issued $5.5 million in stock in connection with the purchase of Uman. The acquisition closed with respect to 95% of the outstanding shares of capital stock of Uman on July 1, 2019 and with respect to the remaining 5% of the outstanding shares of capital stock of Uman on August 1, 2019.

Cash Flows

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

	Year Ended December 31,	
	2021	2020
Net cash used in operating activities	$ (47,907)	$ (23,365)
Net cash used in investing activities	(6,338)	(626)
Net cash provided by financing activities	270,795	96,236
Net increase in cash and cash equivalents	$ 216,550	$ 72,245

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 our infrastructure and this may continue in the future.

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 operating activities was $23.4 million during the year ended December 31, 2020. Net cash used in operating activities primarily consisted of net loss of $31.5 million offset by non-cash charges of $10.1 million of stock-based compensation expense and $4.3 million of depreciation and amortization expense. Cash used as a result of changes in operating assets and liabilities of $8.0 million was primarily due to an increase in an increase in accounts receivable of $6.7 million, an increase in inventory of $5.1 million, and an increase in prepaid expenses and other assets of $3.9 million, offset by a decrease in accrued compensation and benefits and other accrued expenses of $6.2 million.

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.

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.

We used $0.6 million of cash in investing activities during the year ended December 31, 2020, consisting of $3.9 million in additions to property and equipment, offset by $3.3 million in grant proceeds related to assets acquired under WP2.

Net Cash Provided by Financing Activities

Historically, we have financed our operations principally through private placements of our convertible preferred stock and borrowings from credit facilities, the sale of shares of our common stock in our IPO or other offerings and revenues from our commercial operations.

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.

Financing activities provided $96.2 million of cash during the year ended December 31, 2020, primarily from net proceeds of our underwritten public offering during the third quarter of 2020.

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. 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:

- market acceptance of our products and services;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- the cost of our research and development activities;
- our ability to enter into collaborations in the future, and the success of any such collaborations;
- 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 assure you 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. On November 6, 2020, we filed an automatically effective shelf registration statement with the SEC. Each issuance of securities under the shelf registration statement will require the filing of a prospectus supplement identifying the amount and terms of securities to be issued. The registration statement does not limit the amount of securities that may be issued thereunder. Our ability to issue securities is subject to market

conditions and other factors. This registration statement will expire on November 6, 2023, three years after its date of effectiveness.

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. 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 premises covered by these leases serves as our principal office and laboratory space effective the second quarter of 2019. 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. The initial term of the Bedford lease is eight years and nine months beginning on the earlier of our occupancy, or May 1, 2022.

In addition, our subsidiary, Uman, leases a total of approximately 6,500 square feet of office, laboratory, manufacturing and storage space in Umeå, Sweden. These leases expire at various dates through February 28, 2023.

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

	As of December 31, 2021
2022	$ 3,466
2023	3,515
2024	3,557
2025	3,655
2026	3,765
thereafter	14,782
Total	$ 32,740

Backlog

We generally expect to ship all instrument and consumable orders received in a given period with the exception of orders received near the end of a fiscal quarter; and as a result, our backlog at the end of any period 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, with original maturities of three months or less. Cash equivalents consist primarily of bank deposits and certain investments, such as government securities, with maturities less than 90 days at the date of purchase. Deposits of cash held outside the United States totaled approximately $3.4 million and $1.1 million at December 31, 2021 and 2020, 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, 2021, one company represented 18% of our gross accounts receivable. As of December 31, 2020, one company represented 19% 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. Historically, we have not recorded material losses due to customers' nonpayment. For the years ended December 31, 2021 and 2019, no customer individually accounted for more than 10% of our total revenue. For the year ended December 31, 2020, one company accounted for 13% of our total revenue. For the quarter ended December 31, 2021, one company accounted for 14% 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. Historically, the substantial majority of our revenue has been denominated in U.S. dollars. For the years ended December 31, 2021, 2020, and 2019, approximately 36%, 31% and 41%, 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, 2021 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, 2022 would not be 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 $396.5 million as of December 31, 2021. 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 periods presented, our interest income would not have been materially affected. If overall interest rates decrease by 10% during the year ending December 31, 2022, our interest income would not be 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 that 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, 2021. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2021.

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 Rule 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, 2021 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 effective at the reasonable assurance level as of December 31, 2021.

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

Changes in Internal Control over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including the principal executive officer and principal financial officer, of any change in our internal controls over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to affect, our internal controls over financial reporting.

There has been no change in our internal controls over financial reporting during the fiscal quarter ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal controls 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, 2021, 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, Quanterix Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Quanterix Corporation as of December 31, 2021 and 2020, 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, 2021, and the related notes and financial statement schedule listed in the Index at Item 15(2) and our report dated March 1, 2022 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 Annual 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 1, 2022

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 2022 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 2022 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 2022 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 2022 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 2022 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*

Schedule II – Valuations and Qualifying Accounts

Description	Balance at Beginning of Period (in thousands)	Charged to Costs and Expenses (in thousands)	Deductions (in thousands)	Balance at End of Period (in thousands)
Allowance for credit losses:				
Year ended December 31, 2021	$ 370	$ 213	$ (164)	$ 419
Year ended December 31, 2020	$ 162	$ 493	$ (285)	$ 370
Year ended December 31, 2019	$ 36	$ 160	$ (34)	$ 162

(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
4.3	Fourth Amended and Restated Registration Rights Agreement, dated as of June 2, 2017, by and among the Registrant and the investors named therein		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

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
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
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+	Employment Agreement, dated January 1, 2015, by and between the Registrant and E. Kevin Hrusovsky		S-1	11/9/2017	333-221475
10.4+	Employment Agreement, dated June 22, 2021, between the Registrant and Michael Doyle		8-K	6/28/2021	001-38319
10.5+	Employment Agreement, dated May 10, 2021, between the Registrant and Dr. Masoud Toloue		8-K	5/11/2021	001-38319
10.6+	Letter Agreement, dated May 31, 2019, by and between the Registrant and John Fry		10-Q	8/6/2019	001-38319
10.7+	Letter Agreement, dated August 8, 2014, by and between the Registrant and Mark T. Roskey, Ph.D.		S-1	11/9/2017	333-221475
10.8+	Letter Agreement, effective as February 5, 2018, by and between the Registrant and Dawn Mattoon		10-Q	5/15/2018	001-38319
10.9.1*	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
10.9.2*	Second Amendment, dated August 22, 2017, to the Exclusive License Agreement between the Registrant and Tufts University		S-1	11/9/2017	333-221475

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.9.3@	Third Amendment, dated September 25, 2020, to the Exclusive License Agreement between the Registrant and Tufts University		10-Q	11/6/2020	001-38319
10.10.1*	Supply and Manufacturing Agreement, dated September 14, 2011, between the Registrant and STRATEC Biomedical AG		S-1	11/9/2017	333-221475
10.10.2	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
10.11.1*	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
10.11.2*	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
10.12*	Manufacturing Services Agreement, dated November 23, 2016, between the Registrant and Paramit Corporation		S-1	11/9/2017	333-221475
10.13+	Form of Indemnification Agreement		S-1/A	11/27/2017	333-221475
10.14	Lease Agreement by and between SSI 900 Middlesex MA LP and the Registrant, dated October 2, 2018.		8-K	10/5/2018	001-38319
10.15	Lease Agreement by and between the Registrant and XChange Owner LLC, dated January 28, 2022.		8-K	1/31/2022	001-38319

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.16@	Non-Exclusive License Agreement, dated September 29, 2020, by and between Abbott Laboratories and the Registrant.		8-K	10/5/2020	001-38319
10.17+	Separation Agreement dated November 11, 2021 by and between the Registrant and William Geist.		8-K	11/12/2021	001-38319
10.18+	Amended and Restated 2018 Non-Employee Director Compensation Policy	X			
21.1	Subsidiaries of Registrant		10-K	3/5/2021	001-38319
23.1	Consent of Ernst & Young LLP	X			
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.

@ Certain confidential portions of this exhibit have been omitted and replaced with "[***]". Such identified information has been excluded from this exhibit because it is (i) not material and (ii) would likely cause competitive harm to the company if disclosed.

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 1, 2022

By: /s/ E. KEVIN HRUSOVSKY
E. Kevin Hrusovsky
Chairman 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/ E. KEVIN HRUSOVSKY E. Kevin Hrusovsky	Chairman and Chief Executive Officer and Director (principal executive officer)	March 1, 2022
/s/ MICHAEL A. DOYLE Michael A. Doyle	Chief Financial Officer (principal financial officer and principal accounting officer)	March 1, 2022
/s/ KEITH L. CRANDELL Keith L. Crandell	Director	March 1, 2022
/s/ SARAH E. HLAVINKA Sarah E. Hlavinka	Director	March 1, 2022
/s/ MARTIN D. MADAUS, PH.D. Martin D. Madaus, Ph. D.	Director	March 1, 2022
/s/ PAUL M. MEISTER Paul M. Meister	Director	March 1, 2022
/s/ LAURIE J. OLSON Laurie J. Olson	Director	March 1, 2022
/s/ DAVID R. WALT, PH.D. David R. Walt, Ph.D.	Director	March 1, 2022

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
QUANTERIX CORPORATION
Years ended December 31, 2021, 2020, and 2019

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, 2021 and 2020, 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, 2021, and the related notes and financial statement schedule listed in the Index at Item 15(2) (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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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 1, 2022 expressed an unqualified 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 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 future demand. 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 in the estimation of future demand. 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 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 1, 2022

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 396,465	$ 181,584
Accounts receivable (less allowance for credit losses of $419 and $370 as of December 31, 2021 and December 31, 2020, respectively; including $200 and $172 due from related parties as of December 31, 2021 and December 31, 2020, respectively)	23,786	17,184
Inventory	22,190	14,856
Prepaid expenses and other current assets	6,514	5,981
Total current assets	448,955	219,605
Restricted cash	2,577	1,000
Property and equipment, net	17,960	13,912
Intangible assets, net	10,534	13,716
Goodwill	9,632	10,460
Right-of-use assets	11,491	11,995
Other non-current assets	378	357
Total assets	$ 501,527	$ 271,045
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable (including $42 and $14 to related parties as of December 31, 2021 and December 31, 2020, respectively)	$ 9,209	$ 6,799
Accrued compensation and benefits	13,252	10,777
Other accrued expenses (including $0 and $1,377 to related parties as of December 31, 2021 and December 31, 2020, respectively)	6,486	4,845
Deferred revenue (including $54 and $90 with related parties as of December 31, 2021 and December 31, 2020, respectively)	6,361	5,421
Current portion of long term debt	—	7,673
Short term lease liabilities	1,428	1,234
Other current liabilities	241	3,054
Total current liabilities	36,977	39,803
Deferred revenue, net of current portion	1,099	577
Long term lease liabilities	20,464	21,891
Deferred tax liabilities	2,035	2,649
Total liabilities	60,575	64,920
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value:		
Authorized—120,000,000 shares as of December 31, 2021 and December 31, 2020; issued and outstanding — 36,768,035 and 31,796,544 shares as of December 31, 2021 and December 31, 2020, respectively	37	32
Additional paid-in capital	745,936	451,433
Accumulated other comprehensive income	441	2,434
Accumulated deficit	(305,462)	(247,774)
Total stockholders' equity	440,952	206,125
Total liabilities and stockholders' equity	$ 501,527	$ 271,045

See accompanying notes.

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

	Years Ended December 31,		
	2021	2020	2019
Product revenue (including related party activity of $505, $580, and $720 for the years ended December 31, 2021, 2020, and 2019, respectively)	$ 81,062	$ 44,017	$ 40,491
Service and other revenue (including related party activity of $114, $202, and $118 for the years ended December 31, 2021, 2020, and 2019, respectively)	23,629	24,129	16,059
Collaboration revenue	648	11,809	184
Grant revenue	5,217	6,422	—
Total revenue	110,556	86,377	56,734
Costs of goods sold:			
Cost of product revenue (including related party activity of $1,936, $205, and $234 for the years ended December 31, 2021, 2020, and 2019, respectively)	34,149	25,950	20,900
Cost of service and other revenue (including related party activity of $74, $52, and $0 for the years ended December 31, 2021, 2020, and 2019, respectively)	14,679	11,245	8,998
Cost of collaboration and license revenue (including related party activity of $0, $1,000, and $0 for the years ended December 31, 2021, 2020, and 2019, respectively)	—	1,000	—
Total costs of goods sold, services, and licenses	48,828	38,195	29,898
Gross profit	61,728	48,182	26,836
Operating expenses:			
Research and development (including related party activity of $565, $235, and $152 for the years ended December 31, 2021, 2020, and 2019, respectively)	27,978	20,174	16,190
Selling, general and administrative (including related party activity of $89, $37, and $180 for the years ended December 31, 2021, 2020, and 2019, respectively)	92,336	59,592	52,246
Total operating expenses	120,314	79,766	68,436
Loss from operations	(58,586)	(31,584)	(41,600)
Interest (expense) income, net	(403)	(273)	627
Other income (expense), net	1,265	(49)	(10)
Loss before income taxes	(57,724)	(31,906)	(40,983)
Income tax benefit	36	376	187
Net loss	$ (57,688)	$ (31,530)	$ (40,796)
Net loss per share, basic and diluted	$ (1.60)	$ (1.07)	$ (1.63)
Weighted-average common shares outstanding, basic and diluted	35,997,473	29,589,132	25,090,708

See accompanying notes.

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

	Years Ended December 31,		
	2021	2020	2019
Net loss	$ (57,688)	$ (31,530)	$ (40,796)
Other comprehensive (loss) income:			
Cumulative translation adjustment	(1,993)	2,587	(153)
Total other comprehensive (loss) income	(1,993)	2,587	(153)
Comprehensive loss	$ (59,681)	$ (28,943)	$ (40,949)

See accompanying notes.

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

	Year Ended December 31,		
	2021	2020	2019
Operating activities			
Net loss	$ (57,688)	$ (31,530)	$ (40,796)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	4,851	4,312	3,009
Inventory step-up amortization	275	722	611
Credit loss expense on accounts receivable	213	493	160
Reduction in the carrying amounts of right-of-use assets	499	245	—
Stock-based compensation expense	15,975	10,099	6,388
Non-cash interest expense	65	86	89
Loss on disposal of fixed assets	89	171	140
Changes in operating assets and liabilities:			
Accounts receivable	(6,853)	(6,733)	(3,525)
Prepaid expenses and other assets	(393)	(3,927)	289
Inventory	(8,090)	(5,119)	(3,447)
Other non-current assets	(2)	198	(21)
Accounts payable	2,414	649	621
Accrued compensation and benefits, other accrued expenses and other current liabilities	1,061	6,219	822
Contract acquisition costs	(192)	87	336
Operating lease liabilities	(1,230)	316	—
Other non-current liabilities	(363)	(488)	9,845
Deferred revenue	1,462	835	(708)
Net cash used in operating activities	(47,907)	(23,365)	(26,187)
Investing activities			
Purchases of property and equipment	(13,616)	(3,930)	(10,847)
Acquisitions, net of cash acquired	—	—	(14,529)
Proceeds from RADx grant on assets purchased	7,278	3,304	—
Net cash used in investing activities	(6,338)	(626)	(25,376)
Financing activities		—	—
Proceeds from stock options exercised	7,750	4,019	2,820
Sale of common stock in at-the-market offering, net	—	—	48,019
Sale of common stock in underwritten public offering, net	269,718	91,404	64,529
Proceeds from ESPP purchase	1,065	888	879
Payments on notes payable	(7,738)	(75)	(50)
Net cash provided by financing activities	270,795	96,236	116,197
Net increase in cash and cash equivalents	216,550	72,245	64,634
Effect of foreign currency exchange rate on cash	(92)	158	118
Cash, restricted cash, and cash equivalents at beginning of period	182,584	110,181	45,429
Cash, restricted cash, and cash equivalents at end of period	$ 399,042	$ 182,584	$ 110,181
Supplemental cash flow information			
Cash paid for interest	$ 389	$ 625	$ 656
Purchases of property and equipment included in accounts payable and other accrued expenses	$ 229	$ 1,029	$ 164
Purchase of property and equipment included in other non-current liabilities	$ —	$ —	$ 7,572
Common stock issued in connection with the acquisition of UmanDiagnostics AB	$ —	$ —	$ 5,468
Reconciliation of cash, cash equivalents, and restricted cash:			
Cash and cash equivalents	$ 396,465	$ 181,584	$ 109,155
Restricted cash	$ 2,577	$ 1,000	$ 1,026
Total cash, cash equivalents, and restricted cash	$ 399,042	$ 182,584	$ 110,181

See accompanying notes.

Quanterix Corporation
Consolidated Statements of Stockholders' Equity

	Common stock shares	Common stock value	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2018	**22,369,036**	**$ 22**	**$ 216,931**	**$ —**	**$ (175,888)**	**$ 41,065**
Cumulative effect of adoption of Accounting Standards Codification Topic 606	—	—	—	—	440	440
Exercise of common stock warrants	45,690	—	—	—	—	—
Exercise of common stock options and vesting of restricted stock	550,734	—	2,820	—	—	2,820
Sale of common stock in "at-the-market" offering, net	2,186,163	2	48,017	—	—	48,019
Sale of common stock in underwritten public offering, net	2,732,673	3	64,526	—	—	64,529
Issuance of shares for the acquisition of UmanDiagnostics AB	191,152	1	5,467	—	—	5,468
Stock-based compensation expense	—	—	6,388	—	—	6,388
Employee stock purchase plan	36,753	—	878	—	—	878
Accumulated other comprehensive income	—	—	—	(153)	—	(153)
Net loss	—	—	—	—	(40,796)	(40,796)
Balance at December 31, 2019	**28,112,201**	**$ 28**	**$ 345,027**	**$ (153)**	**$ (216,244)**	**$ 128,658**
Exercise of common stock options and vesting of restricted stock	589,723	1	4,018	—	—	4,019
Sale of common stock in underwritten public offering, net	3,048,774	3	91,401	—	—	91,404
ESPP stock purchase	45,846	—	888	—	—	888
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**
Exercise of common stock warrants	7,347	—	—	—	—	—
Exercise of common stock options and vesting of restricted stock	823,796	1	7,749	—	—	7,750
Issuance of common stock	4,169					
Sale of common stock in underwritten public offering, net	4,107,142	4	269,714	—	—	269,718
ESPP stock purchase	29,037	—	1,065	—	—	1,065
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**

See accompanying notes.

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 acquired UmanDiagnostics AB (Uman), a Swedish company located in Umeå, Sweden, in August 2019. The acquisition closed with respect to 95% of the outstanding shares of capital stock of Uman on July 1, 2019 and with respect to the remaining 5% of the outstanding shares of capital stock of Uman on August 1, 2019. Uman 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. With the acquisition of Uman, the Company has secured a long-term source of supply for a critical technology.

"At-the-market offering"

On March 19, 2019, the Company entered into a Sales Agreement (the Sales Agreement) with Cowen and Company, LLC (Cowen) with respect to an "at-the-market" offering program under which the Company could offer and sell, from time to time at its sole discretion, shares of its common stock, par value $0.001 per share, having an aggregate offering price of up to $50.0 million through Cowen as its sales agent.

On June 5, 2019, the Company issued approximately 2.2 million shares of common stock at an average stock price of $22.73 per share pursuant to the terms of the Sales Agreement. The "at-the-market" offering resulted in gross proceeds of $49.7 million. The Company incurred $1.7 million in issuance costs associated with the "at-the-market" offering, resulting in net proceeds to the Company of $48.0 million. On August 6, 2020, the Company delivered written notice to Cowen to terminate the Sales Agreement, which termination the parties agreed to make immediately effective.

Underwritten public offering

On August 8, 2019, the Company entered into an underwriting agreement with J.P. Morgan Securities LLC (J.P. Morgan) and SVB Securities LLC (f/k/a SVB Leerink) (Leerink), as representatives of the several underwriters, relating to an underwritten public offering of approximately 2.7 million shares of the Company's common stock, par value $0.001 per share. The underwritten public offering resulted in gross proceeds of $69.0 million. The Company incurred $4.5 million in issuance costs associated with the underwritten public offering, resulting in net proceeds to the Company of $64.5 million.

On August 6, 2020, the Company entered into an underwriting agreement with Leerink 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 (Goldman Sachs), 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 $305.5 million at December 31, 2021 and the Company incurred a net loss of $57.7 million, $31.5 million, and $40.8 million for the years ended December 31, 2021, 2020, and 2019, respectively. At December 31, 2021, the Company had $396.5 million of unrestricted cash and cash equivalents. The Company expects the current cash balance will be sufficient to fund 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, fair value of assets acquired and liabilities assumed in acquisitions, 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.

Revenue recognition

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.

The Company adopted Accounting Standards Codification (ASC) Topic 606 *Revenue from Contracts with Customers* (ASC 606), on January 1, 2019, using the modified retrospective method for all contracts not completed as of the date of adoption. The reported results for 2021, 2020, and 2019 reflect the application of ASC 606 guidance. The Company recorded an adjustment to the accumulated deficit of $0.4 million as of January 1, 2019 for the cumulative effect primarily related to the deferral of sales commissions. In accordance with the reporting requirements of ASC 606, the disclosure of the impact on the Company's consolidated statement of operations, as a result of adopting the provisions of ASC 606, was as follows (in thousands):

	For the Year Ended December 31, 2019		
	Under ASC 606	Adjustment	Under ASC 605
Product revenue	$ 40,491	$ 55	$ 40,546
Service revenue	16,059	273	16,332
Costs of goods sold and services	29,898	1	29,899
Gross profit	26,836	327	27,163
Selling general and administrative expenses	52,246	27	52,273
Net loss	$ (40,796)	$ 300	$ (40,496)

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 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. Revenues from other services are immaterial.

Collaboration and license revenue

The Company may enter into agreements to license the intellectual property and know-how associated with its 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. The Company has recognized revenues from sales- or usage based royalties related to the Company's licensing technology and intellectual property. 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. The Company has recorded sales- or usage-based royalty revenue for the years ended December 31, 2021, 2020, and 2019 related to the intellectual property licensed by Uman. The Company recognizes 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.

Payment terms

The Company's 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 the Company provides extended payment terms or financing arrangements to 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 based on their location by revenue type:

(in thousands)	Year Ended December 31, 2021 NA	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
Total	$ 360	$ 288	$ —	$ 648

(in thousands)	Year Ended December 31, 2020 NA	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
Total	$ 11,685	$ 124	$ —	$ 11,809

(in thousands)	Year Ended December 31, 2019 NA	EMEA	Asia Pacific	Total
Product revenues:				
Instruments	$ 6,250	$ 5,243	$ 3,393	$ 14,886
Consumable and other products	14,148	9,674	1,783	25,605
Total	$ 20,398	$ 14,917	$ 5,176	$ 40,491
Service and other revenues:				
Service-type warranties	$ 3,139	$ 1,323	$ 171	$ 4,633
Research services	8,845	704	456	10,005
Other services	825	565	31	1,421
Total	$ 12,809	$ 2,592	$ 658	$ 16,059
Collaboration and license revenue:				
Collaboration and license revenue	$ 167	$ 17	$ —	$ 184
Total	$ 167	$ 17	$ —	$ 184

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.

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, 2021 is $7.5 million. Of the performance obligations not yet satisfied or that are partially satisfied, $6.4 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 $7.5 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.

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

	Year Ended December 31, 2021
Balance at December 31, 2020	$ 5,998
Deferral of revenue	8,090
Recognition of deferred revenue	(6,628)
Balance at December 31, 2021	$ 7,460

Costs to obtain a contract

The Company's sales commissions are generally based on revenues 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 changes in the balance of costs to obtain a contract are as follows (in thousands):

	Year Ended December 31, 2021
Balance at December 31, 2020	$ 248
Deferral of costs to obtain a contract	905
Recognition of costs to obtain a contract	(713)
Balance at December 31, 2021	$ 440

The Company has classified the balance of capitalized costs to obtain a contract as a component of prepaid expenses and other current assets as of December 31, 2021 and classifies 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 will exclude from its transaction price any amounts collected from customers related to sales and other similar taxes. The Company has elected to account for 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.

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.

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 for the years ended December 31, 2021, 2020 and 2019.

Grant revenue

The Company recognizes grant revenue as it 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 government assistance to for-profit business entities, the Company has accounted for grants by analogy to International Accounting Standards (IAS) 20, *Accounting for Government Grants and Disclosure of Government Assistance* (IAS 20).

Grants to the Company 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.

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.

On June 22, 2020, the Company entered into a workplan 1 award (WP1) with the National Institute of Health (NIH), under the Rapid Acceleration of Diagnostics (RADx) program to assess the feasibility of a novel SARS-CoV-2 antigen detection test using the Company's Simoa technology. WP1 was complete as of December 31, 2020.

On September 29, 2020, the Company entered into WP2 with the NIH under its RADx program. The contract, which has a total award value of $18.2 million, accelerates the continued development, scale-up, and deployment of the novel SARS-CoV-2 antigen detection test using the Company's Simoa technology. The contract provides funding to expand assay kit manufacturing capacity and commercial deployment readiness. Release of the $18.2 million of funding under WP2 is 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, 2021, the Company had received $17.7 million out of the full $18.2 million under 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 following table summarizes the cumulative activity under WP2 as of December 31, 2021 and December 31, 2020 (in thousands):

	December 31, 2021	December 31, 2020
Total grant revenue from research and development activities	$ 9,576	$ 4,362
Total proceeds used for assets	8,104	826
Total deferred proceeds for assets	—	2,478
Total deferred grant revenue	—	304
Total recognized	$ 17,680	$ 7,970
Total recognized	$ 17,680	$ 7,970
Total amount accrued	—	(2,968)
Total cash received	$ 17,680	$ 5,002
Total proceeds received	$ 17,680	$ 5,002
Total proceeds reasonably assured	520	13,198
Total WP2 grant amount	$ 18,200	$ 18,200

Business combinations

Under the acquisition method of accounting, the Company generally recognizes the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values on the date of acquisition. The fair values recognized, defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between willing market participants, are based on estimates and assumptions determined by management. The excess consideration over the aggregate value of acquired tangible and intangible assets, net of liabilities recognized, is recorded as goodwill. These valuations require significant estimates and assumptions, especially with respect to intangible assets.

The Company typically uses the discounted cash flow method to value acquired intangible assets. This method requires significant management judgment to forecast future operating results and establish residual growth rates and discount factors. The estimates used to value and amortize intangible assets are consistent with the plans and estimates that are used to manage the business and are based on available historical information. If the subsequent actual results and updated projections of the underlying business activity change compared with the assumptions and projections used to develop these values, the Company could experience impairment charges. In addition, the Company has estimated the

economic lives of certain acquired assets and these lives are used to calculate depreciation and amortization expense. If estimates of the economic lives change, depreciation or amortization expenses could be accelerated or slowed.

Cost of revenue

Cost of product revenue consists of raw materials, parts costs and associated freight, shipping and handling costs, contract manufacturer costs, personnel costs, yield loss, in-license payments and royalties, stock-based compensation, other direct costs and overhead.

Cost of service and other revenue consists of personnel, facility costs associated with operating the Accelerator Laboratory on behalf of the customers, costs related to instrument maintenance and servicing equipment at customer sites, other direct and overhead.

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 are primarily composed of compensation and benefits associated with sales and marketing, finance, human resources, and other administrative personnel, outside marketing, advertising, allocated facilities costs, legal expenses, and other general and administrative costs.

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.

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because to do so would be anti-dilutive (in common stock equivalent shares):

	Year Ended December 31,		
	2021	2020	2019
Unvested restricted common stock and restricted stock units	531,473	518,387	409,929
Outstanding stock options	2,304,543	2,494,045	2,507,062
Outstanding common stock warrants	—	10,000	10,000

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,	
	2021	2020
Cash	$ 64,372	$ 19,535
Money market funds invested in U.S. Treasury obligations	332,093	162,049
Total cash and cash equivalents	$ 396,465	$ 181,584

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, 2021.

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.

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. To date, no such impairment losses have been recorded. 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, using the optional transition method allowing entities to recognize a cumulative effect adjustment to the opening balance sheet without restating comparative prior periods presented. At adoption the Company elected the package of practical expedients which was applied consistently to all of its leases at the transition date: i) the Company did not reassess whether any expired or existing contracts are or contain leases; ii) the Company did not reassess the lease classification for any expired or existing leases (that is, all existing leases that were classified as operating leases in accordance with ASC 840, *Leases* (ASC 840), are classified as operating leases); and iii) the Company did not reassess initial direct costs for any existing leases.

ASC 842 requires a lessee to recognize assets and liabilities on the balance sheet for most leases and changes many key definitions, including the definition of a lease. 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 the instrument. 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. The carrying value of the long-term debt approximates its fair value as the debt arrangement is based on interest rates the Company believes it could obtain for borrowings with similar terms.

Fair value measurements are as follows (in thousands):

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	$ 332,093	$ 332,093	$ —	$ —
	$ 332,093	$ 332,093	$ —	$ —

December 31, 2020	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Financial assets				
Cash equivalents	$ 162,049	$ 162,049	$ —	$ —
	$ 162,049	$ 162,049	$ —	$ —

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, 2021 and 2020, 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 39% and 29% of the Company’s gross trade accounts receivable balance as of December 31, 2021 and 2020, respectively.

As of December 31, 2021, one customer represented 18% of the Company’s aggregate accounts receivable. As of December 31, 2020, one customer represented 19% of the Company’s aggregate accounts receivable. During the years ended December 31, 2021 and 2019, no individual customer represented 10% of the Company’s total revenue. During the year ended December 31, 2020, one company represented 13% 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). ASC 718 requires all stock-based payments to employees including grants of employee 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. Prior to the adoption of Accounting Standards Update (ASU) No. 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07), the measurement date for non-employee awards was generally the date the services were completed, resulting in financial reporting period adjustments to stock-based compensation during the vesting period for changes in the fair value of the awards. The Company adopted ASU 2018-07 on January 1, 2020. After the adoption of ASU 2018-07, the measurement date for non-employee awards is the date of grant without changes in the fair value of the award. 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, 2021, 2020, and 2019.

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 grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

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,		
	2021	2020	2019
Risk-free interest rate	0.4% - 1.3%	0.4% - 1.7%	1.4% - 2.6%
Expected dividend yield	None	None	None
Expected term (in years)	6.0	6.0	6.0
Expected volatility	49.2% - 55.6%	43.9% - 49.2%	33.5% - 39.7%
Weighted-average grant date fair value	$ 29.96	$ 12.66	$ 9.09

Expected volatility was calculated based a proportional weighting of reported volatility data for a representative group of guideline publicly traded companies for which historical information was available, as well as the Company's 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 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 uses 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. Inventory

Inventory consists of the following (in thousands):

	As of December 31,	
	2021	2020
Raw materials	$ 7,892	$ 5,265
Work in process	4,923	3,306
Finished goods	9,375	6,285
Total	$ 22,190	$ 14,856

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

4. Property and equipment

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

	As of December 31,	
	2021	2020
Laboratory and manufacturing equipment	$ 9,742	$ 8,523
Office furniture and equipment	1,617	1,556
Computers and software	3,893	1,504
Leasehold improvements	10,413	8,765
Total cost	$ 25,665	$ 20,348
Less: accumulated depreciation	(7,705)	(6,436)
Property and equipment, net	$ 17,960	$ 13,912

The Company incurred depreciation expense of $2.8 million, $2.2 million and $1.6 million for the years ended December 31, 2021 2020, and 2019, respectively. The Company has instruments included in laboratory and manufacturing equipment, which are used internally by the Company. 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. As of December 31, 2020, the laboratory and manufacturing equipment balance includes $3.4 million of cost and $1.8 million of accumulated depreciation related to these instruments.

5. Other accrued expenses

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

	As of December 31,	
	2021	2020
Accrued inventory purchases	$ 568	$ 527
Accrued property and equipment purchases	229	670
Accrued royalties	1,250	1,845
Accrued professional services	2,126	797
Accrued development costs	566	323
Accrued tax liabilities	430	156
Accrued other	1,317	527
Total accrued expenses	$ 6,486	$ 4,845

6. Income taxes

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

	Year Ended December 31,		
	2021	2020	2019
United States	$ (56,554)	$ (29,896)	$ (40,010)
Foreign	(1,170)	(2,010)	(973)
Total loss before income taxes	$ (57,724)	$ (31,906)	$ (40,983)

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

	Year Ended December 31,		
	2021	2020	2019
Current:			
United States			
Federal	$ —	$ —	$ —
State	(30)	(13)	(20)
Foreign	(342)	(102)	(93)
Total current income tax provision	(372)	(115)	(113)
Deferred			
United States			
Federal	5	(8)	(3)
State	(6)	(3)	(1)
Foreign	409	502	304
Total deferred income tax benefit	408	491	300
Total income tax benefit	$ 36	$ 376	$ 187

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

	Year Ended December 31,		
	2021	2020	2019
Federal statutory income tax rate	21.0 %	21.0 %	21.0 %
Foreign tax rate differential	— %	0.30 %	— %
State taxes, net of federal benefit	6.5 %	2.5 %	3.2 %
Tax credits	2.0 %	1.6 %	2.3 %
Share-based compensation	7.4 %	5.2 %	2.3 %
Permanent items	(1.8)%	(0.4)%	(0.9)%
Deferred tax rate change	0.2 %	0.3 %	(1.4)%
Change in valuation allowance	(34.8)%	(29.7)%	(24.6)%
Other	(0.4)%	0.4 %	(1.4)%
Effective income tax rate	0.1 %	1.2 %	0.5 %

The effective income tax rate of 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.

During 2019, the Company acquired Uman, a Swedish entity. The Company analyzed the transaction from an income tax perspective and found that there was no tax deductible goodwill or other identifiable intangible assets related to the transaction.

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,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 67,543	$ 50,233
Tax credits	6,113	5,101
Deferred revenue	1,862	2,167
Amortization	962	1,054
Stock-based compensation	3,138	1,956
Inventory	686	—
Lease liability	5,464	5,703
Other deferred tax assets	2,340	2,533
Total deferred tax assets	88,108	68,747
Less: valuation allowances	(83,121)	(63,609)
Net deferred tax assets	4,987	5,138
Deferred tax liabilities:		
Right-of-Use Assets	(2,867)	(2,957)
Depreciation	(1,752)	(1,775)
Amortization acquired intangibles	(2,208)	(2,880)
Inventory	—	(64)
Goodwill	(66)	(49)
Other deferred tax liabilities	(129)	(61)
Net deferred tax liabilities	$ (2,035)	$ (2,648)

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

	2021	2020
Balance, beginning of year	$ 63,609	$ 54,137
Change in valuation allowance	19,512	9,472
Balance, end of year	$ 83,121	$ 63,609

The valuation allowance increased during the year ended December 31, 2021 as compared to the year ended December 31, 2020, primarily as a result of the U.S. operating losses incurred, stock-based compensation windfall benefits 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, 2021, the Company maintains a full valuation allowance against its worldwide net deferred tax assets.

As of December 31, 2021, the Company had U.S. federal NOLs of approximately $267.2 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 $158.7 million do not expire. As of December 31, 2021, the Company had $178.8 million of state NOLs, approximately $168.8 million expire at various dates through 2041, and certain state NOLs of approximately $10.0 million do not expire. As of December 31, 2021, the Company had U.S. federal tax credit carryforwards of approximately $5.1 million that expire at various dates

through 2041. As of December 31, 2021, the Company had U.S. state tax credit carryforwards of approximately $1.3 million that expire at various dates through 2036.

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 Coronavirus Aid, Relief and Economic Security Act (the CARES Act) was enacted in the United States on March 27, 2020. The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides extensive tax changes in response to the COVID-19 pandemic, the provisions do not have a significant impact on the Company's financial results. In July 2021, the Company filed for a $2.1 million refund under the CARES Act relating to an employee retention credit (ERC). The ERC is a refundable payroll tax credit. The Company expects receipt of the ERC refund during the first half of 2022, and this amount is included in prepaid expenses and other current assets on the consolidated balance sheet as of December 31, 2021.

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, 2021, 2020, and 2019, 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, 2021, the Company is generally no longer subject to examination by taxing authorities in the United States for years prior to 2018. However, NOLs and 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 2016 onward.

As of December 31, 2021, the Company's foreign subsidiaries had immaterial undistributed earnings and the tax payable on the earnings that are indefinitely reinvested would be immaterial.

7. Stockholders' equity

Stock-based compensation

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

	December 31,		
	2021	2020	2019
Cost of product revenue	$ 471	$ 189	$ 86
Cost of service and other revenue	403	311	238
Research and development	1,807	1,129	718
Selling, general, and administrative	13,294	8,470	5,346
Total stock-based compensation	$ 15,975	$ 10,099	$ 6,388

At December 31, 2021, there was $35.8 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 IPO, the Company terminated the 2007 Plan. As of December 31, 2021, 709,772 shares were outstanding. No shares were 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, 2021, 2,026,021 shares were outstanding and there were 1,434,072 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: 4% of the number of shares of common stock outstanding as of such date; and an amount determined by the Company's Board of Directors or Compensation Committee. On January 3, 2022, the number of shares of common stock available for issuance under the 2017 plan was automatically increased by 1,469,428 shares.

In December 2017, the Company adopted the 2017 Employee Stock Purchase Plan (the 2017 ESPP). As December 31, 2019, the 2017 ESPP allowed for the issuance of up to 612,572 shares of common stock. As of December 31, 2021, 1,137,595 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: 1% of the number of shares of common stock outstanding on the last day of the immediately preceding fiscal year or an amount determined by the Company's Board of Directors or Compensation Committee. The number of shares available for grant under the 2017 ESPP increased by 367,357 shares on January 3, 2022 due to this 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.

Warrants

The following table summarizes the Company's outstanding warrants:

	Issued and exercisable	Weighted Average Exercise Price
As of December 31, 2020	10,000	$ 21.00
Issued	—	—
Exercised	(10,000)	21.00
Cancelled	—	—
As of December 31, 2021	—	$ —

Stock options

Under the 2007 and 2017 Plans, 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)	intrinsic value (in thousands)
Outstanding at December 31, 2020	2,494,045	$ 17.73	7.27	$ 71,760
Granted	439,209	$ 62.06		
Exercised	(516,804)	$ 15.24		
Cancelled	(211,637)	$ 36.32		
Outstanding at December 31, 2021	2,204,813	$ 25.36	6.76	$ 44,813
Exercisable at December 31, 2021	1,493,289	$ 16.34	5.90	$ 39,191
Vested and expected to vest at December 31, 2021	2,204,813	$ 25.36	6.76	$ 44,813

Restricted stock awards

In January 2015, the Company issued 781,060 shares of restricted common stock to an executive of the Company under the 2007 Plan. The majority of these shares were issued subject to a four-year vesting schedule with 25% vesting on the first anniversary and the remaining vesting 75% ratably on a monthly basis over the remaining three years, while another portion was issued subject to performance-based vesting. The vesting of performance-based awards is dependent upon achievement of specified financial targets of the Company. The majority of the performance criteria were achieved during the years ended December 31, 2016 and 2015 and the remaining unvested awards with performance conditions are not material. No restricted stock awards were granted during the years ended December 31, 2021, 2020, or 2019. As of December 31, 2021, the Company had 39,803 shares of unvested restricted common stock with a weighted average grant date fair value of $3.12 per share.

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, 2020	478,581	$ 28.08	8.83	$ 22,254
Granted	428,235	$ 58.20		
Vested	(267,189)	$ 27.31		
Cancelled	(109,756)	$ 44.64		
Unvested RSUs as of December 31, 2021	529,871	49.32	9.68	$ 22,467
Expected to convert at December 31, 2021	529,871	$ 49.32		$ 22,467

8. Leases

The Company is a lessee under leases of offices, lab spaces, and certain office equipment. Some of the Company's leases include options to extend the lease, and these options are included in the lease term to the extent they are reasonably certain to be exercised.

900 Middlesex Turnpike Lease

The Company's primary lease is the 900 Middlesex Turnpike Lease. On October 2, 2018, the Company entered into a 137-month operating lease for the Company's new headquarters in Billerica, Massachusetts. The lease is for approximately 92,000 square feet of office and laboratory space and commenced on April 1, 2019. The lease contains a period of free rent and escalating monthly rent payments. As part of the lease, the Company was required to enter into a $1.0 million Letter of Credit drawable by the lessor under specifically outlined conditions, which will be subsequently reduced throughout the lease term. Pursuant to a work letter entered into in connection with the 900 Middlesex Turnpike Lease, the landlord contributed an aggregate of $8.2 million toward the cost of construction and tenant improvements for the building. Under the lease, the Company has the option to extend the lease for two successive five-year terms, and the renewal options are not reasonably certain to be exercised.

In applying the ASC 842 transition guidance, the 900 Middlesex Turnpike Lease remained classified as an operating lease and the Company recorded ROU assets of $12.2 million and lease liability of $22.7 million on the effective date. The difference between the ROU and the lease liability was driven by the Company derecognizing deferred rent of $3.0 million and the lease obligation incentive of $7.6 million. The Company is recognizing rent expense on a straight-line basis throughout the remaining term of the leases.

48 Tvistevägen

The Company has multiple leases at 48 Tvistevägen Umeå, Sweden for laboratory spaces, manufacturing spaces, and office space (the Uman leases). All of these Uman leases have been assessed as operating leases.

In applying the ASC 842 transition guidance, the Uman leases remained classified as operating leases and the Company recorded ROU assets of less than $0.1 million and lease liability of less than $0.1 million on the effective date. The Company is recognizing rent expense on a straight-line basis throughout the remaining term of the leases.

Summary of all lease costs recognized under ASC 842

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating leases:

	Year Ended December 31,	
Operating leases (in thousands)	**2021**	**2020**
Lease costs (1)		
Operating lease costs	$ 2,660	$ 2,663
Total lease cost	$ 2,660	$ 2,663
Other information		
Operating cash flows used for operating leases	$ 3,388	$ 2,108
Weighted average remaining lease term (years)	8.6	9.8
Weighted average discount rate	9.73%	9.73%

(1) Short-term lease costs and variable lease costs incurred by the Company for the year ended December 31, 2021 were considered immaterial.

Rent expense is calculated on a straight-line basis over the term of the lease. Rent expense recognized under all leases was $5.4 million, $4.8 million, and $3.3 million for the years ended December 31, 2021, 2020, and 2019, respectively. Note that the Company adopted ASC 842 effective January 1, 2020 using the required modified retrospective approach and utilizing the effective date as its date of initial application. Therefore, the amount disclosed pertaining to the year ended December 31, 2019 is presented under previous accounting guidance and is not comparable to the amounts recorded in the 2021 and 2020 periods under ASC 842.

Future minimum commitments under ASC 842 under the Company's operating leases in effect at December 31, 2021 were as follows:

Maturity of lease liabilities (in thousands)	As of December 31, 2021
2022	$ 3,466
2023	3,515
2024	3,557
2025	3,655
2026	3,765
thereafter	14,782
Total lease payments	$ 32,740
Less: imputed interest	10,850
Total operating lease liabilities	$ 21,890

9. Commitments and contingencies

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, 2021, 2020, and 2019, the Company recorded royalty expense of $1.6 million, $1.1 million and $1.0 million, respectively, 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) (see Note 13).

Other licenses

During the year ended December 31, 2012, the Company entered into a license agreement for certain intellectual property with a third party. The non-exclusive, non-sublicensable third party's license provides the Company access to certain patents specifically for protein detection and shall be in effect until the expiration of the last licensed patent. In consideration for these rights, the Company committed to certain license fees, milestone payments, minimum annual royalties and a mid-single digit royalty. The Company is required to make mid-single digit royalty payments on net sales of products and services which utilize the licensed technology. The Company must pay the greater of calculated royalties on net sales or an annual minimum royalty of $50 thousand. In September 2019, all remaining patents related to the intellectual property expired and the license agreement terminated. As this agreement was terminated in 2019, the Company recorded no royalty expense during the years ended December 31, 2021 and 2020. During the year ended December 31, 2019, the Company recorded royalty expense of $0.8 million in cost of product revenue on the consolidated statements of operations.

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.

10. 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 this term loan is variable based on the greater of 8% or 8% plus the prime rate less 5.25%. Interest is 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 contains 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.

11. “At-the-market offering”

On March 19, 2019, the Company entered into the Sales Agreement with Cowen with respect to an “at-the-market” offering program under which the Company could offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering price of up to $50.0 million through Cowen as its sales agent.

On June 5, 2019, the Company issued approximately 2.2 million shares of common stock at an average stock price of $22.73 per share pursuant to the terms of the Sales Agreement. The “at-the-market” offering resulted in gross proceeds of $49.7 million. The Company incurred $1.7 million in issuance costs associated with the “at-the-market” offering, resulting in net proceeds to the Company of $48.0 million. On August 6, 2020, the Company delivered written notice to Cowen to terminate the Sales Agreement, which termination the parties agreed to make immediately effective.

12. Underwritten public offerings

On August 8, 2019, the Company entered into an underwriting agreement with J.P. Morgan and Leerink, as representatives of the several underwriters, relating to an underwritten public offering of approximately 2.7 million shares of the Company’s common stock, par value $0.001 per share. The underwritten public offering resulted in gross proceeds of $69.0 million. The Company incurred $4.5 million in issuance costs associated with the underwritten public offering, resulting in net proceeds to the Company of $64.5 million.

On August 6, 2020, the Company entered into an underwriting agreement with Leerink and 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, 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.

13. 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. The Company recognized revenue of less than $0.1 million for the years ended December 31, 2021, 2020, and 2019 associated with these licenses.

During the year ended December 31, 2020, the Company recognized $1.2 million of previously deferred revenue as a result of entering into a license agreement with a diagnostics company. As of December 31, 2021 and 2020, 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 year ended December 31, 2021 and 2020, the Company recognized no revenue and $10.0 million, respectively, within collaboration and license revenue related to the initial license fee under the Abbott License Agreement.

14. 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, 2021, 2020, and 2019, the Company made contributions of $1.1 million, $0.7 million, and $0.5 million, respectively.

15. Business combinations

UmanDiagnostics AB

On August 1, 2019, the Company completed its acquisition of Uman for an aggregate purchase price of $21.2 million, comprised of (i) $15.7 million in cash plus (ii) 191,152 shares of common stock (representing $5.5 million based on the closing prices of the Company's common stock on the Nasdaq Global Market on July 1, 2019 and August 1, 2019, the dates of issuance). The acquisition of Uman closed with respect to 95% of the outstanding shares of capital stock of Uman on July 1, 2019 and with respect to the remaining 5% of the outstanding shares of capital stock of Uman on August 1, 2019.

Uman supplies 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. With the acquisition of Uman, the Company has secured a long-term source of supply for a critical technology. This acquisition was considered a business acquisition for accounting purposes.

The Company has accounted for the acquisition of Uman as a purchase of a business under U.S. GAAP. Under the acquisition method of accounting, the assets and liabilities of Uman are recorded as of the acquisition date of July 1, 2019, at their respective fair values, and consolidated with those of the Company. Purchase consideration in excess of the amounts recognized for the net assets acquired was recognized as goodwill and is not expected to be tax deductible in any taxing jurisdiction.

The following table summarizes the acquisition accounting, net of $1.2 million in cash and cash equivalents acquired (in thousands):

Purchase price:		
Cash and stock paid	$	21,217
Cash and cash equivalents acquired		1,221
Purchase price, net		19,996
Assets (liabilities) acquired:		
Accounts receivable	$	638
Inventory		1,680
Prepaids and other current assets		114
Property and equipment		33
Intangibles		13,450
Goodwill		8,111
Accounts payable		(20)
Accrued expense and other current liabilities		(871)
Deferred tax liabilities		(3,139)
Total	$	19,996

Revenue and net income related to Uman’s operations were $1.8 million and $0.1 million, respectively for the year ended December 31, 2021, and is included in the Company’s consolidated statement of operations. Revenue and net loss related to Uman’s operations were $1.5 million and $0.1 million, respectively, for the year ended December 31, 2020, and is included in the Company’s consolidated statement of operations. Revenue and net income related to Uman’s operations were $1.1 million and less than $0.1 million, respectively, for the six months following the July 1, 2019 acquisition date, and is included in the Company’s consolidated statements of operations for the year ended December 31, 2019.

The following unaudited pro forma information presents the condensed consolidated results of operations of the Company and Uman for the year ended December 31, 2019, as if the acquisition of Uman had been completed on January 1, 2018. These pro forma condensed consolidated financial results have been prepared for comparative purposes only and include certain adjustments that reflect pro forma results of operations, such as increased amortization for the fair value of acquired intangible assets, increased cost of sales related to the inventory valuation adjustment, and adjustments relating to the tax effect of combining the Company and Uman businesses.

The unaudited pro forma results do not reflect any operating efficiencies or potential cost savings which may result from the consolidation of the operations of the Company and Uman. Accordingly, these unaudited pro forma results are presented for informational purposes only and are not necessarily indicative of the results of operations that actually would have been achieved had the acquisition occurred as of January 1, 2018, nor are they intended to represent or be indicative of future results of operations (in thousands):

	Year Ended December 31, 2019
Revenue (unaudited)	$ 57,597
Pre-tax loss (unaudited)	$ (38,636)

During the year ended December 31, 2021 and 2020, the Company incurred no costs associated with the acquisition of Uman. During the year ended December 31, 2019, the Company incurred $1.9 million in costs associated with the acquisition of Uman. Costs associated with the acquisition of Uman are recorded as selling, general, and administrative expenses within the consolidated statements of operations.

16. Goodwill and intangible assets

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

	Goodwill
Balance as of December 31, 2020	$ 10,460
Cumulative translation adjustment	(828)
Balance as of December 31, 2021	$ 9,632

Acquired intangible assets consist of the following (dollars in thousands):

		December 31, 2021				
	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	$ (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	

		December 31, 2020				
	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	$ (2,296)	$ 1,374	$ 12,078	7.0
Developed technology	7	1,650	(1,036)	—	614	4.1
Customer relationships	8.5 - 10	1,360	(618)	12	754	7.1
Non-compete agreements	5.5	340	(102)	31	269	4.0
Trade names	3	50	(49)	—	1	0.1
Total		$ 16,400	$ (4,101)	$ 1,417	$ 13,716	

The Company recorded amortization expense of $2.0 million, $2.1 million, and $1.4 million for the years ended December 31, 2021, 2020, and 2019, 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, 2021 is as follows (amounts in thousands):

	As of December 31, 2021
2022	$ 1,930
2023	1,848
2024	1,733
2025	1,618
2026	1,589
Thereafter	1,816
Total amortization expense	$ 10,534

17. Related party transactions

As described in Note 9, 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 a board member of the Company's Board of Directors was affiliated with Tufts. During the years ended December 31, 2021, 2020, and 2019, the Company recorded royalty expense of $1.6 million, $1.1 million, and $1.0 million, respectively, 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.

During the year ended December 31, 2017, Harvard University became a related party because a member of the Company's Board of Directors is affiliated with Harvard University. Revenue recorded from sales to Harvard University was $0.2 million, $0.1 million, and $0.1 million for the years ended December 31, 2021, 2020, and 2019, respectively.

On November 28, 2018, the Company entered into a sponsor agreement with Powering Precision Health (PPH), a 501(c)(6) not-for-profit entity of which an executive of the Company is a board member, through December 31, 2018. The agreement committed a maximum of $120,000 in funds and services to be provided to PPH for the term of the agreement. On November 14, 2019, the Company entered into the first amendment to the PPH sponsorship agreement. The agreement amended the $120,000 annual committed maximum amount to $200,000 for the annual committed amount. The agreement is terminable by either party and does not bind the Company to beyond the term of the agreement. For the years ended December 31, 2021 and 2020, the Company did not make any contributions. For the year ended December 31, 2019, the Company had total contributions of $0.1 million.

18. Subsequent events

On January 28, 2022, the Company entered into a multi-year lease agreement for approximately 53,000 square feet of new principal office space and approximately 32,770 square feet of new laboratory space in Bedford, Massachusetts. The initial lease term is eight years and nine months beginning on the earlier of the Company occupancy, or May 1, 2022. The Company was required to provide an initial security deposit of $0.9 million, which was provided in a form of a letter of credit to the landlord during 2021, and is included in the Company's restricted cash balance as of December 31, 2021. The security deposit is scheduled to be reduced to $0.5 million after 60 months.

Amended and Restated Quanterix Corporation
Non-Employee Director Compensation Policy

Effective as of January 1, 2022

I. Overview

The Board of Directors (the "Board") of Quanterix Corporation (the "Company") has approved this Amended and Restated Non-Employee Director Compensation Policy (the "Policy") to provide an inducement to attract and retain the services of qualified persons to serve as directors.

II. Eligibility

This Policy shall apply to each director of the Board who is not an employee of, or compensated consultant to, the Company or any of its Affiliates (as defined in the 2017 Employee, Director and Consultant Equity Incentive Plan, or any successor plan ("the Plan")) (a "Non-Employee Director"). Employees of the Company and their affiliates are not eligible to receive compensation under this Policy.

III. Director Compensation

The following is a description of the compensation arrangements under which our Non-Employee Directors are compensated for their service as directors, including as members of the various committees of our Board, consisting of the cash retainers described in Section III.A and the equity awards described in Section III.B.

A. Cash Compensation

1. *Terms for Cash Payment*

Subject to Section III.A.2, each Non-Employee Director shall receive the following annual cash compensation for his or her service on the Board and committees of the Board:

Base Board Retainer	$40,000
Additional Lead Director/Non-Employee Board Chairman Retainer	$20,000
Additional Audit Committee Chairman Retainer	$20,000
Additional Compensation Committee Chairman Retainer	$15,000
Additional Nominating and Governance Committee Chairman Retainer	$10,000
Additional Audit Committee Member Retainer	$10,000
Additional Compensation Committee Member Retainer	$7,250
Additional Nominating and Governance Committee Member Retainer	$5,000

Cash payments to Non-Employee Directors shall be paid quarterly in arrears on the first Company payroll date, or as soon as administratively practicable, following the end of the fiscal quarter to which service relates (each, a "Payment Date").

Each Non-Employee Director: (i) who is elected or appointed to the Board after the date hereof

or (ii) ceases to be a Non-Employee Director during a fiscal quarter, shall receive a prorated cash retainer for the portion of such partial fiscal quarter during which he or she served on the Board or a committee of the Board (the "Prorated Retainer"). The Prorated Retainer shall be an amount equal to the product of (A) the aggregate amount payable in respect of such Non-Employee Director's service for a full fiscal quarter multiplied by (B) a fraction, the numerator of which is (x) the number of days during such fiscal quarter which the Non-Employee Director served on the Board or committees, and the denominator of which is (y) the total number of days during such fiscal quarter. The Prorated Retainer shall be paid on first Payment Date following such fiscal quarter.

2. *Election for Equity in Lieu of Cash Retainers*

Prior to the end of each calendar year, each Non-Employee Director shall make an annual election by delivery to the Company of an election form, substantially in the form attached hereto as Exhibit A (the "Election Form"), with respect to cash retainers for the following calendar year, indicating whether he or she elects to receive the retainers in cash, as described in Section III.A.1, or in the Company's common stock, $0.001 par value per share ("Common Stock"), in lieu of the cash retainers. If no election has been made as of the first day of the year, the Non-Employee Director shall receive all retainers in cash as set forth in Section III.A.1 or, if a previous election has been made to receive Common Stock in lieu of the cash retainers, such election shall remain in effect for subsequent calendar years until such election is changed by the completion, signature and delivery to the Company of a new Election Form, in accordance with the terms of this Policy. Each newly elected or appointed Non-Employee Director shall make an election prior to, or within 30 days of, his or her initial appointment or election to the Board, for the remainder of the year of such appointment or election, whether to receive the retainers in cash or in Common Stock.

In the event an election is made to receive Common Stock in lieu of cash retainers, such director shall automatically be granted, without any further action by the Board, on the first trading day following each fiscal quarter a number of shares of Common Stock having an aggregate fair market value equal to the aggregate amount of such Non-Employee Director's cash retainer for such fiscal quarter, determined by dividing (A) the aggregate amount of the retainers by (B) the Fair Market Value (as defined in the Plan) of the Common Stock on such trading day.

All Common Stock granted to Non-Employee Directors under this Policy shall be granted under the Plan and will be subject to the terms and conditions set forth in the Plan.

B. Equity Compensation

1. *Annual Equity Awards*

Each Non-Employee Director will automatically be granted, without any further action by the Board, on the first trading day of each fiscal year, an annual equity award valued at $200,000, rounded to the nearest whole share (the "Annual Award"). The Annual Award is comprised of (A) 60% non-qualified stock options to purchase Common Stock at an exercise price equal to the Fair Market Value as of such grant date (the "Options") and (B) 40% restricted stock units, (each RSU relating to one (1) share of Common Stock (the "RSUs")). The number of Options shall be determined on a value basis using the Company's standard Black-Scholes valuation

methodology. The number of RSUs shall be determined by dividing total value of the RSUs by the Fair Market Value (as defined in the Plan) of the Common Stock on such grant date. The Annual Awards shall become vested in full on December 31st of the year in which such awards were granted, provided that the Non-Employee Director is a director of the Company on the applicable vesting date.

2. *Initial Equity Awards for Newly Elected Directors*

Upon initial election or appointment of a Non-Employee Director to the Board, such Non-Employee Director will automatically be granted, on his or her election or appointment date, without any further action by the Board, an award valued at $400,000, rounded to the nearest whole share (the "Initial Award"). The Initial Award is comprised of (A) 60% Options at an exercise price equal to the Fair Market Value as of such grant date and (B) 40% RSUs. The number of Options shall be determined on a value basis using the Company's standard Black-Scholes valuation methodology. The number of RSUs shall be determined by dividing total value of the RSUs by the Fair Market Value (as defined in the Plan) of the Common Stock on such grant date. The Options granted pursuant to Initial Awards shall vest over a three-year period, with one-third vesting on the first anniversary of the applicable grant date, and the remainder vesting over the following two years in 24 successive equal monthly installments at the end of each month until the third anniversary of such grant date, provided that the Non-Employee Director is a director of the Company on the applicable vesting date. The RSUs granted pursuant to Initial Awards shall vest over a three-year period, with one-third vesting on each of the first, second, and third anniversaries of the applicable grant date, provided that the Non-Employee Director is a director of the Company on the applicable vesting date.

All Annual Awards and Initial Awards granted to Non-Employee Directors under this Policy shall be granted under the Plan, and will be subject to the terms and conditions set forth in the Plan, and the form of Stock Option Agreement and form of Restricted Stock Unit Agreement, each as approved by the Board.

C. Expense Reimbursement

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each Non-Employee Director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board and its committees or in connection with other business related to the Board. Each Non-Employee Director shall also be reimbursed for his or her reasonable out-of-pocket business expenses authorized by the Board or one of its committees that are incurred in connection with attendance at meetings with the Company's management. Each Non-Employee Director shall abide by the Company's travel and other policies applicable to Company personnel.

IV. Policy Review / Amendments

The Compensation Committee or the Board shall review this Policy from time to time to assess whether any amendments in the type and amount of compensation provided herein should be adjusted in order to fulfill the objectives of this Policy. This Policy may only be amended by the Board.

EXHIBIT A

QUANTERIX CORPORATION

NON-EMPLOYEE DIRECTOR COMPENSATION ELECTION FORM

In accordance with the Amended and Restated Director Compensation Policy, effective January 1, 2022 (the "Policy"), of Quanterix Corporation (the "Company"), the undersigned hereby makes the following election for the period from January 1, ____ through December 31, ____ (the "Period") with respect to the non-employee director board and committee cash retainers (the "Retainers") to be earned by the undersigned during the Period:

I elect to receive my Retainers during the Period (please check one of the following):

_____ in cash

_____ in the Company's common stock, $0.001 par value per share ("Common Stock")

In accordance with the Policy, Common Stock shall be granted quarterly in arrears on the first trading day following the end of the fiscal quarter to which service relates and the undersigned shall be granted automatically and without any further action required by the Board of Directors ("Board") under the Company's 2017 Employee, Director and Consultant Equity Incentive Plan or any successor plan (the "Plan") a number of shares of Common Stock having an aggregate fair market value equal to the aggregate amount of the Retainers for such fiscal quarter, determined by dividing (A) the aggregate amount of the Retainers by (B) the Fair Market Value (as defined in the Plan) of the Common Stock on such trading day (rounded down to the nearest whole share), in lieu of the aggregate amount of the Retainers that would otherwise be paid in cash in respect of such fiscal quarter.

Signature	Print Name	Date

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-3ASR No. 333-249925) of Quanterix Corporation,

(2) 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;

(3) 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;

(4) 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; and

(5) 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;

of our report dated March 1, 2022, with respect to the consolidated financial statements of Quanterix Corporation, included in this Annual Report (Form 10-K) of Quanterix Corporation for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 1, 2022

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, E. Kevin Hrusovsky, 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 1, 2022

/s/ E. KEVIN HRUSOVSKY
E. Kevin Hrusovsky
Chairman 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 1, 2022

/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, 2021 (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 1, 2022

/s/ E. KEVIN HRUSOVSKY
E. Kevin Hrusovsky
Chairman and Chief Executive Officer

Dated: March 1, 2022

/s/ MICHAEL A. DOYLE
Michael A. Doyle
Chief Financial Officer