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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, 2018

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

(State or other jurisdiction of
incorporation or organization)

20-8957988

(I.R.S. Employer Identification No.)

**113 Hartwell Avenue, Lexington,
MA**

(Address of principal executive
offices)

02421

(Zip Code)

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

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value per share	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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of June 30, 2018, 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 \$162.8 million.

As of March 1, 2019, the registrant had 22,461,202 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2019 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, 2018, 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;
- the commercialization and adoption of our existing products and services and the success of our new product 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;
- our new principal office and laboratory space; and
- our financial performance.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those 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.

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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, or 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 June 2017, 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.

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. "Quanterix," "Simoa," "Simoa HD-1," "SR-X," "SP-X", "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.

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 and have been discovered using technologies such as mass spectrometry. 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 are currently focusing on protein detection, which we believe is an area of significant unmet need and where we have significant competitive advantages. However, in addition to enabling new applications and insights in protein analysis, we are also developing our Simoa bead-based technology to detect nucleic acids in biological samples.

We believe that our Simoa platforms are the most sensitive commercially available protein detection platforms and significantly advance ELISA technology, which has been the industry standard for protein detection for over forty years. Proteins are complex molecules that are required for the structure, function and regulation of the body's tissues and organs, and are the functional units that carry out specific tasks in every cell. The human body contains approximately 20,000 genes, each of which can produce multiple proteins. It is estimated that these 20,000 genes can produce over 100,000 different proteins, approximately 10,500 of which are known to be secreted in blood. Accordingly, while research on nucleic acids provides valuable information about the role of genes in health and disease, proteins are more prevalent and, we believe, more relevant to a precise understanding of the nuanced continuum between health and disease. Protein measurement goes beyond genetic predisposition, reflecting 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.

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 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 by published research in more than 400 articles in peer-reviewed 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 420 customers across our end markets, and includes 19 of the 20 largest biopharmaceutical companies.

Our Market Opportunities

Our Simoa platforms have applications across the life science research, diagnostics and precision health screening markets. Our initial target market has been the life science research market, and according to estimates in the Third-Party Research Report, we believe that the life science research market, including both proteomics and genomics research, is \$3 billion per year and has the potential to reach \$8 billion per year. However, as our customers continue to gain experience with our proprietary Simoa technology, we believe the opportunity to access markets beyond research, such as diagnostics and precision health screening, will be significant. The Third-Party Research Report also estimates that the diagnostic and precision health screening markets have the potential to reach an aggregate of \$30 billion per year.

Life Science Research

Our initial target market is the large and growing life science research market. We believe our Simoa platforms are well-positioned to capture a significant share of this market 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, we believe that Simoa is penetrating the existing market for protein analysis and holds potential to significantly grow the life science research market as researchers expand their research into the diseases associated with the thousands of proteins that were previously undetectable. Simoa also enables earlier detection of the proteins that are currently detectable by other technologies only after they have reached levels that reflect more advanced disease or injury. As an indication of the market's acceptance of our technology, biopharmaceutical researchers are also integrating our platforms into drug development protocols to more efficiently and effectively develop drugs. In addition to enabling new applications and insights in protein analysis, our Simoa bead-based technology can be used to detect nucleic acids, which expands our market opportunity. We believe that this technology has the potential to ultimately provide the same sensitivity as polymerase chain reaction, or PCR, which is the most commonly used technology for nucleic acid detection, without the distortion and bias issues associated with amplification used in PCR.

Diagnostics

We believe the diagnostic market represents a significant commercial opportunity for our Simoa technology as well. We believe existing 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. We also believe that the ultra-sensitive protein detection provided by Simoa can enable the development of a new category of non-invasive diagnostic tests and tools based on blood, serum, saliva 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. Drug developers can use Simoa to stratify patients into categories, enabling selection of those patients for whom a drug is expected to be most effective and safe. Not only does Simoa have the potential to be used to develop companion diagnostics to stratify patients in clinical trials and for treatment, but Simoa's sensitivity may also enable the development of companion diagnostics based on protein biomarkers that can regularly monitor whether an approved drug is having the desired biological effect, enabling doctors to quickly and efficiently adjust the course of treatment as appropriate.

Precision Health Screening

The ability of our Simoa platforms to detect and quantify normal physiological levels of proteins in low abundance that are undetectable using conventional, analog immunoassay technologies may 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. 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.

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, 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 Products and Services

Our proprietary Simoa technology is based on traditional enzyme-linked immunosorbent assay, or 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 January 2018, we acquired Aushon BioSystems, Inc., or 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 the most sensitive protein detection platforms commercially available today:

- **HD-1:** We commercially launched our HD-1 instrument in January 2014. The HD-1 is based on our bead-based technology, and assays run on the HD-1 are fully automated. The full automation of the HD-1 provides us with an additional significant competitive advantage with biopharmaceutical customers.
- **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-1 in a compact benchtop form with a lower price point, more flexible assay preparation, and a wider range of potential applications, including direct detection of nucleic acids.
- **SP-X:** We initiated an early-access program for the SP-X instrument in January 2019, with the full commercial launch planned for April 2019. The SP-X is based on our 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 and oncology for both human and mouse samples. The current menu of Simoa planar array reagent kits includes approximately 50 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 intend to continue to increase the number of Simoa digital biomarker assays.

We continually seek to improve and expand our product offerings to meet the needs of our customers. To that end, we are developing the next generation HD instrument, the HD-X, which we expect to launch in the second half of 2019. The HD-X will increase the multiplexing capability from 4-plex (current HD-1 limit) to six-plex and will include software features to facilitate compliance with 21 CFR part 11 procedures.

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 500 projects for more than 179 customers from all over the world using our Simoa platform. 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 more than 45 customers for whom we have provided contract research services have subsequently purchased an instrument from us.

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. We have an extensive base of customers in world class academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies, using our technology to gather information to better understand human health.

Our Competitive Strengths

We believe that our competitive strengths include the following:

- **Proprietary ultra-sensitive digital immunoassay Simoa technology platforms, that enable researchers and clinicians to obtain information from less invasive procedures in smaller sample sizes.** We believe our Simoa platforms are 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 have also recently implemented a research and development effort with a goal to increase the sensitivity of our Simoa technology 100-fold by 2021.
- **Technology platforms that leverage and improve upon industry standard ELISA technology.** Simoa uses the basic principles of conventional bead-based ELISA. 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.
- **Leader in large and growing market for detecting proteins in low abundance.** We believe Simoa is the most sensitive commercially available protein detection technology, and our growing market acceptance is establishing Simoa as the reference technology for detecting proteins in low abundance across sample types in our end markets.
- **Deep and expanding scientific validation.** Our Simoa technology has been cited in more than 400 articles in peer-reviewed publications, including *JAMA Neurology* and *Nature*, and is becoming a vital tool in cutting edge life sciences research. As of March 1, 2019, Simoa technology had been

cited in 409 publications, with 192 related to neurology and 88 related to oncology and inflammation. We have established relationships with key opinion leaders, and our growing base of over 420 customers includes some of the world's leading academic and government research institutions as well as 19 of the 20 largest pharmaceutical and biotechnology companies.

- **Leading position in market solidified by robust customization capabilities, assay design flexibility and automation of our HD-1 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-1 instrument provides fully automated analysis from sample introduction to analytical results. Furthermore, our proprietary array 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.** As we continue to grow our installed base, optimize workflows and expand our assay menu, we expect to increase our revenues derived from consumables. The integration of our technology in our customers' projects also provides ongoing sales of assays and consumables, resulting in a growing revenue stream. Our consumables revenue increased to \$13.8 million in 2018 from \$7.6 million in 2017.
- **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 drug development.
- **Continue to drive adoption of our Simoa technology in the life science research, diagnostics and precision health screening markets.** 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 believe Simoa has the capability to enable the development of a new category of non-invasive diagnostic tests and tools based on blood, serum, saliva and other fluids that could replace current invasive, expensive and inconvenient diagnostic methods, including spinal tap, diagnostic imaging and biopsy. In the precision health screening market, we believe that Simoa technology has the potential to 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 Simoa "ecosystem" to grow our customer base and further penetrate our existing customer base.** In an effort to enhance the productivity of our instrument base, we employ an extensive customer outreach program that we call Catalyzing Customer Engagement, or CCE. Through CCE, we actively engage customers to optimize their workflow and better understand our instruments' and products' capabilities, resulting in increased utilization of our installed instrument base.
- **Utilize the flexibility of the Simoa platforms to expand into complementary markets, including nucleic acid detection.** We plan to utilize the flexibility of the Simoa platforms to expand our product offering to include other testing capabilities, including detection of nucleic acids. We believe that our Simoa bead-based technology has the potential to provide the same sensitivity as PCR-based assays in detecting nucleic acids without the issues associated with amplification. We believe the ability to integrate nucleic acid and protein testing capabilities into a full service instrument would hold significant value to our customers.
- **Leverage the data generated by Simoa to drive adoption of our technology.** Technology being employed in the healthcare industry has become increasingly sophisticated, creating the need to aggregate and digitize the significant amount of data being created in order to better achieve the goals of higher quality and more efficient care. Simoa generates digitized data for highly relevant biomarkers that can provide a nuanced view into the continuum of health and disease. We plan to use the data generated by the Simoa technology to improve and create additional assays, with the goal of enabling more precise research today and contributing to precision health in the future.
- **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, Simoa's unprecedented sensitivity has the potential to uncover research insights that could identify novel biomarkers, which could help stratify patients in clinical trials potentially leading to a companion diagnostic, and ultimately a precision health test that could monitor and identify early disease. This progression with our customers will help us move into new markets organically in a cost effective manner, while also retaining significant upside. Additionally, we currently have a partnership in place with a leading diagnostics company in the field of blood screening and plan to continue evaluating strategic collaborations that could help us access these new markets.
- **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 for which we initiated an early-access program in January 2019, with the full commercial launch planned for April 2019. This will continue to be an important part of our strategy to increase scale. 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.

Industry Background

We intend to pursue the application of our Simoa technology to the life science research, diagnostics and precision health screening markets. Our initial commercial strategy targets the large and growing life science research market, 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 \$38 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, approximately 10,500 of which 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. To date, across our platforms, we have developed assays that address approximately 120 of the proteins secreted in blood. We estimate that the current sensitivity of our Simoa technology has the potential to detect and measure up to one-third of the approximately 9,200 proteins secreted in blood that are not consistently detectable using conventional immunoassay technologies.

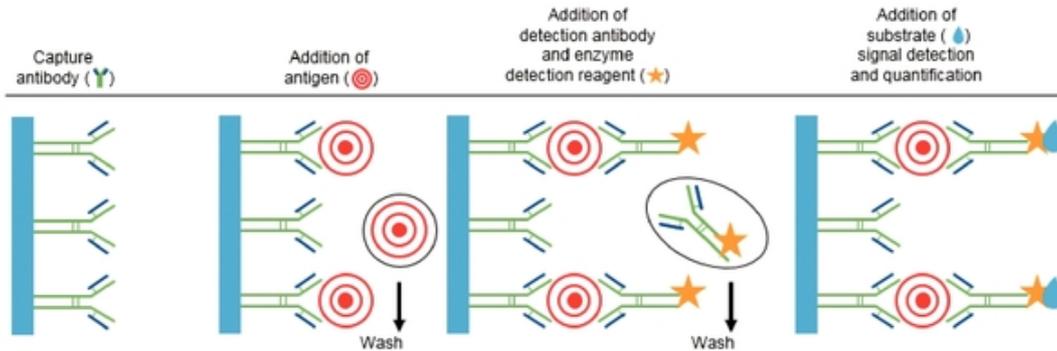
While genomic research provides valuable information about the role of genes in health and disease, proteins are both more prevalent than nucleic acids and, we believe, more relevant to understand precisely the nuanced continuum between health and disease. Genes may indicate the risk of developing a 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

The enzyme-linked immunosorbent assay, or 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 what is estimated to be approximately 10,500 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 more effectively 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.

Due to the complexity, susceptibility to contamination and significant costs related to PCR and other existing technologies, the genomic testing market generally remains limited to reference laboratories, research facilities and laboratories associated with large hospitals. A typical molecular diagnostics laboratory in a hospital or research laboratory setting is a dedicated facility that employs highly skilled technologists and is supervised by a technician with a Ph.D. or M.D./Ph.D. To guard against contamination, which is a common result of target amplification, a typical laboratory will require at least three separate rooms, or isolation areas, to perform PCR-based assay methods for genomic testing.

Our Simoa Technology

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

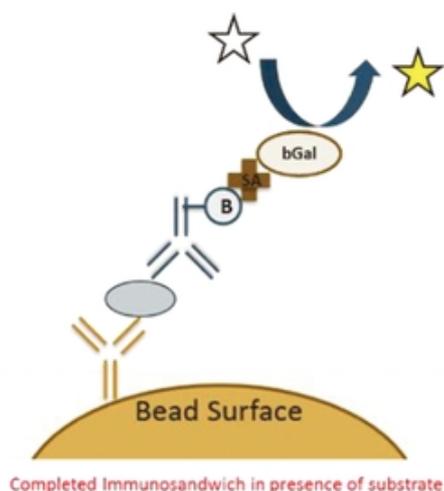
Simoa Bead-Based Technology

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:

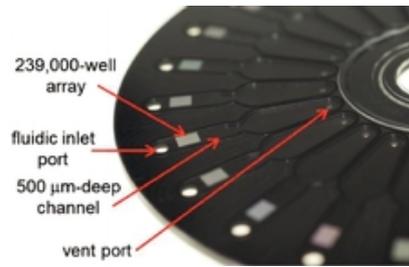
Simoa Bead-Based Analytic Process

Sample Preparation of ELISA Sandwich



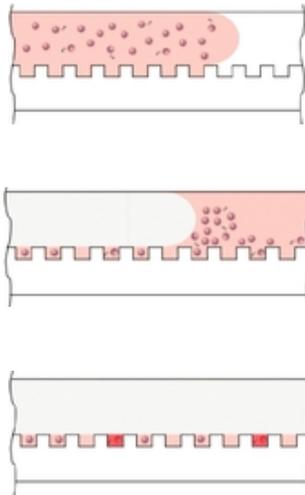
Simoa bead-based technology uses beads coated with capture antibodies that bind specifically to the protein being measured. After an enzyme-linked detection antibody binds to the protein, the enzyme substrate is added (as depicted by the white star in the graphic on the left). The enzyme associated with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



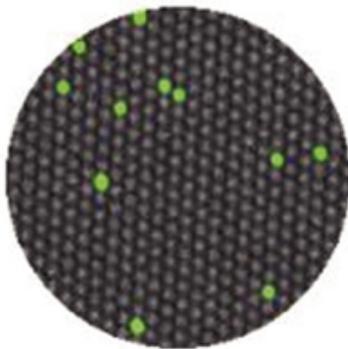
This mixture of beads and enzyme substrate is then injected into our proprietary Simoa disk, which contains 24 arrays of microwells arranged radially. Each 3×4 millimeter array contains approximately 239,000 microwells, each of which is large enough to accommodate only a single bead.

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.

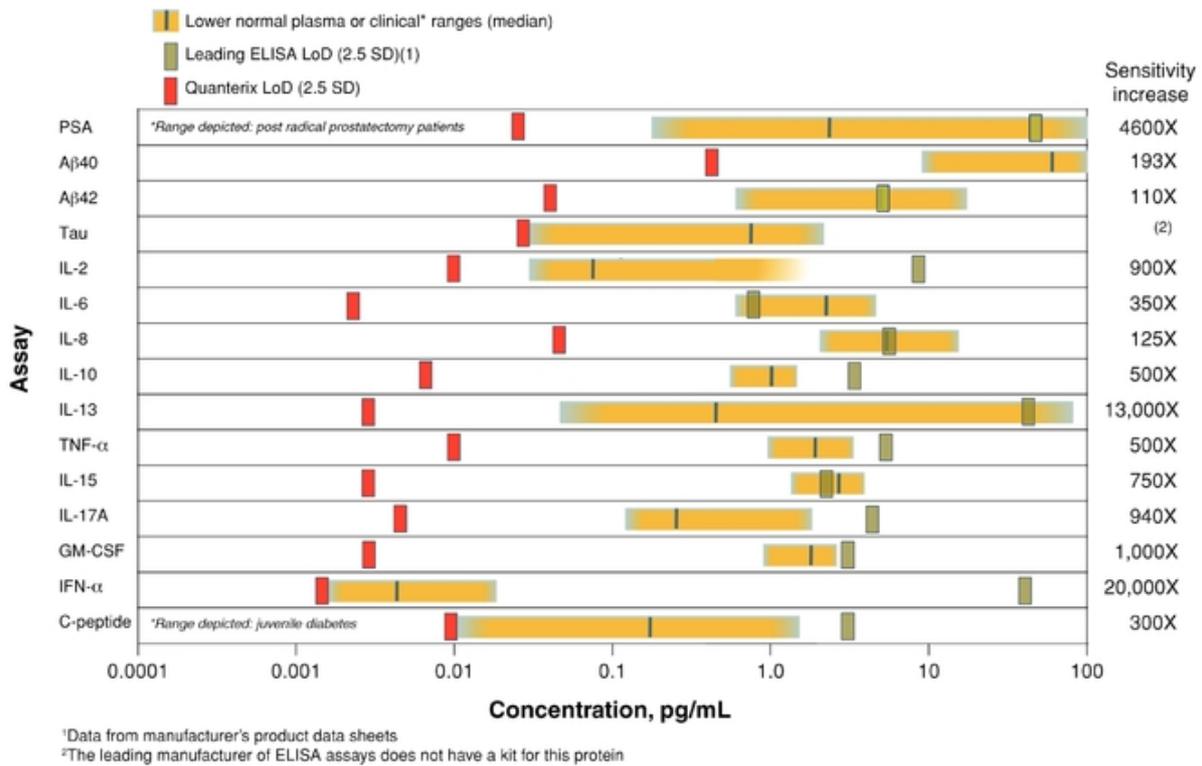
Simoa Readout



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. The following chart shows examples of the levels of detection, or LoD, of certain Simoa bead-based assays and commercially available ELISA assays compared to the median lower normal plasma or clinical ranges of various protein biomarkers. As shown below, the LoD for most of the assays from a leading manufacturer of commercial ELISA assays is above the median lower normal plasma or clinical ranges, making these biomarkers undetectable at normal physiological levels with these assays.

LoD Comparison



Each of the increments in the horizontal axis in the table above represents a 10-fold increase in sensitivity. Using the protein IL-2 as an example from the graphic above, the LoD for the leading commercially available IL-2 assay is approximately 9 pg/mL, whereas the LoD for our Simoa assay is approximately 0.01 pg/mL, representing a 900-fold increase in sensitivity.

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.

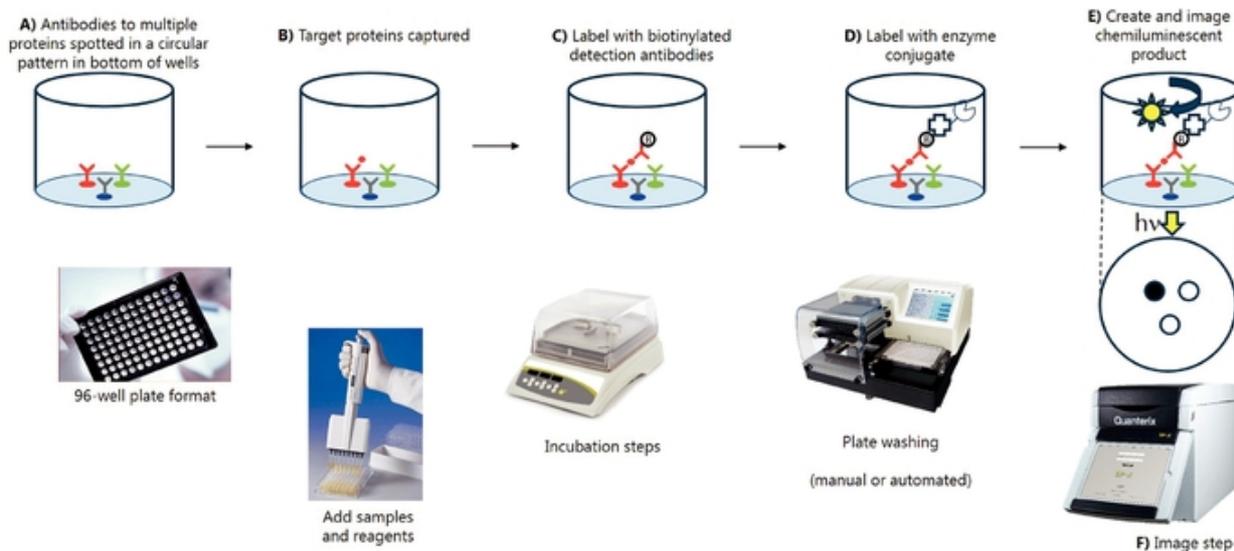
Multiplexing is achieved with our Simoa bead-based technology by using beads labeled with different fluorescent dyes specific to the biomarker being analyzed. After the assay is run, the array of microwells is imaged across the wavelengths of the different labeled beads. The results are measured for each protein captured by each of the different beads. While we have demonstrated the ability to identify and differentiate up to 35 different bead subpopulations on the HD-1, 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 may be 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. In 2017, we commercially launched a Simoa neurology 4-plex (Nf-L, Tau, GFAP and UCH-L1) bead-based assay for the study of traumatic brain injury and other neurodegenerative conditions. Simoa is the only technology with the sensitivity to detect all four of these markers in blood, whereas other assay technologies require cerebrospinal fluid, or CSF, to detect all four of these markers due to sensitivity limitations. This is a significant advantage in terms of ease of use, patient comfort, speed and cost-effectiveness. We plan to introduce a new 6-plex human cytokine panel using Simoa bead-based assay in the middle of 2019.

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:

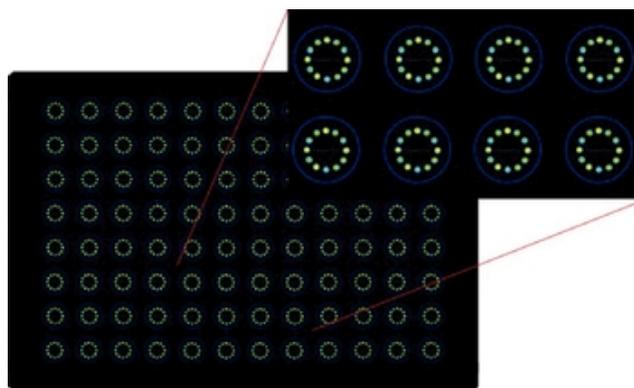
Simoa Planar Array Analytic Process



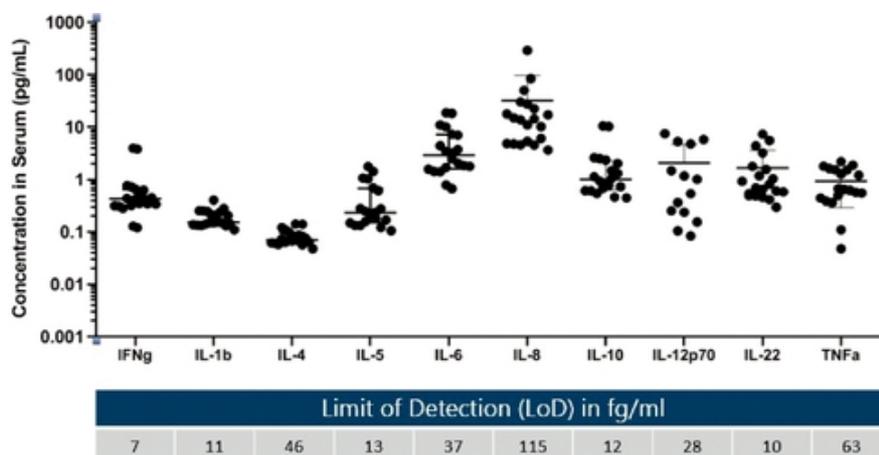
- Analyte-specific capture antibodies are printed in microspots (100 microns) in a circular pattern in the bottom of a 96-well microtiter plate. Each microspot contains capture antibodies that are specific for different analytes. Up to 12 spatially resolved microspots can be printed in each well.
- Samples 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.
- A mixture of biotinylated detection antibodies are added to the plate to form the antibody sandwich. Excess detection antibodies are removed by washing.
- 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.
- A high-sensitivity chemiluminescent substrate 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.
- 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.



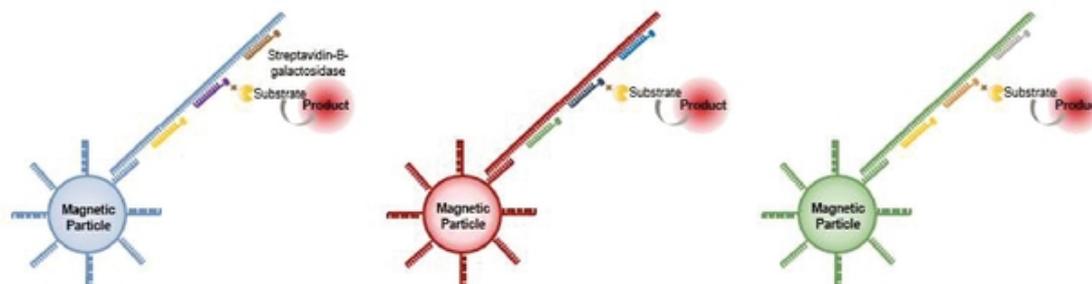
Nucleic Acid Testing

Our initial focus has been on the use of Simoa technology to detect protein biomarkers. However, we are also developing our Simoa bead-based technology 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

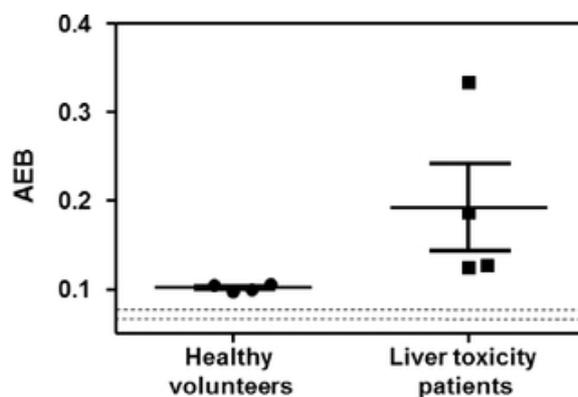
acid being measured. In nucleic acid analysis, we believe that Simoa has the potential to provide the same sensitivity as traditional PCR-based assays with the following benefits:

- 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.

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. This assay is pictured below:



Simoa has been used to detect short sequences of RNA, known as microRNA, that are important in a number of biological systems, and are widely used in innovative therapeutic and gene editing technologies. The assay was used to detect microRNA-122, or miR-122, a marker of liver toxicity, from the serum of patients who had overdosed with acetaminophen. As shown in the graph below, these patients had elevated miR-122 levels compared to healthy controls.



This approach suggests potential for applications for measuring drug-induced liver injury for both safety testing of drugs in development and for monitoring of approved drugs.

Our Market Opportunities

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

Life Science Research

Our initial target market is the large and growing life science research market. We believe our Simoa platforms are well-positioned to capture a significant share of this market 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.

As an indication of the market's acceptance of our Simoa technology, researchers at pharmaceutical and biotechnology companies are integrating our platforms into drug development protocols to more efficiently and effectively develop drugs. 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. We estimate that our Simoa technology has been utilized in over 800 clinical trials to date.

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, we believe that the total life science research market, including both proteomics and genomics research, is \$3 billion per year and has the potential to reach \$8 billion per year.

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.

For example, researchers have conducted studies using Simoa that indicate that neurological biomarkers, including tau and Nf-L, may someday be able to replace diagnostic imaging to diagnose traumatic brain injury, or TBI. Our Simoa assays for tau and Nf-L are 3,500-fold and 840-fold more sensitive, respectively, than the leading assay platforms, and are the only assays that can reliably detect these critical protein biomarkers in blood. Almost 90% of patients who visit U.S. hospital emergency rooms and receive a computerized tomography, or CT, scan show no structural brain injury. In addition, CT scans have approximately 100 times more radiation than a chest x-ray, and are suspected of causing cancer in up to 29,000 people per year, underscoring the need for development of a safe and accurate blood-based diagnostic test for TBI, which we believe may be enabled by our Simoa technology.

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 to study 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 can Simoa be used to develop companion diagnostics to stratify patients in clinical trials and for treatment, but Simoa's sensitivity also enables 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 can quickly and efficiently enable doctors to adjust the course of treatment as appropriate by increasing or decreasing dosages or even switching therapies.

There has been significant interest from third parties to use our technology to develop applications for the diagnostic market.

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 may 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.

According to estimates in the Third-Party Research Report, we believe that the total diagnostic and precision health screening markets addressable using Simoa technology have the potential to reach an aggregate of \$30 billion per year upon receipt of the necessary regulatory approvals, which we have not yet begun the process to obtain.

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 the following areas: neurology, oncology, cardiology, infectious disease and inflammation.

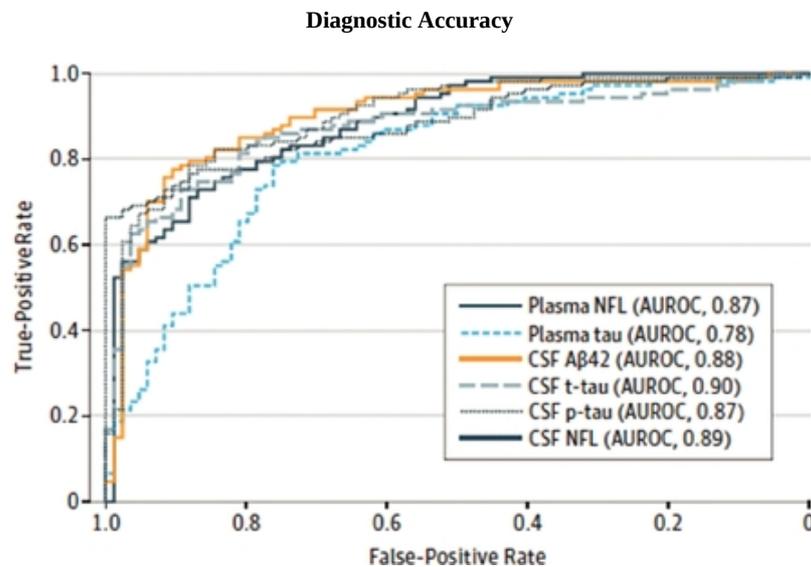
Neurology

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, or CSF, has the potential to rapidly advance neurology research and drug development, and transform the way brain injuries and diseases 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 these neural biomarkers in the blood are so low that they are undetectable by conventional, analog immunoassay technologies.

As one example, we have developed ultra-sensitive protein assays for the neural biomarkers Ab42 and tau that are approximately 2,000 and 3,500-fold more sensitive, respectively, than benchmark commercial assays. Our protein assays are the only currently available assays on the market capable of precise measurement of these neural biomarkers in blood in diseased and healthy individuals.

To date, there have been over 190 neurology related scientific publications using our Simoa technology, 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 CTE, Alzheimer's disease, dementia, Parkinson's disease, multiple sclerosis and TBI. The goal of this research is to eventually develop accurate diagnostic tools, predictive health screens and, ultimately, more effective treatments.

In 2017, researchers using Simoa technology published a paper in *JAMA Neurology* demonstrating that a simple blood test for the neurological biomarker 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.



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. Nf-L is becoming an increasingly important biomarker for neurology research, with over 90 Nf-L-related research publications in 2018 alone, covering a number of neurological disorders, including multiple sclerosis, Alzheimer's disease, ALS, Parkinson's disease and others.

Traumatic brain injuries, or 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 UCHL-1, 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, or 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 2017, we commercially launched a Simoa neurology 4-plex assay (Nf-L, tau, GFAP and UCH-L1) for the study of traumatic brain injury and other neurodegenerative conditions. Whereas other assay technologies require cerebrospinal fluid, or CSF, to detect all four of these markers, due to Simoa's sensitivity, this is the only assay that can detect all of these biomarkers directly from blood samples. This is a significant advantage in terms of ease of use, patient comfort, speed and cost-effectiveness.

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.

We estimate that the total addressable market for Simoa technology in neurology has the potential to reach \$6 billion across research, diagnostic and precision health screening indications.

Oncology

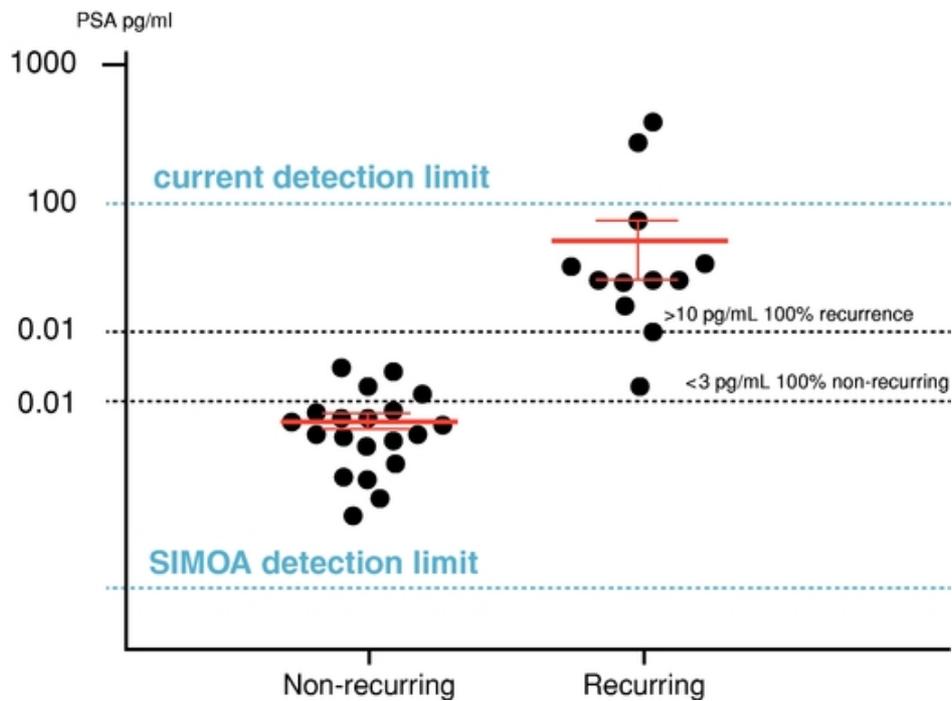
Our ultra-sensitive Simoa technology has the potential to detect increased levels of oncology biomarkers during the very early stages in disease development. Biomarkers can be useful tools for diagnostics, prognostics and predictive cancer detection. However, many traditional assay technologies can only 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 an alternative to more invasive diagnostic procedures.

Simoa technology was used in a recent 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, which is estimated to grow to almost \$3 billion by 2026.

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 38 ultra-sensitive immune modulation assays (cytokines and chemokines) that can be used to monitor the 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 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, or PSA, that is over 1,000-fold more sensitive than benchmark commercial PSA 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.



We estimate that the total addressable market for Simoa in oncology has the potential to reach \$25 billion across research, diagnostic and precision health screening indications.

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.

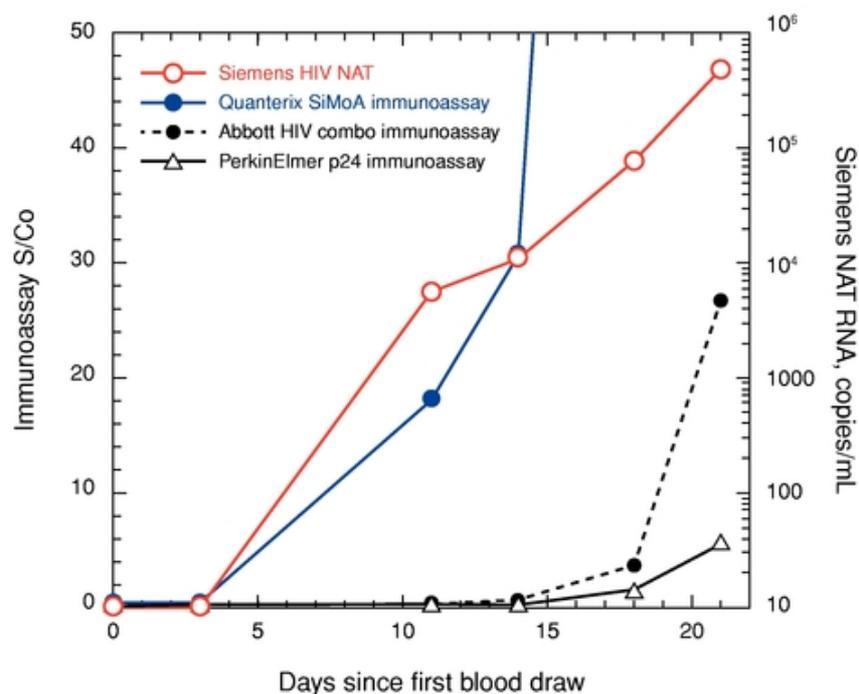
Infectious Disease

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 benchmark commercial protein 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.

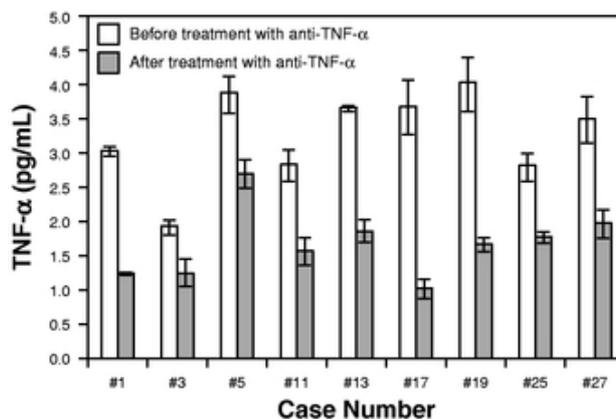
We will continue to develop Simoa assays for pathogenic antigens that are competitive in sensitivity to PCR but more specific to the pathogenicity of the offending organism. We believe that these Simoa assays could also be invaluable tools for the development of anti-infective drugs and treatment monitoring of anti-viral and anti-bacterial drugs.

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 limit of detection, or 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.

Our Products and Services

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

Product
HD-1/HD-X



Key attributes

- commercially launched the HD-1 in January 2014
- expect to commercially launch the next-generation HD-X in the second half of 2019
- 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 with small sample volume
- up to 400 samples per eight-hour shift
- homebrew capabilities
- HD-1 supports multiplexing up to 4-plex; HD-X will support up to 6-plex

Product
SR-X



SP-X



Assays and other consumables



Services



Key attributes

- commercial launch 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-1
- multiplexing capability: SR-X currently has up to 6-plex capability
- sample prep and assay protocol flexibility
- early access program in January 2019; commercial launch expected 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-1
- multiplexing capability: SP-X currently has up to 10-plex capability
- sample prep and assay protocol flexibility
- over 120 biomarker assays developed for neurology, oncology, cardiology, infectious diseases and immunology 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
- contract research services provided through our Accelerator Laboratory
- over 500 projects completed to date
- extended warranty and service contracts
- CLIA-certified lab available

Instruments and Consumables

HD-1/HD-X

We commercially launched the HD-1 instrument in January 2014. The HD-1 uses our Simoa bead-based technology and is the most sensitive automated multiplex protein detection platform commercially available. Assays for the HD-1 are fully automated (i.e. sample in to result out), and results for up to 66 samples are available in approximately one hour. We believe that this automation

provides us an additional significant competitive advantage with pharmaceutical and biotechnology customers. 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-1 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.

We continually seek to improve our platforms and technology and to that end, we expect to commercially launch our next-generation fully automated, bead-based Simoa instrument, the HD-X, in the second half of 2019. The HD-X will increase the multiplexing capability from 4-plex (current HD-1 limit) to six-plex and will include software features to facilitate compliance with 21 CFR part 11 procedures.

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-1 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-1, 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 initiated an early-access program for the SP-X instrument in January 2019, with the full commercial launch planned for April 2019. The SP-X uses the Simoa planar array technology developed initially by Aushon Biosystems 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.

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 50 biomarkers ranging from 1-10 analytes per assay in the areas of immunology and oncology research.

In addition to these assays we have developed, the Simoa platform allows ease and flexibility in assay design, enabling our customers to develop their own proprietary in-house assays, called homebrew assays, using our bead-based Homebrew Assay Development Kit. 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. Our consumables portfolio for our planar array platform also includes assay-specific reagent kits as well as the Simoa Planar Array Homebrew Starter Kit which enables our customers to run tests using their own antibodies and reagents in a similar manner to the bead-based homebrew kits.

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.

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 500 projects for over 179 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 more than 45 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 have implemented a research and development program that aims to increase the sensitivity of our Simoa technology 100-fold by 2021. 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 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 such as Australia, Brazil, Czech Republic, China, India, Israel, Japan, Mexico, South Korea, Lebanon, Qatar, Singapore and Taiwan. 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 March 1, 2019, we had approximately 78 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 technology, demonstrate its benefits relative to existing technologies and accelerate its 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.

To develop a thought leadership position in the precision health arena, we have been a Platinum Sponsor of the annual Powering Precision Health Summit, or PPHS. PPHS is an annual summit founded in 2016 by our President and Chief Executive Officer, Kevin Hrusovsky, that aims to gather many of the world's top innovators, scientists, physicians, medical professionals, patient advocates, government officials, regulators and investors to debate and collaborate around crucial issues from neurology, oncology and cardiology to inflammation and infectious disease. At PPHS in 2016, there were 22 cutting edge scientific talks covering neurology, cardiology, oncology and inflammation. There were over 200 registered attendees, including senior scientists, patient advocates, investors, and potential partners. At PPHS in 2017, there were 37 scientific talks and over 425 registered attendees and at PPHS Europe in 2018, there were 20 scientific talks and over 150 registered attendees.

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-1 and HD-X instruments are manufactured by STRATEC Biomedical AG, 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 this agreement. HD-1 instruments are shipped by STRATEC to our global customers' locations. Installation of, and training on, our products is provided by our employees in the markets where we conduct direct sales, and by distributors in those markets where we operate with distributors. The SR-X is manufactured by Paramit Corporation, based in Morgan Hill, California, and is shipped to global customers by Paramit.

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-1, the HD-X or the SR-X, we would experience additional costs, delays and difficulties in doing so, and our business would 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. To mitigate this risk, we typically carry significant inventory of critical components.

Consumables

We assemble our assay kits for our bead-based platform in our Lexington, 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.

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 assay 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.

Key Agreements

Development Agreement and Supply Agreement with STRATEC

In August 2011, we entered into a Strategic Development Services and Equity Participation Agreement, or the Development Agreement, with STRATEC Biomedical Systems AG, pursuant to which STRATEC undertook the development of the Simoa HD-1 instrument. Under the 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 Development Agreement was amended in November 2016. The Amendment reduced our obligation to satisfy a minimum purchase commitment under the Supply and Manufacturing 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 Development Agreement. The services are expected to be completed in the second half of 2019.

The 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, or the Supply Agreement, pursuant to which STRATEC agreed to supply HD-1 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 Supply Agreement was amended in November 2016 to reduce the number of instruments we are committed to procure from STRATEC. The instrument price stipulated in the Supply Agreement was established based on certain specified assumptions and is subject to certain adjustments.

The Supply Agreement is terminable by either party on 12 months' notice to the other party, provided that neither party may terminate the 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 committed to procure. The 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, or the Paramit Agreement, with Paramit Corporation, or 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 nine months' written notice to the other party given at least nine months prior to the end of the then-current term. The agreement may also be terminated by us with three months' notice to Paramit upon the occurrence of (i) a failure of Paramit to obtain any necessary governmental licenses, registrations or approvals required to manufacture our instrument or (ii) an assignment by Paramit of its rights or obligations under the agreement without our consent. The Paramit Agreement is terminable by Paramit with 30 days' notice to us in the event of a material breach after written notice and a 60-day opportunity to cure the breach.

Competition

We compete with both established and development-stage life science companies that design, manufacture and market instruments for protein detection, nucleic acid detection and additional applications. For example, companies such as Bio-Techne, Luminex Corporation, MesoScale Diagnostics, Singulex, Gyros Corporation, Nanostring Technologies, Inc., and others, have products for protein detection that compete in certain segments of the market in which we sell our products. 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 industry is 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, 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. We believe our proprietary platforms are a core strength of our business and our strategy includes the continued development of our patent portfolio.

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

Simoa and Related Technology

As of March 1, 2019, we had exclusively licensed 17 patents and two patent applications from Tufts. These patents and patent applications include eight issued U.S. patents and two pending U.S. patent applications, three granted European patents, three granted Japanese patents, two granted Canadian patents and one granted Australian patent.

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

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

A third patent family licensed from Tufts is directed to methods for analyzing analytes using a sensor system with cross-reactive elements. This patent family includes one granted U.S. patent. The standard patent expiration date for the U.S. patent in this family is March 14, 2021.

A fourth 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.

As of March 1, 2019, we owned 19 issued U.S. patents and 16 pending U.S. patent applications, three pending Patent Cooperation Treaty applications, eight granted European patents and six pending European patent applications, eight granted Japanese patents and one pending Japanese patent applications, four granted Chinese patents and two pending Chinese patent applications, five granted Canadian patents and two pending Canadian patent applications, and four registered Hong Kong patent applications.

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 three granted U.S. patents and one pending U.S. patent application, two granted European patent (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 four 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 one granted U.S. patent and one pending U.S. patent application, one granted Japanese patent and one pending Japanese patent application, one granted Chinese patent and two pending Chinese patent applications, three registered Hong Kong patent applications 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 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 2038.

We own or co-own seven patent families directed to the measurement of particular types of analytes, including prostate specific antigen (PSA), b-amyloid peptide, tau protein, toxin B of *C. difficile*, and DNA or RNA molecules. Any patents that may issue from these patent applications would have standard expiration dates between 2032 and 2039.

With the acquisition of Aushon in January 2017, we acquired their patent portfolio for our planar array technology. As of March 1, 2019, the acquired patent portfolio includes at least eight issued U.S. patents and five pending U.S. patent applications, one granted Australian patent, three granted Canadian patents and one pending Canadian patent application, five granted European patents (each nationalized and active in between eight and 14 countries) and three pending European patent applications, three granted Japanese patents, one registered Hong Kong patent application and one pending Patent Cooperation Treaty patent application.

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 and August 2017, we entered into a license agreement with Tufts University, or 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. 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

Our products are currently intended for research use only, or RUO, applications, although our customers may use our products to develop their own products that are subject to regulation by the FDA. Although most products intended for RUO are not currently subject to clearance or approval by the FDA, RUO products fall under the FDA's jurisdiction if they are used for clinical rather than research purposes. Consequently, our products 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," or the RUO/IUO Guidance. The purpose of an FDA guidance document is to provide the FDA's current thinking on when IVD products are properly labeled for RUO or for 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, or 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, or 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, or 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, or 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, or 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, or 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.

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, or 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, or 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.

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 manufacture's 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 manufacture's 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 Biosystems, Inc. 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 Laboratory Developed Tests, or 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, or 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, or EU, recently published new regulations that will result in greater regulation of medical devices and IVDs. The IVD Regulation is significantly different from the IVD Directive that it replaces in that it 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 conformity assessment process results in the receipt of a CE designation which has been sufficient to begin marketing many types of IVDs. That process will become more difficult and costly to complete.

Other Governmental Regulation

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, or 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

As of December 31, 2018, we had 177 employees, of which 78 work in sales, sales support, field service, and marketing, 38 work in engineering and research and development, 36 work in manufacturing and operations and 25 work in general and administrative. As of December 31, 2018, of our 177 employees, 160 were located in the United States and 17 were employed outside the United States. None of our employees is represented by a labor union or is subject to a collective bargaining agreement.

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 113 Hartwell Avenue, Lexington, Massachusetts 02421, and our telephone number is (617) 301-9400. We expect to relocate our principal executive offices in the second quarter of 2019 to 900 Middlesex Turnpike, Billerica, Massachusetts 01821.

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, or the 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 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.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred 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 \$31.5 million, \$27.0 million and \$23.2 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of \$175.9 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 invest significant additional funds toward expansion of our commercial organization and the development of our technology and related assays. In addition, as a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. These increased expenses will 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, 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 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.

Our operating results have varied in the past. In addition to other risk factors listed in this section, some of the important factors that may cause fluctuations in our quarterly and annual operating results include:

- adoption of our Simoa technology platforms and products by customers;
- the timing of customer orders to purchase our Simoa instruments;
- the rate of utilization of consumables by our customers;
- receipt and timing of revenue for services provided in our Simoa Accelerator Laboratory;
- the timing of the introduction of new products, product enhancements and services; and
- the receipt and timing of revenue from collaborations.

In addition, a significant portion of our operating expenses is relatively fixed in nature, and planned expenditures are based in part on expectations regarding future revenue. Accordingly, unexpected revenue shortfalls might decrease our gross margins and could cause significant changes in our operating results from quarter to quarter. If this occurs, the trading price of our common stock could fall substantially.

We are an early, commercial-stage company and have a limited commercial history, which may make it difficult to evaluate our current business and predict our future performance.

We are an early, commercial-stage company and have a limited commercial history. Our revenues are derived from sales of our instruments, consumables and services, which are all based on our Simoa technology. We commercially launched our first Simoa instrument and consumables in 2014. Our limited commercial history may make it difficult to evaluate our current business and make predictions about our future success or viability subject to significant uncertainty. We will continue to encounter risks and difficulties frequently experienced by early, commercial-stage companies, including scaling up our infrastructure and headcount. If we do not address these risks successfully, our business will suffer.

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 additional products are commercialized, 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, 2018, together with our cash generated from commercial sales, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. However, we may need to raise substantial additional capital to:

- 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 United States Food and Drug Administration, or FDA, to be medical devices or otherwise subject to additional regulation by the FDA;
- seek premarket approval, or 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 (see "Risk Factors—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." and "Business—Government Regulation" for further information about the FDA approvals that we may be required to seek and obtain in that circumstance);
- build out our new facility as we continue to grow our employee headcount;
- hire additional personnel;
- enter into collaboration arrangements, if any, or in-license other products and technologies;
- add operational, financial and management information systems; and
- incur increased costs as a result of operating as a public company.

Our future funding requirements will depend on many factors, including:

- market acceptance of our products, including our SP-X instrument;
- 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, 2018, we had federal net operating loss carry forwards, or NOLs, to offset future taxable income of approximately \$136.8 million, which begin to expire in 2026, if not utilized. 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, or 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 one or more 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.

Provisions of our secured term loan facility with Hercules Capital, Inc. may restrict our ability to pursue our business strategies. In addition, repayment of our outstanding debt and other obligations under our secured term loan facility with Hercules is subject to acceleration upon the occurrence of an event of default, which would have a material adverse effect on our business, financial condition and results of operations.

Our secured term loan facility with Hercules Capital, Inc., or Hercules, requires us, and any debt instruments we may enter into in the future may require us, to comply with various covenants that limit our ability to take on new indebtedness, to permit new liens, to pay dividends, to dispose of our property (including to license in certain situations), to engage in mergers or acquisitions and make certain other changes in our business. Debt instruments we may enter into in the future may also include financial covenants such as a requirement to maintain a specified minimum liquidity level or achieve a minimum annual revenue level. These restrictions could inhibit our ability to pursue our business strategies, including our ability to raise additional capital and make certain dispositions or investments without the consent of our lenders.

The obligations under our secured term loan facility with Hercules are subject to acceleration upon the occurrence of specified events of default, including our failure to make payments when due, our breach or default in the performance of our covenants and obligations under the facility following a cure period, bankruptcy and similar events, and the occurrence of a circumstance that would reasonably be expected to have a material adverse effect on (i) our business, operations, properties, assets or financial condition, (ii) our ability to perform our obligations in accordance with the facility documents, (iii) the lender's ability to enforce any of its rights or remedies with respect to our obligations, or (iv) the collateral, the liens on the collateral or the first priority of the lender's liens. While we do not believe it is probable that the lender would accelerate the obligations under the facility, the definition of a material adverse effect is inherently subjective in nature, and we cannot assure that a material adverse effect will not occur or be deemed to have occurred by the lender.

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 as reliable, enabling and cost-effective. Most of the potential customers for our products already use expensive research systems in their laboratories that they have used for many years and may be reluctant to replace those systems with ours. Market acceptance of our Simoa technology will depend on many factors, including our ability to convince potential customers that our technology is an attractive alternative to other available technologies. Compared to some competing technologies, our Simoa technology is new and complex, and many potential customers have limited knowledge of, or experience with, our products. Prior to adopting our systems, some potential customers may need to devote time and effort to testing and validating our systems. Any failure of our systems to meet these customer benchmarks could result in potential customers choosing to retain their existing systems or to purchase systems other than ours. In addition, it is important that our Simoa technology be perceived as accurate and reliable by the scientific and medical research community as a whole. 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. 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 current customer base is primarily composed of academic and governmental research institutions, as well as biopharmaceutical and contract research companies. Our success will depend upon our ability to respond to the evolving needs of, and increase our market share among, existing customers and additional potential customers, marketing new products as we develop them. Identifying, engaging and marketing to customers who are unfamiliar with our current products 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;
- 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 execute successful commercial activities.

We have utilized third parties to assist with sales, distribution and customer support in certain regions of the world. There is no guarantee, when we enter into such arrangements, 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 have become increasingly important to our business, and any significant decrease in sales of that assay could have a material adverse effect on our business.

Neurology has been a primary focus area 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. We estimate that revenue from services and sales of consumables relating to Nf-L represented approximately 17% of our total revenue for the fiscal year ended December 31, 2018. There can be no assurance that we will continue to derive meaningful revenues from the sale of our Nf-L assay, from services related to that assay or from sales of instruments driven by customers desiring access to the Nf-L assay. Further, we rely on a single source supplier for the antibodies used in our Nf-L assay. Although we have a supply agreement with this supplier, any disruption in the supply of this antibody, or 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.

Some of the reagents used in our products are labeled for "research use only" and will have to undergo additional testing before we could use them in a product intended for clinical use.

Some of the materials that are used in our consumable products, including certain reagents, are purchased from suppliers with a restriction that they be used for research use only, or RUO. While we have focused initially on the life sciences research market, part of our business strategy is to expand our product line, either alone or in collaboration with third parties, to encompass systems and products that can be used for clinical purposes. Whether or not we continue to use the same RUO materials that we currently use, or obtain similar materials that are not labeled with the RUO restriction, we or a collaborator will be required to demonstrate that the use of our system and products as a clinical test complies with all applicable requirements. In addition, if the supplier of any material or component used in a clinical test were changed, it would require confirmation through additional testing that the change does not adversely affect the reliability of the test. Any such additional testing may be expensive and time-consuming and delay the introduction of new products based on our technology.

In the near term, our business will depend on levels of research and development spending by academic and governmental research institutions and biopharmaceutical companies, a reduction in which could limit demand for our products and adversely affect our business and operating results.

In the near term, we expect that our revenue will be derived primarily from sales of our instruments and consumables to academic and governmental research institutions, as well as biopharmaceutical and contract research companies worldwide for research applications. The demand for our products will depend in part upon the research and development budgets of these customers, which are impacted by factors beyond our control, such as:

- changes in government programs that provide funding to research institutions and companies;
- macroeconomic conditions and the political climate;
- changes in the regulatory environment;
- differences in budgetary cycles; and
- market acceptance of relatively new technologies, such as ours.

For example, in March 2017, the federal government announced the intent to cut federal biomedical research funding by as much as 18%. The uncertainty regarding the availability of research funding for potential customers may adversely affect our operating results. Our operating results may fluctuate substantially due to reductions and delays in research and development expenditures by these customers. Any decrease in customers' budgets or expenditures, or in the size, scope or frequency of capital or operating expenditures, could materially and adversely affect our business, operating results and financial condition.

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 to in the future 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, use existing assays not requiring capital equipment or purchase systems other than ours.

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

Our business is dependent on the continued improvement of our existing Simoa products and our development of new products utilizing our 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. For example, introduction of the SP-X and the anticipated introduction of the HD-X may result in a decrease in revenue from our SR-X and HD-1 instruments. Consistent with our strategy of offering new products and product refinements, we expect to continue to use a substantial amount of capital for product development and refinement. We may need more capital for product development and

refinement than is available on terms favorable to us, if at all, which could adversely affect our business, financial condition or results of operations.

We generally sell our products in industries that are characterized by rapid technological changes, frequent new product introductions and changing industry standards. 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. Our success will depend on several factors, including our ability to:

- correctly identify customer needs and preferences and predict future needs and preferences;
- allocate our research and development funding to products with higher growth prospects;
- anticipate and respond to our competitors' development of new products and technological innovations;
- innovate and develop new technologies and applications, and acquire or obtain rights to third-party technologies that may have valuable applications in the markets we serve;
- successfully commercialize new technologies in a timely manner, price them competitively and manufacture and deliver sufficient volumes of new products of appropriate quality on time; and
- convince customers to adopt new technologies.

In addition, if we fail to accurately predict future customer needs and preferences or fail to produce viable technologies, we may invest heavily in research and development of products that do not lead to significant revenue. Even if we successfully innovate and develop new products and product enhancements, we may incur substantial costs in doing so, and our profitability may suffer.

Our ability to develop new products based on innovation can affect our competitive position and often requires the investment of significant resources. Difficulties or delays in research, development or production of new products and services or failure to gain market acceptance of new products and technologies may reduce future revenues and adversely affect our competitive position.

If we do not successfully develop and introduce new assays for our technology, we may not generate new sources of revenue and may not be able to successfully implement our growth strategy.

Our business strategy includes the development of new assays for our Simoa instruments. New assays require significant research and development and a commitment of significant resources prior to their commercialization. Our technology is complex, and we cannot be sure that any assays we may intend to develop will be developed successfully, be proven to be effective, offer improvements over currently available tests, meet applicable standards, be produced in commercial quantities at acceptable costs or be successfully marketed. Moreover, development of particular assays may require licenses or access to third-party intellectual property which may not be available on commercially reasonable terms, or at all. In addition, we believe that our future success will depend, in part, on our ability to develop and commercialize multiplex assays that can simultaneously measure multiple biomarkers, particularly for oncology indications. While we have developed and validated a 10-plex assay for the SP-X using our Simoa planar array technology, the most robust multiplex assay that we have commercially launched to date using our Simoa bead-based technology is a 4-plex assay. If we do not successfully develop new assays for our Simoa instruments, including multiplex assays with the ability to detect an increased number of biomarkers in a single sample, we could lose revenue opportunities with existing or future customers.

If we do not successfully manage the development and launch of new products, our financial results could be adversely affected.

We initiated an early-access program for the SP-X instrument in January 2019, with the full commercial launch planned for April 2019, and intend to launch the HD-X, our next generation bead-based instrument, in the second half of 2019. We face risks associated with launching new products such as the SP-X and HD-X. If we encounter development or manufacturing challenges or discover errors during our product development cycle, the product launch dates of new products may be delayed. The expenses or losses associated with unsuccessful product development or launch activities or lack of market acceptance of our new products could adversely affect our business or financial condition.

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 investors 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 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 strategic collaborations and licensing agreements with third parties to develop products based on our Simoa technology, such as for certain in vitro diagnostic, or IVD, purposes. However, there is no assurance that we will be successful in doing so. Establishing collaborations and licensing arrangements is difficult and time-consuming, and discussions may not lead to collaborations or licenses on favorable terms, if at all. Even if we establish such relationships, if our partners do not prioritize and commit sufficient resources to develop and sell products based on our Simoa technology, 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 Australia, Brazil, Czech Republic, China, India, Israel, Japan, Mexico,

South Korea, Lebanon, Qatar, Singapore and Taiwan, as well as other foreign countries. 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, 2018, 2017 and 2016, approximately 43%, 45% and 36%, respectively, of our product revenue was generated from customers located outside of North America. We believe that a substantial percentage of our future revenue will 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 foreign regulatory requirements and laws;
- difficulties and costs of staffing and managing foreign operations;
- difficulties protecting or procuring intellectual property rights;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act, data privacy requirements, labor laws and anti-competition regulations;
- export or import restrictions;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability; 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, or 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.

If we are unable to attract, recruit, train, retain, motivate and integrate key personnel, we may not achieve our goals.

Our future success depends on our ability to attract, recruit, train, retain, motivate and integrate key personnel, including our recently expanded senior management team, as well as our research and development, manufacturing and sales and marketing personnel. Competition for qualified personnel is intense. Our growth depends, in particular, on attracting and retaining highly-trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level to effectively identify and sell to potential new customers. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, recruit, train, retain, motivate and integrate qualified personnel could materially harm our operating results and growth prospects.

We have limited experience in marketing and selling our products, and if we are unable to successfully commercialize our products, our business and operating results will be adversely affected.

We have limited experience marketing and selling our products. We currently sell all our products for research use only, through our 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, Czech Republic, China, India, Israel, Japan, Mexico, South Korea, Lebanon, Qatar, Singapore and Taiwan.

The future sales of our products will depend in large part on our ability to effectively market and sell our products, successfully manage and expand our sales force, and increase the scope of our marketing efforts. We may also enter into additional distribution arrangements in the future. Because we have limited experience in marketing and selling our products, our ability to forecast demand, the infrastructure required to support such demand and the sales cycle to customers is unproven. If we do not build an efficient and effective sales force, our business and operating results will be adversely affected.

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 or not perform satisfactorily, our ability to supply these instruments would be negatively and adversely affected.

We currently rely on a single contract manufacturer, STRATEC Biomedical AG, or STRATEC, an analytical and diagnostic systems manufacturer located in Germany, to manufacture and supply all of our Simoa HD1 instruments and will continue to rely on STRATEC when we launch the HD-X. In addition, we currently rely on a single contract manufacturer, Paramit Corporation, or 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.

Pursuant to our Supply Agreement with STRATEC, as amended, we are required to purchase a minimum number of commercial units of HD instruments over a seven-year period ending in May 2021. If we fail to purchase the required minimum number of commercial units, including as a result of the impact of sales of the SR-X and SP-X going forward, we would be obligated to pay a fee based on the shortfall of commercial units purchased compared to the required number. If we fail to purchase the required minimum number of commercial instruments and terminate the arrangement in certain circumstances, we would be obligated to issue a warrant to purchase shares of our common stock. Any amount we may have to pay STRATEC for failing to purchase the minimum number of commercial units of HD instruments will cause our operating results to suffer.

In the event it becomes necessary to utilize a different contract manufacturer for the HD instruments 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 from limited or sole suppliers. If we were to lose such suppliers, there can be no assurance that we will 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 we encounter delays or difficulties in securing these components, or if the quality of the components supplied do not meet specifications, or if we cannot then obtain an acceptable substitute. If any of these events occur, our business and operating results could be harmed.

We may experience manufacturing problems or delays that could limit the growth of our revenue or increase our losses.

We may encounter unforeseen situations that would result in delays or shortfalls in our production as well as delays or shortfalls caused by our outsourced manufacturing suppliers and by other third-party suppliers who manufacture components for our products. 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.

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 the 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 the SP-X instrument. While we periodically forecast our needs for such materials and enter into standard purchase orders with them, we do not have long-term contracts with many of these suppliers. If we were to lose such suppliers, there can be no assurance that we will 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 operations could occur if we encounter delays or difficulties in securing these materials, or 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.

If we cannot provide quality technical and applications support, we could lose customers and our business and prospects will suffer.

The placement of our products at new customer sites, the introduction of our technology into our customers' existing laboratory workflows and ongoing customer support can be complex. Accordingly, we need highly trained technical support personnel. Hiring technical support personnel is very competitive in our industry due to the limited number of people available with the necessary scientific and technical backgrounds and ability to understand our Simoa technology at a technical level. To effectively support potential new customers and the expanding needs of current customers, we will need to substantially expand our technical support staff. If we are unable to attract, train or retain the number of highly qualified technical services personnel that our business needs, our business and prospects will suffer.

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. We believe our principal competitors in the life sciences research and diagnostic markets include Bio-Techne, Luminex Corporation, MesoScale Diagnostics, Singulex, Gyros Corporation and Nanostring Technologies, Inc. As we expand the applications for our products to include health screening, we expect to compete with companies such as Siemens, Abbott, Roche, Ortho Clinical Diagnostics and Thermo Fisher Scientific. In addition, there are a number of new market entrants in the process of developing novel technologies for the life sciences research, diagnostic and screening markets.

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 believe that the principal competitive factors in all of our target markets include:

- accuracy, including sensitivity and specificity, and reproducibility of results;
- cost of instruments and consumables;
- reputation among customers;
- innovation in product offerings;
- flexibility and ease of use; and
- compatibility with existing laboratory processes, tools and methods.

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 January 2018 acquisition of Aushon Biosystems, Inc. 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 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, our products are labeled as "Research Use Only," or RUO, and are not intended for diagnostic uses. While we have focused initially on the life sciences research market and RUO products only, our strategy is to expand 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 as medical devices, or comparable international agencies, 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 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 premarket approval application, or 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 would rely significantly on our foreign independent distributors 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.

IVD products are regulated as medical devices by the FDA and comparable international agencies and may require either clearance from the FDA following the 510(k) pre-market notification process or PMA from the FDA, in each case prior to marketing. 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, or 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 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.

Laboratory developed tests, or LDTs, are a subset of IVD tests that are designed, manufactured and offered as services to 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.

Failure to comply with applicable FDA requirements could subject us to misbranding or adulteration allegations under the Federal Food, Drug, and Cosmetic Act. We could be subject to a range of enforcement actions, including warning letters, injunctions, civil monetary penalties, criminal prosecution, and recall and/or seizure of products, as well as significant adverse publicity. In addition, changes to the current regulatory framework, including the imposition of additional or new regulations, could arise at any time during the development or marketing of our products, which may negatively affect our ability to obtain or maintain FDA or comparable regulatory approval of our products, if required.

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.

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. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. 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 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, on May 25, 2017, the new Medical Devices Regulation (2017/745 or "MDR") entered into force. Following its entry into application on May 26, 2020, the MDR will introduce substantial changes to the obligations with which medical device manufacturers must comply in the EU. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure. Specifically, the EU Medical Devices Regulation repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the European Economic Area ("EEA") Member States, the regulations would be directly applicable, i.e., without the

need for adoption of EEA member state laws implementing them, in all EEA Member States and are intended to eliminate current differences in regulation of medical devices among EEA Member States. The EU MDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices to ensure a high level of safety and health while supporting innovation. The MDR will however only become applicable in three years after publication (in May 2020). Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices which may have to undergo an additional check by experts before they are placed on the market.

Once applicable, the MDR may impose increased compliance obligations for us to access the EU market.

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 MDR. 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, or 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 intend to obtain other state licenses as may be 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 or our customers 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, or 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 President Trump have 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.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent our products from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for regulatory submissions to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our 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, 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, 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.

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, the European Parliament and the Council of the European Union adopted a comprehensive general data privacy regulation, or 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, will impose 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. As of March 1, 2019, we owned or exclusively licensed 27 granted U.S. patents and approximately 18 pending U.S. patent applications. We also owned or exclusively licensed a number of pending patent applications and granted patents in particular jurisdictions outside of the United States. 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. For example:

- We or our licensors might not have been the first to make the inventions covered by each of our pending patent applications or granted patents;
- We or our licensors might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings or derivation proceedings declared by the United States Patent and Trademark Office, or USPTO, that could result in substantial cost to us. No assurance can be given that our patent applications or granted patents (or those of our licensors) will have priority over any other patent or patent application involved in such a proceeding;
- Others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies;
- It is possible that our owned or licensed pending patent applications will not result in granted patents, and even if such pending patent applications grant as patents, they may not provide a basis for intellectual property protection of commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties;
- We may not develop additional proprietary products and technologies that are patentable;
- The patents of others may have an adverse effect on our business; and
- While we apply for patents covering our products and technologies and uses thereof, as we deem appropriate, we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions.

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 of our competitors' products, our competitive position could be adversely affected, as could our business.

Software is a critical component of our instruments. To the extent such software is not protected by our patents, we depend on trade secret protection and non-disclosure agreements with our employees, strategic partners and consultants, which may not provide adequate protection.

The measures that we use to protect the security of our intellectual property and other proprietary rights may not be adequate, which could result in the loss of legal protection for, and thereby diminish the value of, such intellectual property and other rights.

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 the United States may be less willing to protect trade secrets.

In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property does not adequately protect our market share against competitors' products and methods, our competitive position could be adversely affected, as could our business.

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, all 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, or 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 U.S. 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 U.S. 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.

We depend on technology that 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 our Simoa products 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, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

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, such as the types of disputes described above. 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.

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 of our licensors. 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, being found to be unenforceable or being interpreted narrowly and 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.

Most 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 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 be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their other clients or former employers to us, which could subject us to costly litigation.

As is common in the life sciences industry, we engage the services of consultants and independent contractors to assist us in the development of our products. Many of these consultants and independent contractors were previously employed at, or may have previously or may be currently providing consulting or other services to, universities or other technology, biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may become subject to claims that our company, a consultant or an independent contractor inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. We may similarly be subject to claims stemming from similar actions of an employee, such as one who was previously employed by another company, including a competitor or potential competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team. If we were not successful we could lose access or exclusive access to valuable intellectual property.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. For example, even if we have a consulting agreement in place with an academic advisor pursuant to which such academic advisor is required to assign any inventions developed in connection with providing services to us, such academic advisor may not have the right to assign such inventions to us, as it may conflict with his or her obligations to assign all such intellectual property to his or her employing institution.

In addition, we sometimes enter into agreements where we provide services to third parties, such as customers. Under such circumstances, our agreements may provide that certain intellectual property that we conceive in the course of providing those services is assigned to the customer. In those cases, we would not be able to use that particular intellectual property in, for example, our work for other customers without a license.

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 the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, 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 the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not 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 so 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, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license 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, or 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 going forward of the time from invention to 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 providing 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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. In some cases, our licensors may be responsible for, for example, these payments, thereby decreasing our control over compliance with these requirements.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition 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 may use third-party open source software components in future products, and failure to comply with the terms of the underlying open source software licenses could restrict our ability to sell such products.

While our current products do not contain any software tools licensed by third-party authors under "open source" licenses, we may choose to use open source software in future products. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code. Some open source licenses may contain requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source licenses, be required to release the source code of our proprietary software to the public. This would allow our competitors to create similar products with less development effort and time and ultimately could result in a loss of product sales.

Although we intend to monitor any use of open source software to avoid subjecting our products to conditions we do not intend, the terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that any such licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to commercialize our products. Moreover, we cannot assure investors that our processes for controlling our use of open source software in our products will be effective. If we are held to have breached the terms of an open source software license, we could be required to seek licenses from third parties to continue offering our products on terms that are not economically feasible, to re-engineer our products, to discontinue the sale of our products if re-engineering could not be accomplished on a timely basis, or to make generally available, in source code form, our proprietary code, any of which could adversely affect our business, operating results, and financial condition.

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.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents that have issued, or may issue, from our owned or in-licensed patent applications;
- we might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we might not have been the first to file patent applications covering an invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- pending patent applications that we own or license may not lead to issued patents;
- patents, if issued, that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we may not be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business 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 could be subject to wide fluctuations in response to many risk 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 provide to the public;
- issuance of new or updated research or reports by securities analysts or recommendations for our stock;
- 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 the 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 Factor 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.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of December 31, 2018, our executive officers, directors and 5% or greater stockholders owned approximately 56.9% of our outstanding common stock. Accordingly, our executive officers, directors and principal stockholders have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

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. In addition, the terms of our indebtedness with Hercules prohibit us from paying dividends. 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 are an "emerging growth company" and are able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, and we plan to avail ourselves of the ability to adopt new accounting standards on the timeline permitted for private companies, which could make our common stock less attractive to investors and our financial statements less comparable to other companies who are complying with new accounting standards on public company timelines.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, will comply with new or revised accounting standards not later than the relevant dates on which adoption of such standards is required for non-public companies. As a result of this election, the timeline to comply with certain accounting standards will in many cases be delayed as compared to other public companies who

are not eligible to have made or have not made this election. As a result, investors may view our financial statements as not comparable to other public companies. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.07 billion or more; (ii) December 31, 2022; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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, and these expenses may increase even more after we are no longer an "emerging growth 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. The increased 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, beginning with this annual report for the year ending December 31, 2018, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required 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 engaged in a process to document and evaluate our internal control over financial reporting, which was both costly and challenging. We will need to continue 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 30,655 square feet of office, laboratory, and manufacturing space at our headquarters in Lexington, Massachusetts, under a lease that was to expire on June 30, 2020 (the "Lexington Lease"). In addition, pursuant to our acquisition of Aushon Biosystems, Inc. on

January 30, 2018, we currently lease approximately 21,500 square feet of office, laboratory, and manufacturing space in Billerica, Massachusetts, under a lease that was to expire on February 28, 2021 (the "Billerica Lease").

In August 2018, we exercised an option to terminate the Billerica Lease effective as of September 1, 2019. In October 2018, we also notified the landlord of our intent to sublease all of the premises subject to the Lexington Lease from June 1, 2019 until the end of the lease term. The landlord has exercised its right to "recapture" the premises during that period, and, accordingly, the Lexington Lease will terminate as of May 31, 2019.

On October 2, 2018, we entered into a lease for approximately 91,600 square feet of office, laboratory, and manufacturing space in the building located at 900 Middlesex Turnpike, Billerica, Massachusetts. The premises covered by this new lease will serve as our new principal office and laboratory space beginning in the second quarter of 2019. The initial term of the lease is 11 years and five months beginning on April 1, 2019, and we have the option to extend the lease for two additional five-year periods. We believe that this office, laboratory and manufacturing space will be sufficient to meet our needs for the foreseeable future.

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 began trading on The Nasdaq Global Market on December 7, 2017 under the symbol "QTRX."

Stockholders

As of March 1, 2019, there were approximately 53 stockholders of record of the 22,461,202 outstanding shares of common stock.

Unregistered Sales of Securities

There were no unregistered sales of equity securities during the fourth quarter ended December 31, 2018.

Use of Proceeds from Initial Public Offering of Common Stock

On December 11, 2017, we completed the initial public offering of our common stock, which resulted in the sale of 4,916,480 shares, including 641,280 shares sold by us pursuant to the exercise in full by the underwriters of their option to purchase additional shares in connection with the initial public offering, at a price to the public of \$15.00 per share. The offer and sale of all of the shares in our initial public offering was registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-221475), which was declared effective by the SEC on December 6, 2017, and a registration statement on Form S-1 (File No. 333-221932) under Rule 462(b) of the Securities Act that became effective upon its filing. Following the sale of all of the shares in connection with the closing of our initial public offering, the offering terminated. J.P. Morgan Securities LLC, Leerink Partners LLC and Cowen and Company, LLC acted as joint book-running managers for the initial public offering. BTIG, LLC and Evercore Group L.L.C. acted as co-managers.

We received approximately \$65.6 million in net proceeds after deducting underwriting discounts and commissions and offering costs payable by us. As of December 31, 2018, we had used approximately \$21.1 million of the net proceeds from the offering for: operating expenses, capital investments, debt payments and the acquisition of Aushon. None of the offering expenses consisted of direct or indirect payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates, and we have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any such persons. There has been no material change in the planned use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC on December 7, 2017 pursuant to Rule 424(b)(4) under the Securities Act.

Issuer Purchases of Equity Securities

Not applicable.

Item 6. SELECTED FINANCIAL DATA

You should read the following selected financial data together with our consolidated financial statements and the related notes and the information under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K. We have derived the statement of operations data for the years ended December 31, 2018, 2017 and 2016 and the balance sheet data as of December 31, 2018 and 2017 from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Note that the results for the year ended December 31, 2018 include activity related to the acquisition of Aushon which occurred on January 30, 2018. The statement of operations data for the year ended December 31, 2015, and the selected balance sheet data as of December 31, 2016 and 2015 is derived from audited financial statements that are not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that should be expected in the future.

Consolidated statement of operations data (in thousands, except per share data)

	Year ended December 31,			
	2018	2017	2016	2015
Total revenue	\$ 37,632	\$ 22,874	\$ 17,585	\$ 12,180
Cost of revenue	19,684	12,887	9,837	6,465
Gross Profit	17,948	9,987	7,748	5,715
Research and development	15,805	16,304	16,993	10,083
Selling, general and administrative	33,693	19,688	12,466	10,155
Total operating expenses	49,498	35,992	29,459	20,238
Loss from operations	(31,550)	(26,005)	(21,711)	(14,523)
Interest income (expense), net	46	(951)	(1,298)	(1,040)
Other income (expense), net	(7)	(63)	(164)	(380)
Loss before income taxes	(31,511)	(27,019)	(23,173)	(15,943)
Income tax provision	(25)	—	—	—
Net loss	(31,536)	(27,019)	(23,173)	(15,943)
Accretion and accrued dividends on redeemable convertible preferred stock	—	(4,166)	(4,445)	(4,355)
Net loss attributable to common stockholders	\$ (31,536)	\$ (31,185)	\$ (27,618)	(20,298)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.43)	\$ (8.30)	\$ (12.89)	\$ (11.19)
Weighted-average common shares outstanding	21,994	3,757	2,143	1,813

Consolidated balance sheet data (in thousands)

	As of December 31,			
	2018	2017	2016	2015
Cash and cash equivalents	\$ 44,429	\$ 79,682	\$ 29,671	2,323
Total assets	67,611	91,779	37,117	7,351
Total long term debt	7,623	9,382	10,243	9,726
Total redeemable convertible preferred stock	—	—	128,585	73,445
Total Stockholders' equity (deficit)	41,065	65,866	(115,109)	(88,640)

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."

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 and have been discovered using technologies such as mass spectrometry. 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 are currently focusing on protein detection, which we believe is an area of significant unmet need and where we have significant competitive advantages. However, in addition to enabling new applications and insights in protein analysis, we are also developing our Simoa bead-based technology to detect nucleic acids in biological samples.

We currently sell all of our products for life science research, primarily to laboratories associated with academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies, 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, Czech Republic, China, India, Israel, Japan, Mexico, South Korea, Lebanon, Qatar, Singapore and Taiwan. We grew our revenue from \$22.9 million in 2017 to \$37.6 million in 2018.

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. We believe that our recurring consumable revenue is driven by our customers' ability to extract more valuable data using our platform and to process a large number of samples quickly with little hands-on preparation.

We commercially launched our HD-1 instrument 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 Analyzer in a compact benchtop form with a lower price point, more flexible assay preparation, and a wider range of applications. While we expect the SR-X to generate lower consumables revenue per instrument than the Simoa HD-1 Analyzer due to its lower throughput, 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.

On January 30, 2018, we acquired Aushon Biosystems, Inc. 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 planned for April 2019.

As of December 31, 2018, we had cash and cash equivalents of \$44.4 million. Since inception, we have incurred net losses. Our net loss was \$31.5 million, \$27.0 million, and \$23.2 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of \$175.9 million and stockholders' equity of \$41.1 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 United States Food and Drug Administration, or FDA, to be medical devices or otherwise subject to additional regulation by the FDA;
- seek premarket approval, or 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;
- build out our new facility as we continue to grow our employee headcount;
- hire additional personnel;
- enter into collaboration arrangements, if any, or in-license other products and technologies;
- add operational, financial and management information systems; and
- incur increased costs as a result of operating as a public company.

Financial Operations Overview

Revenue

We generate product revenue from sales of our HD-1, SR-X and SP-X instruments and related reagents and other consumables. We currently sell our products for research use only 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.

The following table presents our revenue for the periods indicated (in thousands):

	Year ended December 31,		
	2018	2017	2016
Product revenue	\$ 23,365	\$ 14,124	\$ 10,601
Service and other revenue	12,117	7,676	5,012
Collaboration and license revenue	2,150	1,074	1,972
Total revenue	\$ 37,632	\$ 22,874	\$ 17,585

The following table reflects product revenue (in thousands) by geography and as a percentage of total product revenue, based on the billing address of our customers. North America consists of the United States, Canada and Mexico; EMEA consists of Europe, the Middle East, and Africa; and Asia Pacific includes Japan, China, South Korea, Singapore, Malaysia and Australia.

	Year ended December 31,					
	2018		2017		2016	
North America	\$ 13,365	57%	\$ 7,790	55%	\$ 6,816	64%
EMEA	7,360	32%	4,435	31%	2,679	25%
Asia Pacific	2,640	11%	1,899	13%	1,106	10%
Total	\$ 23,365	100%	\$ 14,124	100%	\$ 10,601	100%

Our revenue is denominated primarily in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States. Changes in foreign currency exchange rates have not materially affected us to date; however, they may become material to us in the future as our operations outside of the United States expand.

Cost of Products, Services and Collaboration Revenue

Cost of goods sold for products consists of HD-1 and SR-X instrument cost from the manufacturer, SP-X cost based on the internal assembly of this item, raw material parts costs and associated freight, shipping and handling costs, contract manufacturer costs, salaries and other personnel costs, royalties, stock-based compensation, overhead and other direct costs related to those sales recognized as product revenue in the period.

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.

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 expenses as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission 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. 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 (1) persuasive evidence of an arrangement exists, (2) shipment and installation, if applicable, has occurred or services have been rendered, (3) the price to the customer is fixed or determinable and (4) collection of the related receivable is reasonably assured. We primarily generate revenue from the sale of products and delivery of services, as well as under license and collaboration agreements. Our product revenue includes the sale of instruments as well as assay kits and other consumables which are used to perform tests on the instrument. Our service revenue is generated from service contracts related to research services performed on behalf of customers and maintenance and support services.

Product Revenue

Revenue for instrument sales is recognized upon installation at the customer's location or upon transfer of title to the customer when installation is not required, which is generally the case with sales to distributors. In sales to end-customers, we always provide the installation service and often payment is tied to the completion of the installation service. When installation is required, we account for the instrument and installation service as one unit of accounting and recognize revenue when installation is completed, assuming all other revenue recognition criteria are met. Instrument transactions often have multiple elements, as discussed below. Included with the purchase of an instrument is a one-year assurance type product warranty assuring that the instrument is free of material defects and will function according to specifications. In addition, the sale of an instrument includes an implied warranty which is promised to the customer during the pre-sales process, at the time that the sales quote is issued to the customer. The implied warranty is provided over the same one-year period as the standard warranty. The services included in the implied warranty are the same as those included in the extended service contracts and include two bi-annual preventative maintenance service visits, minor hardware updates and software upgrades, additional training and troubleshooting, which is beyond the scope of the standard product warranty. The implied warranty has been identified by us as a separate deliverable and unit of accounting. Consideration allocated to the implied one-year warranty is recognized over the one year period of performance as service and other revenue as described below. Consideration allocated to any other elements is recognized as the goods are delivered or the services are performed.

Service and Other Revenue

Service revenue includes revenue from the implied one-year service type warranty obligation, revenue from extended service contracts, research services performed on behalf of customers in our Accelerator Laboratory, and other services that may be performed. Revenue for extended warranty contracts is recognized ratably over the service period. Revenue for the implied one-year service type warranty is initially deferred at the time of instrument revenue recognition and is recognized ratably over a 12-month period starting on the date of instrument installation. Revenue for research and development services and other services is generally recognized based on proportional performance of the contract when our ability to complete project requirements is reasonably assured. Most of these services are completed in a short period of time from the receipt of the customer's order. When significant risk exists in our ability to fulfill project requirements, revenue is recognized upon completion of the contract.

Collaboration and License Revenue

Collaboration and license revenue relates to our agreement with bioMérieux, which was terminated in September 2018, and an agreement with another diagnostic company. For a complete discussion of the accounting policies specific to these collaboration and license agreements, refer to "Collaborations and License Arrangements" (Note 11) in the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Multiple Element Arrangements

Many of our instrument sales involve the delivery of multiple products and services. The elements of an instrument sale typically include the instruments, installation (when required), an implied one-year service type warranty, and in some cases, assays, consumables and other services. Revenue recognition for contracts with multiple deliverables is based on the individual units of accounting determined to exist in the contract. A delivered item is considered a separate unit of accounting when the delivered item has value to the customer on a stand-alone basis. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have standalone

value. Items are considered to have stand-alone value when they are sold separately by any vendor or when the customer could resell the item on a stand-alone basis.

The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units. We determine the estimated selling price for deliverables within the arrangement using vendor-specific objective evidence (VSOE) of selling price, if available. If VSOE is not available, we consider whether third-party evidence is available. If third-party evidence of selling price or VSOE is not available, we use our best estimate of selling price for the deliverable.

In order to establish VSOE of selling price, we must regularly sell the product or service on a standalone basis with a substantial majority priced within a relatively narrow range. If there are not a sufficient number of standalone sales such that VSOE of selling price cannot be determined, then we consider whether third party evidence can be used to establish selling price. Due to the lack of similar products and services sold by other companies within the industry, we have not established selling price using third-party evidence.

For product and service sales, we determine our best estimate of selling price for instruments, consumables, services and assays using average selling prices over a rolling 12-month period coupled with an assessment of market conditions, as VSOE and third-party evidence cannot be established. We recognize revenue for delivered elements only when we determine there are no uncertainties regarding customer acceptance.

Distributor Transactions

In certain markets, we sell products and provide services to customers through distributors that specialize in life science products. In cases where the product is delivered to a distributor, revenue recognition generally occurs when title transfers to the distributor. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers, except the distributors do not require our services to install the instrument at the end customer and perform the services for the customer that are beyond our standard warranty in the first year following the sale. These transactions are accounted for in accordance with our revenue recognition policy described above.

Stock-Based Compensation

We account for stock-based compensation awards in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 718, *Compensation—Stock Compensation*, or 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 adoption of ASU 2016-09 on January 1, 2017, we recognized compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. Effective January 1, 2017, we ceased utilizing an estimated forfeiture rate and began recognizing forfeitures as they occur. We estimate 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.

We recognize compensation costs related to share-based payments granted to non-employees based on the estimated fair value of the awards on the date of grant in the same manner as options for employees; however, the fair value of the stock options granted to non-employees is re-measured each reporting period until the service is complete, and the resulting increase or decrease in value, if any, is

recognized as expense or income, respectively, during the period the related services are rendered to the same financial statement line item as any cash consideration would be recognized. There were no material non-employee awards outstanding during the years ended December 31, 2018, 2017, and 2016.

The fair value of stock options granted to employees and directors for their services on our board of directors 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,		
	2018	2017	2016
Risk-free interest rate	2.6% - 3.0%	1.8% - 2.1%	1.2% - 1.3%
Expected dividend yield	None	None	None
Expected term (in years)	5.9	6.0	6.0
Expected volatility	32.4% - 36.8%	46.0% - 52.0%	44.9% - 49.0%

Using the Black-Scholes option-pricing model, the weighted-average grant date fair value of options granted for the years ended December 31, 2018, 2017, and 2016 was \$7.19, \$4.52, and \$2.41 per share, respectively. Expected volatility was calculated based on reported volatility data for a representative group of guideline publicly traded companies for which historical information was available. 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 its 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.

For the years ended December 31, 2018, 2017, and 2016 stock-based compensation expense was \$4.9 million, \$2.2 million, and \$0.9 million respectively.

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

	Year ended December 31,		
	2018	2017	2016
Cost of product revenue	\$ 55	\$ 24	\$ 6
Cost of service and other revenue	173	52	12
Research and development	513	180	59
General and administrative	4,143	1,912	851
Total	\$ 4,884	\$ 2,168	\$ 928

As of December 31, 2018, we had \$11.7 million of total unrecognized stock-based compensation costs which we expect to recognize over a weighted-average period of 2.88 years.

Prior to our IPO, the fair value of our common stock underlying our stock options was estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying granted stock options, our board of directors considered, among other things, the most recent valuations of our common shares prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.

Given the absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including (1) our business, financial condition and results of operations, including related industry trends affecting our operations; (2) our forecasted operating performance and projected future cash flows discounted to present value using our estimated weighted average cost of capital; (3) the illiquid nature of our common stock; (4) liquidation preferences and other rights and privileges of our preferred stock over our common stock; (5) likeliness and estimated timing of the potential option to have our stock become publicly traded; (6) market multiples of our most comparable public peers; (7) recently completed equity financing transactions; and (8) market conditions affecting our industry.

Since the completion of our IPO, we have determined the fair value of each common share underlying share-based awards based on the closing price of our common shares as reported by Nasdaq on the date of grant.

Preferred Stock Warrant Liability

As of January 1, 2015, we had outstanding warrants to purchase 64,441 shares of Series A-2 redeemable convertible preferred stock, or Series A-2 Preferred Stock, 1,300,000 shares of Series A-3 convertible preferred stock, or Series A-3 Preferred Stock, 562,488 shares of Series B redeemable convertible preferred stock, or Series B Preferred Stock, and 226,733 shares of Series C redeemable convertible preferred stock, or Series C Preferred Stock. On March 4, 2015, we issued a warrant to purchase 46,248 shares of Series C Preferred Stock to a lender related to an amendment to a debt facility. The fair value of the warrant was initially accounted for as a debt discount. On January 29, 2016, we issued a warrant to purchase 57,810 shares of Series C Preferred Stock to a lender related to a second amendment to a debt facility. The fair value of the warrant was initially accounted for as a debt discount. On November 18, 2016, we issued a warrant to purchase 700,000 shares of Series A-3 Preferred Stock to a vendor. The fair value of the warrant was recorded as research and development expense. On March 31, 2017, we issued a warrant to purchase 38,828 shares of Series D redeemable convertible preferred stock (Series D Preferred Stock) to a lender as part of a third amendment to a debt facility. The fair value of the warrant was initially accounted for as a debt discount. All of the warrants were initially recorded at fair value and marked to market on each reporting and exercise date with changes in the fair value recorded in other expense (income) on the statement of operations and comprehensive loss. Holders of warrants to purchase shares of Series A-3 and B Preferred Stock exercised the warrants during the year ended December 31, 2016 and holders of warrants to purchase shares of Series A-3 Preferred Stock exercised the warrants during the three months ended March 31, 2017. Upon exercise, the fair value of the warrants was reclassified to redeemable convertible preferred stock along with any proceeds received. Upon the closing of the IPO, all warrants to purchase Preferred Stock automatically converted to warrants to purchase our common stock.

The changes in preferred stock warrant liability measured at fair value for which we have used Level 3 inputs to determine fair value are as follows (in thousands):

	Warrant liability
Balance at December 31, 2015	\$ 5,547
Issuance of warrants related to debt facility	128
Issuance of warrants related to a vendor	2,078
Changes in fair value of warrants	307
Warrant exercises	(5,258)
Balance at December 31, 2016	2,802
Issuance of warrants related to debt facility	119
Changes in fair value of warrants	90
Warrant exercises	(2,188)
Conversion to warrants in common stock in connection with IPO	(823)
Balance at December 31, 2017	\$ —

The warrants were classified as liabilities because they were exercisable into shares of redeemable convertible preferred stock. On each measurement date, we utilized a Monte Carlo option pricing model to determine the fair value of the warrants and utilized various valuation assumptions based on available market data and other relevant but observable factors. Expected volatility for our redeemable convertible preferred stock was determined based on an analysis of the historical volatility of a representative group of guideline public companies, because, prior to our IPO, there was no market for our common stock and, therefore, a lack of market-based company-specific historical and implied volatility information. The expected term reflects the remaining contractual term of the warrants. The assumed dividend yield is based upon our expectation of not paying dividends in the foreseeable future. The risk-free rate is based upon the U.S. Treasury yield curve in effect at the valuation date, commensurate with the remaining contractual life of the warrants. The fair value of the underlying preferred shares was determined by management, with the assistance of a third-party valuation specialist, using a hybrid valuation method, which includes a weighted analysis of two scenarios. The first scenario was based on the completion of an initial public offering utilizing a market approach and the second scenario was based on remaining privately held utilizing either an income approach or a weighted-average of an income approach and a backsolve to a recent financing event, depending on the proximity of the financing event to the measurement date. The assumption regarding our probability of completing an initial public offering was the primary contributing factor to the changes in fair value of the common stock. See "Significant Accounting Policies" (Note 2) in our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for further details on the changes of the probability of completing an initial public offering. Because all outstanding and exercisable warrants to purchase Preferred Stock were automatically converted to warrants to purchase shares of common stock following the IPO, they are accounted for as equity instruments as of December 31, 2018.

The following assumptions were utilized to determine the fair value of each warrant to purchase preferred stock at each reporting period and as of the change from liability to equity accounting treatment in connection with the IPO:

Balance sheet date	Value of underlying Series D preferred stock	Value of underlying Series C preferred stock	Value of underlying Series B preferred stock	Value of underlying Series A-3 preferred stock	Value of underlying Series A-2 preferred stock	Volatility	Probability of an initial public offering
December 7, 2017	\$4.67	\$ 4.67	N/A	N/A	\$ 4.67	46%	100%
December 31, 2016	N/A	\$ 4.16	N/A	\$ 2.97	\$ 2.95	52%	40%
December 31, 2015	N/A	\$ 3.92	\$3.00	\$ 3.00	\$ 1.90	41%	25%

Results of Operations

Comparison of the Years Ended December 31, 2018 and December 31, 2017 (dollars in thousands):

	Year ended December 31, 2018	% of revenue	Year ended December 31, 2017	% of revenue	\$ change	% change
Product revenue	\$ 23,365	62%	\$ 14,124	62%	\$ 9,241	65%
Service and other revenue	12,117	32%	7,676	34%	4,441	58%
Collaboration and license revenue	2,150	6%	1,074	5%	1,076	100%
Total revenue	37,632	100%	22,874	100%	14,758	65%
Costs of Goods Sold:						
Cost of product revenue	12,729	34%	7,742	34%	4,987	64%
Cost of services and other revenue	6,955	18%	5,145	22%	1,810	35%
Total Costs of Goods Sold and Services	19,684	52%	12,887	56%	6,797	53%
Gross Profit	17,948	48%	9,987	44%	7,961	80%
Operating Expense:						
Research and development	15,805	42%	16,304	71%	(499)	(3)%
Selling, general and administrative	33,693	90%	19,688	86%	14,005	71%
Total operating expenses	49,498	132%	35,992	157%	13,506	38%
Loss from operations	(31,550)	(84)%	(26,005)	(114)%	(5,545)	(21)%
Interest income (expense), net	46	0%	(951)	(4)%	997	(105)%
Other income (expense), net	(7)	(0)%	(63)	(0)%	56	89%
Loss before income taxes	(31,511)	(84)%	(27,019)	(118)%	(4,492)	(17)%
Income tax provision	(25)	(0)%	—	(0)%	(25)	100%
Net loss	\$ (31,536)	(84)%	\$ (27,019)	(118)%	\$ (4,517)	(17)%

Revenue

Revenue increased by \$14.8 million, or 65%, to \$37.6 million for the year ended December 31, 2018 as compared to \$22.9 million for the year ended December 31, 2017. Product revenue consisted of sales of instruments totaling \$9.6 million and sales of consumables and other products of \$13.8 million for the year ended December 31, 2018. Product revenue consisted of sales of instruments totaling \$6.5 million and sales of consumables and other products totaling \$7.6 million for the year ended December 31, 2017. Average sales prices of instruments and consumables did not change materially in the year ended December 31, 2018 as compared with the year ended December 31, 2017. The increase in product revenue of \$9.2 million was primarily due to the sale of more instruments in the 12 months ended December 31, 2018 and increased sales of consumables. The installed base of instruments

increased from December 31, 2017 to December 31, 2018, and as these additional instruments were used by customers, the consumable sales increased. The increase in service and other revenue of \$4.4 million was primarily due to increased services performed in our Accelerator Laboratory; more customers are using these services, and existing customers are using these services more frequently. In addition, an increase in purchased warranties contributed to the service and other revenue increase. Collaboration and license revenue in the year ended December 31, 2018 included \$2.1 million in revenue related to the termination of the collaboration arrangement with bioMérieux in the third quarter of 2018.

Cost of Product, Service and License Revenue

Cost of product revenue increased by \$5.0 million, or 64%, to \$12.7 million for the year ended December 31, 2018 as compared to \$7.7 million for the year ended December 31, 2017. The increase was primarily due to increased sales of consumables and instruments. Cost of service revenue increased to \$7.0 million for the year ended December 31, 2018 from \$5.1 million for the year ended December 31, 2017. The increase was primarily due to higher utilization of the Accelerator Laboratory, plus increased personnel costs from the build out of our field service organization. Overall cost of goods sold as a percentage of revenue decreased to 52% of total revenue for the year ended December 31, 2018 as compared to 56% for the year ended December 31, 2017, primarily as a result of the change in revenue mix to more consumables revenue and collaboration revenue in 2018.

Research and Development Expense

Research and development expense decreased slightly by \$0.5 million, or 3%, to \$15.8 million for the year ended December 31, 2018 as compared to \$16.3 million for the year ended December 31, 2017. The decrease was primarily due to a reduction in outside development costs related to our SR-X instrument for which development was completed and product launched commercially in the fourth quarter of 2017. The reduction in project costs for the SR-X instrument offset an increase in research and development costs due to increased headcount in research and development and the increased use of outside development firms as we increased our new product development efforts.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by \$14.0 million, or 71%, to \$33.7 million for the year ended December 31, 2018 as compared to \$19.7 million for the same period in 2017. The increase was primarily due to headcount additions in various departments as we build out our organization to support future growth, public company costs, transaction fees and amortization of intangibles associated with the Aushon acquisition, and stock compensation expense.

Interest and Other Expense, Net

Interest and other expense, net decreased by \$1.1 million, to a net income position of less than \$0.1 million for the year ended December 31, 2018 as compared to \$1.0 million of net expense for the same period in 2017, primarily due to an increase in interest income as a result of the higher cash balances in 2018.

Tax Expense

Tax expense increased by less than \$0.1 million to an amount less \$0.1 million for the year ended December 31, 2018. The increase is primarily due to certain state taxes in 2018, which we did not have in the prior year.

Comparison of the Years Ended December 31, 2017 and December 31, 2016 (dollars in thousands):

	Year ended December 31, 2017	% of revenue	Year ended December 31, 2016	% of revenue	\$ change	% change
Product revenue	\$ 14,124	61.7%	\$ 10,601	60.3%	\$ 3,523	33.2%
Service and other revenue	7,676	33.6%	5,012	28.5%	2,664	53.2%
Collaboration and license revenue	1,074	4.7%	1,972	11.2%	(898)	(45.5)%
Total revenue	22,874	100.0%	17,585	100.0%	5,289	30.1%
Costs of Goods sold:						
Cost of product revenue	7,742	33.8%	6,299	35.8%	1,443	22.9%
Cost of services revenue	5,145	22.5%	3,163	18.0%	1,607	30.4%
Cost of license revenue	—	—%	375	2.1%	(375)	(100)%
Total Costs of Goods sold and services	12,887	56.3%	9,837	55.9%	3,050	57.7%
Gross Profit	9,987	43.7%	7,748	44.1%	2,239	42.3%
Operating Expenses:						
Research and development	16,304	71.3%	16,993	96.6%	(689)	(4.1)%
Selling, general and administrative	19,688	86.1%	12,466	70.9%	7,222	57.9%
Total operating expenses	35,992	157.6%	29,459	167.5%	9,583	24.4%
Loss from operations	(26,005)	(113.7)%	(21,711)	(123.5)%	(4,294)	(19.8)%
Interest expense, net	(951)	(4.2)%	(1,298)	(7.4)%	347	(26.7)%
Other income (expense), net	(63)	(0.2)%	(164)	(0.9)%	102	(61.6)%
Loss before income taxes	(27,019)	(118.1)%	(23,173)	(131.8)%	(3,846)	16.6%
Income tax provision	—	—	—	—	—	—
Net loss	\$ (27,019)	(118.1)%	\$ (23,173)	(131.8)%	\$ (3,846)	(16.6)%

Revenue

Revenue increased by \$5.3 million, or 30%, to \$22.9 million for the year ended December 31, 2017 as compared to \$17.6 million for the year ended December 31, 2016. Product revenue consisted of sales of instruments totaling \$6.5 million and sales of consumables and other products of \$7.6 million for the year ended December 31, 2017. Product revenue consisted of sales of instruments totaling \$6.2 million and sales of consumables and other products totaling \$4.4 million for the year ended December 31, 2016. Average sales prices of instruments and consumables did not change materially in the year ended December 31, 2017 as compared with the year ended December 31, 2016. The increase in product revenue of \$3.5 million was primarily due to the sale of more instruments in the twelve months ended December 31, 2017 and increased sales of consumables. The installed base of Simoa instruments increased from December 31, 2016 to December 31, 2017, and as these additional instruments were used by customers, the consumable sales increased. The increase in service and other revenue of \$2.7 million was due to increased services performed in our Simoa Accelerator Laboratory; more customers are using these services, and existing customers are using the Accelerator Laboratory more frequently. Collaboration and license revenue in the year ended December 31, 2017 consists of revenue related to the collaboration arrangement with bioMérieux that was modified in the fourth quarter of 2016. Collaboration and license revenue in the year ended December 31, 2016 consists of one-time payment of \$1.8 million of revenue related a licensing arrangement executed in the fourth quarter of 2016, and revenue related to the collaboration arrangement with bioMérieux of \$0.2 million.

As part of the modification in the fourth quarter of 2016, we received \$2.0 million in additional consideration. This additional consideration along with the deferred revenue on the date of the modification is being recognized over our estimated period of performance, which was initially

determined to be 36 months. The estimated performance period is evaluated each reporting period and continues to be consistent with the initial estimate.

Cost of Product, Service and License Revenue

Cost of product revenue increased by \$1.4 million, or 23%, to \$7.7 million for the year ended December 31, 2017 as compared to \$6.3 million for the year ended December 31, 2016. The increase was primarily due to increased sales of consumables and instruments. Cost of service revenue increased to \$5.1 million for the year ended December 31, 2017 from \$3.2 million for the year ended December 31, 2016. The increase was primarily due to higher utilization of the Accelerator Laboratory, plus increased personnel costs from the build out of our field service organization. Overall cost of goods sold as a percentage of revenue remained consistent at 56% of total revenue for the year ended December 31, 2017 as compared to 56% for the year ended December 31, 2016, primarily as a result of increased headcount in field service and accelerator service groups.

Research and Development Expense

Research and development expense decreased slightly by \$0.7 million, or 4%, to \$16.3 million for the year ended December 31, 2017 as compared to \$17.0 million for the year ended December 31, 2016. The decrease was primarily due to a reduction in outside development costs related to our SR-X instrument for which development was completed and product launched commercially in the fourth quarter of 2017. The reduction in project costs for the SR-X instrument offset other increase in research and development costs as we have increased headcount in research and development and the increased use of outside development firms as we increased our new product development efforts.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by \$7.2 million, or 58%, to \$19.7 million for the year ended December 31, 2017 as compared to \$12.5 million for the same period in 2016. The increase was primarily due to headcount additions in various departments as we build out our organization to support future growth, and stock compensation expense.

Interest and Other Expense, Net

Interest and other expense, net decreased by \$0.5 million, to \$1 million for the year ended December 31, 2017 as compared to \$1.5 million for the same period in 2016, primarily due to the amortization of debt discounts from warrants we have issued to a lender.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from operations. We incurred net losses of \$31.5 million, \$27.0 million and \$23.2 million and used \$28.7 million, \$22.1 million and \$17.7 million of cash from our operating activities for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of \$175.9 million.

As of December 2018, we had cash and cash equivalents of \$44.4 million and no additional amounts were available to borrow under our debt facility.

Sources of Liquidity

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

Equity Offerings

In December 2017, we completed our IPO in which we sold 4,916,480 shares of common stock at an initial public offering price of \$15.00 per share. The aggregate net proceeds received by us from the offering, net of underwriting discounts and commissions and offering expenses, were \$65.6 million. Prior to the IPO, we had raised capital through the sale of redeemable convertible preferred stock in private placement transactions.

Loan Facility with Hercules

On April 14, 2014, we executed a Loan Agreement with Hercules Capital, Inc. (formerly known as Hercules Technology Growth Capital, Inc.). The Loan Agreement provided a total debt facility of \$10.0 million, which is secured by substantially all of our assets. At closing, we borrowed \$5.0 million in principal and had the ability to draw the additional \$5.0 million over the period from November 1, 2014 to March 31, 2015. 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. Principal payments were scheduled to begin on September 1, 2015, unless we achieved certain milestones which would have extended this date to December 1, 2015 or March 1, 2016. In connection with the execution of the Loan Agreement, we issued Hercules a warrant to purchase up to 173,428 shares of our Series C Preferred Stock at an exercise price of \$3.3299 per share. Upon closing of the IPO, this warrant was automatically converted into a warrant to purchase up to 53,960 shares of our common stock at an exercise price of \$10.70 per share.

On March 4, 2015, we executed Amendment 1 to the Loan Agreement and drew the additional \$5.0 million available under the Loan Agreement at that time. The terms of the amendment deferred principal payments to start on December 1, 2015 or March 1, 2016 if we obtained at least \$10.0 million in equity financing before December 1, 2015. This equity financing did not occur before December 1, 2015.

In January 2016, we executed Amendment 2 to the Loan Agreement, which increased the total facility available by \$5.0 million to a total of \$15.0 million and further delaying the start of principal payments to July 1, 2016. Following the Series D Preferred Stock financing in March 2016, we could have elected to further delay the start of principal payments until January 1, 2017, however we voluntarily began paying principal on July 1, 2016. Upon signing this amendment, we drew an additional \$3.0 million under the debt facility. The remaining \$2.0 million available for borrowing expired unused in 2016, decreasing the amounts available under the debt facility to \$13.0 million.

In March 2017, we signed Amendment 3 to the Loan Agreement increasing the total facility available by \$5.0 million to a total of \$18.0 million. We did not draw any of this additional amount, which was available for us to draw until February 28, 2018. Additionally, we did not request an optional term loan for an incremental \$5.0 million which was available for us to request until September 3, 2018. Principal payments were delayed to September 1, 2018 and the loan maturity date was extended to March 1, 2019. We voluntarily made principal payments in the months of March, April, and May 2018. No principal payments were made in June, July or August 2018. The amendment did not affect the due date of the existing end of term fees (in aggregate \$0.5 million) which were due on February 1, 2018. In connection with this amendment, we issued Hercules a warrant to purchase up to 38,828 shares of our Series D Preferred Stock at an exercise price of \$3.67 per share. Upon closing of the IPO, this warrant was automatically converted into a warrant to purchase up to 12,080 shares of our common stock at an exercise price of \$11.80 per share.

In July 2017, we signed Amendment 4 to the Loan Agreement, which capped the "Term Loan Interest Rate" with respect to the 2017 Term Loan Advance only at 10%. Amendment 4 to the Loan

Agreement did not change or affect any other element of the Loan Agreement or the Term Loan Advance.

In August 2018, we signed Amendment 5 to the Loan Agreement, which extends the interest only payment period through March 1, 2020 and also extends the loan maturity date to March 1, 2020. We accounted for the August 2018 amendment as a modification pursuant to ASC 470-50 and determined that no material change occurred as a result of the modification. In addition, the amendment deferred the payment of principal until the maturity date. \$0.1 million of end of term payments are due March 2020.

In October 2018, we signed Amendment 6 to the Loan agreement, which amends the Loan Agreement's collateral clause to exclude the \$1 million certificate of deposit associated with the lease on our new headquarters in Billerica, MA.

The Loan Agreement and amendments contain end of term payments and are recorded in the debt accounts. \$0.5 million of end of term payments were paid in the year ended December 31, 2018.

The Loan Agreement contains negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions, incurring indebtedness or liens, paying dividends or making investments and certain other business transactions. There are no financial covenants associated with the Loan Agreement. The obligations under the Loan Agreement are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in our business, operations or financial or other condition, which is subjective in nature. We have determined that the risk of subjective acceleration under the material adverse events clause is not probable and therefore have classified the outstanding principal in current and long-term liabilities based on scheduled principal payments.

Debt principal repayments, including the end of term fees, due as of December 31, 2018 are (in thousands):

<u>Years ending December 31:</u>	
2019	\$ 0
2020	7,763
	<u>\$ 7,763</u>

Cash Flows

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

	<u>Year ended December 31,</u>		
	<u>2018</u>	<u>2017</u>	<u>2016</u>
Net cash used in operating activities	\$ (28,721)	\$ (22,106)	\$ (17,742)
Net cash used in investing activities	(5,454)	(1,132)	(826)
Net cash (used in) provided by financing activities	(78)	73,249	45,916
Net decrease in cash and cash equivalents	<u>\$ (34,253)</u>	<u>\$ 50,011</u>	<u>\$ 27,348</u>

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 \$28.7 million during the year ended December 31, 2018. Net cash used in operating activities primarily consisted of net loss of \$31.5 million, a decrease of \$1.9 million in deferred revenue and an increase of \$1.6 million in inventory, primarily offset by non-cash stock compensation expense of \$4.9 million and an increase of \$1.3 million in accounts payable.

Net cash used in operating activities was \$22.1 million during the year ended December 31, 2017. Net cash used in operating activities primarily consisted of net loss of \$27.0 million and an increase of \$2.0 million in inventory and an increase in accounts receivable of \$1.7 million, primarily offset by non-cash stock compensation expense of \$2.2 million, an increase of \$2.9 million in deferred revenue, an increase of \$2.0 million in accrued expenses and an increase of \$1.0 million in accounts payable.

Net cash used in operating activities was \$17.7 million during the year ended December 31, 2016. Net cash used in operating activities primarily consisted of a net loss of \$23.2 million and an increase in accounts receivable of \$1.7 million, primarily offset by non-cash charges related to issuance of warrants of \$2.1 million, other non-cash items including depreciation and stock based compensation, of \$1.8 million, and an increase in current liabilities of \$2.3 million and an increase in deferred revenue of \$0.9 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 \$5.5 million of cash in investing activities during the year ended December 31, 2018 consisting of cash paid in the acquisition of Aushon, net of cash acquired, and for purchases of capital equipment to support our infrastructure.

We used \$1.1 million of cash in investing activities during the year ended December 31, 2017 for purchases of capital equipment to support our infrastructure.

We used \$0.8 million of cash in investing activities during the year ended December 31, 2016 primarily for purchases of capital equipment to support our infrastructure, and for a \$0.3 million equity investment in another company.

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 and revenues from our commercial operations.

We used \$0.1 million cash in financing activities during the year ended December 31, 2018, which primarily was from payments on debt of \$1.9 million offset by cash generated by the exercise of stock options.

We generated \$73.2 million of cash in financing activities during the year ended December 31, 2017, which primarily was from the sale of 4,916,480 shares of common stock in our IPO in December 2017 for net proceeds of \$65.6 million, and the sale of 2,113,902 shares of our Series D-1 Preferred Stock in June 2017 for net proceeds of \$8.4 million, which was partially offset by payments of outstanding debt.

We generated \$45.9 million of cash from financing activities during the year ended December 31, 2016, which was primarily from the sale of our Series D Preferred Stock in March 2016 for net proceeds of \$45.4 million.

Capital Resources

We have not achieved profitability on a quarterly or 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. Additionally, as a public company, we have incurred and will continue to incur significant audit, legal and other expenses that we did not incur as a private company. 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, our current cash and cash equivalents, and interest income we earn on these balances will be sufficient to meet our anticipated operating cash requirements for at least into the second quarter of 2020. 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, including our SP-X instrument;
- 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.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Contractual Obligations, Commitments and Contingencies

The following table summarizes our contractual obligations as of December 31, 2018 (in thousands):

(in thousands)	Payments due by period				Total
	Less than 1 Year	1 to 3 years	3 to 5 years	More than 5 years	
Contractual Obligations:(1)					
Operating lease obligations	\$ 1,172	\$ 5,303	\$ 10,377	\$ 22,202	\$ 39,054
Principal payments and end of term fees on the term loan	\$ 0	\$ 7,763	\$ 0	\$ 0	\$ 7,763
Total	\$ 1,172	\$ 13,066	\$ 10,377	\$ 22,202	\$ 46,817

(1) See "—Development and Supply Agreement" for additional contractual obligations.

We currently lease approximately 30,655 square feet of office, laboratory, and manufacturing space at our headquarters in Lexington, Massachusetts, under a lease that was to expire on June 30, 2020 (the "Lexington Lease"); however in November 2018, the Company agreed to terminate the lease with the lessor effective May 2019. The termination of the lease was connected to the Company signing a new lease on October 2, 2018 (see below). In addition, pursuant to our acquisition of Aushon in January 2018, we currently lease approximately 21,500 square feet of office, laboratory, and manufacturing space in Billerica, Massachusetts, under a lease that was to expire on February 28, 2021 (the "Billerica Lease").

In August 2018, we exercised an option to terminate the Billerica Lease effective as of September 1, 2019. The Company is required to pay a termination fee of \$75,000 no later than July 1, 2019 in consideration for the early termination.

On October 2, 2018, we entered into a lease for approximately 91,600 square feet of office, laboratory, and manufacturing space in the building located at 900 Middlesex Turnpike, Billerica, Massachusetts. The premises covered by this new lease will serve as our new principal office and laboratory space beginning in the second quarter of 2019. The initial term of the lease is 11 years and five months beginning on April 1, 2019, and we have the option to extend the lease for two additional five-year periods. We believe that this office, laboratory and manufacturing space will be sufficient to meet our needs for the foreseeable future.

We also have ongoing obligations related to license agreements which contain immaterial minimum annual payments that are credited against the actual royalty expense.

Purchase orders or contracts for the purchase of supplies and other goods and services are not included in the table above. We are not able to determine the aggregate amount of such purchase orders that represent contractual obligations, as purchase orders may represent authorizations to purchase rather than binding agreements. Our purchase orders are based on our current procurement or development needs and are fulfilled by our vendors within short time horizons.

Development and Supply Agreement

We do not have significant agreements for the purchase of supplies or other goods specifying minimum quantities or set prices that exceed our expected requirements for the next three to six months, with the exception of the agreement with STRATEC, who manufactures our HD-1 instrument and will manufacture the HD-X that we expect to commercialize in the second half of 2019. In 2013, we entered into a supply agreement, or the Supply Agreement, with STRATEC which requires us to purchase a minimum number of commercial units over a seven-year period ending in May 2021. We

could be obligated to pay a fee based on the shortfall of commercial units purchased compared to the required number. Based on the commercial units purchased as of December 31, 2018, assuming no additional commercial units were purchased thereafter but prior to May 2021, this fee would equal \$11.1 million. The amount we could be obligated to pay under the minimum purchase commitment is reduced as each commercial unit is purchased. We believe that we will purchase sufficient units to meet the requirements of the minimum purchase commitment and, therefore, have not accrued for any of the minimum purchase commitment.

Also, if we terminate the Supply Agreement under certain circumstances and do not purchase up to a required number of commercial units, we would be required to issue warrants to purchase 93,341 shares of common stock at \$0.003214 per share. We believe that we will not issue such warrant and therefore have not recorded any amounts related to the potential equity consideration.

In August 2011, we entered into a Strategic Development Services and Equity Participation Agreement, or the Development Agreement, with STRATEC, pursuant to which STRATEC undertook the development of the HD-1 for manufacture and sale to us or a partner whom we designate. During the year ended December 31, 2016, the Development Agreement was amended to modify the deliverables related to the final milestone, to agree on instrument design changes to be implemented, and to reduce the minimum purchase commitment in the Supply Agreement. Additionally, the parties agreed on additional development services for a total fee of \$1.5 million, which is payable when development is completed and of which \$0.9 million was paid in 2018. The total amount includes the final milestone payment that was due under the terms of the original agreement.

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

Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in foreign currency exchange rates and interest rates. We do not hold or issue financial instruments for trading purposes.

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. 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, 2018 would not have been material.

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

Interest Rate Sensitivity

We had cash and cash equivalents of \$44.4 million as of December 31, 2018. 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.

As of December 31, 2018, the principal amount of our term debt outstanding with Hercules was \$7.8 million. If overall interest rates had increased by 10% during the periods presented, our interest expense would have increased by approximately \$0.1 million on an annualized basis.

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

(a) *Evaluation of Disclosure Controls and Procedures.* Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us 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 SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(b) *Changes in Internal Controls.* There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the fourth quarter of our last fiscal year that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

(c) *Management's Annual Report on Internal Control Over Financial Reporting.* Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, as a process designed by, or under the supervision of, our principal executive officer and principal financial officer and effected by our board of directors, management and other personnel 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. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our

receipts and expenditures are being made only in accordance with authorizations of management and our directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our 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. 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.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under that framework, our management concluded that our internal controls over financial reporting were effective as of December 31, 2018.

Item 9B. OTHER INFORMATION

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 2019 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 2019 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 2019 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 2019 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. PRINCIPAL ACCOUNTING 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 2019 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES(1) *Financial Statements*

The consolidated financial statements are included on pages F-1 through F-53 attached hereto and are filed as part of this Annual Report on Form 10-K.

(2) *Financial Statement Schedules*

Schedules have been omitted since they are either not required or not applicable or the information is otherwise included herein.

(3) *Exhibits*

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

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg. Number</u>
3.1	Amended and Restated Certificate of Incorporation		8-K	12/15/17	001-38319
3.2	Restated Bylaws		8-K	12/15/17	001-38319
4.1	Form of Common Stock Certificate		S-1	11/9/17	333-221475
4.2	Form of Warrant to Purchase Series C Preferred Stock of the Registrant		S-1	11/9/17	333-221475
4.3	Warrant Agreement, dated as of April 14, 2014, by and between the Registrant and Hercules Capital, Inc. (formerly known as Hercules Technology Group Capital, Inc.)		S-1	11/9/17	333-221475
4.4	Warrant Agreement, dated as of January 29, 2016, by and between the Registrant and Hercules Capital, Inc. (formerly known as Hercules Technology Group Capital, Inc.)		S-1	11/9/17	333-221475
4.5	Warrant Agreement, dated as of March 31, 2017, by and between the Registrant and Hercules Capital, Inc. (formerly known as Hercules Technology Group Capital, Inc.)		S-1	11/9/17	333-221475
4.6	Fourth Amended and Restated Stockholders Agreement, dated as of June 2, 2017, by and among the Registrant and the stockholders named therein		S-1	11/9/17	333-221475

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg. Number</u>
4.7	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	11/9/17	333-221475
4.8	Warrant Agreement, dated as of January 30, 2018, by and between the Registrant and Azul Divinal Consultoria Unipessoal LDA		10-K	3/19/18	001-38319
10.1.1+	2007 Stock Option and Grant Plan, as amended		S-1	11/9/17	333-221475
10.1.2+	Form of Incentive Stock Option Agreement under the 2007 Stock Option and Grant Plan, as amended		S-1	11/9/17	333-221475
10.1.3+	Form of Non-qualified Stock Option Agreement under the 2007 Stock Option and Grant Plan, as amended		S-1	11/9/17	333-221475
10.1.4+	Form of Restricted Stock Agreement under the 2007 Stock Option and Grant Plan, as amended		S-1	11/9/17	333-221475
10.2.1+	2017 Employee, Director and Consultant Equity Incentive Plan		S-1/A	11/27/17	333-221475
10.2.2+	Form of Stock Option Agreement under the 2017 Employee, Director and Consultant Equity Incentive Plan		S-1/A	11/27/17	333-221475
10.2.3+	Form of Restricted Stock Agreement under the 2017 Employee, Director and Consultant Equity Incentive Plan		S-1/A	11/27/17	333-221475
10.2.4+	Form of Restricted Stock Unit Agreement under the 2017 Employee, Director and Consultant Equity Incentive Plan		S-1/A	11/27/17	333-221475
10.3+	Employment Agreement, dated January 1, 2015, by and between the Registrant and E. Kevin Hrusovsky		S-1	11/9/17	333-221475
10.4+	Letter Agreement, dated April 8, 2017, by and between the Registrant and Joseph Driscoll		S-1	11/9/17	333-221475
10.5+	Letter Agreement, dated December 1, 2011, by and between the Registrant and Ernest Orticerio		S-1	11/9/17	333-221475

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg. Number</u>
10.6+	Letter Agreement, dated April 6, 2016, by and between the Registrant and Bruce Bal		S-1	11/9/17	333-221475
10.7+	Letter Agreement, dated August 8, 2014, by and between the Registrant and Mark T. Roskey, Ph.D.		S-1	11/9/17	333-221475
10.8+	Letter Agreement, effective as February 5, 2018, by and between the Registrant and Dawn Mattoon		10-Q	5/15/18	001-38319
10.9+	Letter Agreement, effective as October 22, 2018, by and between the Registrant and Jackson Streeter	X			
10.10+	Letter Agreement, dated March 20, 2017, by and between the Registrant and Marijn Dekkers, Ph.D.		S-1	11/9/17	333-221475
10.11+	Letter Agreement, dated August 7, 2013, by and between the Registrant and Paul M. Meister		S-1	11/9/17	333-221475
10.12	Lease Agreement, dated as of November 22, 2011, between the Registrant and King 113 Hartwell LLC		S-1	11/9/17	333-221475
10.13	First Amendment to lease dated August 22, 2014, by and between the Registrant and King 113 Hartwell LLC		S-1	11/9/17	333-221475
10.14.1*	Exclusive License Agreement, dated June 18, 2007, between the Registrant and Tufts University, as amended on April 29, 2013		S-1	11/9/17	333-221475
10.14.2*	Second Amendment, dated August 22, 2017, to the Exclusive License Agreement between the Registrant and Tufts University		S-1	11/9/17	333-221475
10.15.1*	Supply and Manufacturing Agreement, dated September 14, 2011, between the Registrant and STRATEC Biomedical AG		S-1	11/9/17	333-221475
10.15.2	First Amendment to Supply and Manufacturing Agreement, dated October 17, 2013, between the Registrant and STRATEC Biomedical AG		S-1	11/9/17	333-221475

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg. Number</u>
10.16.1*	STRATEC Development Services and Equity Participation Agreement, dated August 15, 2011, between the Registrant and STRATEC Biomedical Systems AG		S-1	11/9/17	333-221475
10.16.2*	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	11/9/17	333-221475
10.17*	Manufacturing Services Agreement, dated November 23, 2016, between the Registrant and Paramit Corporation		S-1	11/9/17	333-221475
10.18.1	Loan and Security Agreement, dated April 14, 2014, by and between the Registrant and Hercules Capital, Inc. (formerly known as Hercules Technology Growth Capital, Inc.)		S-1	11/9/17	333-221475
10.18.2	Amendment No. 1 to Loan and Security Agreement, dated March 4, 2015, by and between the Registrant and Hercules Capital, Inc. (formerly known as Hercules Technology Growth Capital, Inc.)		S-1	11/9/17	333-221475
10.18.3	Amendment No. 2 to Loan and Security Agreement, dated January 29, 2016, by and between the Registrant and Hercules Capital, Inc. (formerly known as Hercules Technology Growth Capital, Inc.)		S-1	11/9/17	333-221475
10.18.4	Amendment No. 3 to Loan and Security Agreement, dated March 31, 2017, by and between the Registrant and Hercules Capital, Inc. (formerly known as Hercules Technology Growth Capital, Inc.)		S-1	11/9/17	333-221475
10.18.5	Amendment No. 4 to Loan and Security Agreement, dated July 24, 2017, by and between the Registrant and Hercules Capital, Inc. (formerly known as Hercules Technology Growth Capital, Inc.)		10-Q	11/7/18	001-38319

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg. Number</u>
10.18.6	Amendment No. 5 to Loan and Security Agreement, dated August 30, 2018, by and between the Registrant and Hercules Capital, Inc. (formerly known as Hercules Technology Growth Capital, Inc.)		10-Q	11/7/18	001-38319
10.18.7	Amendment No. 6 to Loan and Security Agreement, dated September 28, 2018, by and between the Registrant and Hercules Capital, Inc. (formerly known as Hercules Technology Growth Capital, Inc.)		10-Q	11/7/18	001-38319
10.19+	Form of Indemnification Agreement		S-1/A	11/27/17	333-221475
10.20.1	Lease, dated September 24, 2007, between RAR2 Boston Industrial QRS-MA, Inc. and Aushon Biosystems, Inc.		10-K	3/19/18	001-38319
10.20.2	First Amendment, dated October 28, 2009, to Lease, dated September 24, 2007, between RAR2 Boston Industrial QRS-MA, Inc. and Aushon Biosystems, Inc.		10-K	3/19/18	001-38319
10.20.3	Second Amendment, dated September 23, 2015, to Lease, dated September 24, 2007, between RAR2 Boston Industrial QRS-MA, Inc. and Aushon Biosystems, Inc.		10-K	3/19/18	001-38319
10.21	Lease Agreement between SSI 900 Middlesex MA LP and the Registrant, dated October 2, 2018.		8-K	10/5/18	001-38319
10.22+	2018 Non-Employee Director Compensation Policy	X			
21.1	Subsidiaries of Registrant	X			
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			

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg. Number</u>
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	XBRL Instance Document.	X			
101.SCH	XBRL Taxonomy Extension Schema Document.	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X			
101.DEF	XBRL Taxonomy Extension Definition.	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X			
101.PRE	XBRL Taxonomy Presentation Linkbase Document.	X			

+ 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 Securities and Exchange Commission.

Item 16. FORM 10-K SUMMARY

Not applicable.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ PAUL M. MEISTER</u> Paul M. Meister	Director	March 18, 2019
<u>/s/ DAVID R. WALT, PH.D.</u> David R. Walt, Ph.D.	Director	March 18, 2019

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QUANTERIX CORPORATION
Years ended December 31, 2018, 2017 and 2016

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Report of Independent Registered Public Accounting Firm

To the Stockholders 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, 2018 and 2017, the consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' (deficit) equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with US generally accepted accounting principles.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2008.
Boston, Massachusetts
March 18, 2019

Quanterix Corporation

Consolidated Balance Sheets

(amounts in thousands, except share and per share data)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 44,429	\$ 79,682
Accounts receivable (less reserve for doubtful accounts of \$36; including \$48 and \$123 from related parties as of December 31, 2018 and 2017, respectively)	6,792	5,599
Inventory	5,945	3,571
Prepaid expenses and other current assets	2,330	400
Total current assets	59,496	89,252
Restricted Cash	1,000	—
Property and equipment, net	2,923	1,874
Intangible assets, net	2,348	—
Goodwill	1,308	—
Other non-current assets	536	653
Total assets	<u>\$ 67,611</u>	<u>\$ 91,779</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable (including \$36 and \$0 to related parties as of December 31, 2018 and 2017, respectively)	\$ 5,110	\$ 3,552
Accrued compensation and benefits	4,449	2,624
Other accrued expenses (including \$226 and \$170 to related parties as of December 31, 2018 and 2017, respectively)	3,129	3,560
Deferred revenue (including \$33 and \$1,182 with related parties as of December 31, 2018 and 2017, respectively)	5,437	4,942
Current portion of long term debt	—	5,036
Total current liabilities	18,125	19,714
Deferred revenue, net of current portion (including \$0 and \$1,074 with related parties as of December 31, 2018 and 2017, respectively)	520	1,709
Long term debt, net of current portion	7,623	4,346
Other non-current liabilities	278	144
Total liabilities	26,546	25,913
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, \$0.001 par value:		
Authorized—120,000,000 shares as of December 31, 2018 and December 31, 2017; issued and outstanding—22,369,036 and 21,707,041 shares as of December 31, 2018 and 2017, respectively	22	22
Additional paid-in capital	216,931	210,196
Accumulated deficit	(175,888)	(144,352)
Total stockholders' equity	41,065	65,866
Total liabilities and stockholders' equity	<u>\$ 67,611</u>	<u>\$ 91,779</u>

See accompanying notes.

Quanterix Corporation**Consolidated Statements of Operations and Comprehensive Loss**

(amounts in thousands, except share and per share data)

	Twelve Months Ended December 31,		
	2018	2017	2016
Product revenue (including related party activity of \$294, \$339, and \$509 for the years ended December 31, 2018, 2017, and 2016 respectively)	\$ 23,365	\$ 14,124	\$ 10,601
Service and other revenue (including related party activity of \$149, \$165, and \$107 for the years ended December 31, 2018, 2017, and 2016 respectively)	12,117	7,676	5,012
Collaboration and license revenue (including related party activity of \$2,150, \$1,074, and \$172 for the years ended December 31, 2018, 2017, and 2016 respectively)	2,150	1,074	1,972
Total revenue	37,632	22,874	17,585
Costs of Goods Sold:			
Cost of product revenue (including related party activity of \$191, \$235, and \$322 for the years ended December 31, 2018, 2017, and 2016 respectively; including stock compensation of \$228, \$76, and \$18 for the years ended December 31, 2018, 2017, and 2016 respectively)	12,729	7,742	6,299
Cost of services and other revenue	6,955	5,145	3,163
Costs of license revenue, related party	—	—	375
Total Costs of Goods Sold and Services	19,684	12,887	9,837
Gross Profit	17,948	9,987	7,748
Operating Expense:			
Research and development (including stock compensation of \$513, \$180, and \$59 for the years ended December 31, 2018, 2017, and 2016, respectively)	15,805	16,304	16,993
Selling, general and administrative (including stock compensation of \$4,143, \$1,912, and \$851 for the years ended December 31, 2018, 2017, and 2016, respectively)	33,693	19,688	12,466
Total operating expenses	49,498	35,992	29,459
Loss from operations	(31,550)	(26,005)	(21,711)
Interest income (expense), net	46	(951)	(1,298)
Other (expense) income, net	(7)	(63)	(164)
Loss before income taxes	(31,511)	(27,019)	(23,173)
Income tax provision	(25)	—	—
Net loss	\$ (31,536)	\$ (27,019)	\$ (23,173)
Reconciliation of net loss to net loss attributable to common stockholders:			
Net loss	\$ (31,536)	\$ (27,019)	\$ (23,173)
Accretion of preferred stock to redemption value	—	(4,110)	(4,437)
Accrued dividends on preferred stock	—	(59)	(8)
Net loss attributable to common stockholders	\$ (31,536)	\$ (31,188)	\$ (27,618)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.43)	\$ (8.30)	\$ (12.89)
Weighted-average common shares outstanding, basic and diluted	21,994,317	3,756,954	2,142,840

See accompanying notes.

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

	Twelve Months Ended December 31,		
	2018	2017	2016
Operating activities			
Net loss	\$ (31,536)	\$ (27,019)	\$ (23,173)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	1,352	482	444
Stock-based compensation expense	4,884	2,168	928
Non-cash interest expense	170	238	388
Gain on disposal of fixed assets	(14)	—	11
Non-cash research and development expense for issuance of warrants to a vendor	—	—	2,078
Change in fair value of preferred stock warrants	—	90	307
Changes in operating assets and liabilities:			
Accounts receivable	(983)	(1,682)	(1,655)
Deposits	—	—	200
Prepaid expenses and other assets	(1,828)	(273)	6
Inventory	(1,603)	(2,043)	(526)
Other non-current assets	267	—	—
Accounts payable	1,318	1,003	1,131
Accrued compensation and benefits, other accrued expenses and other liabilities	1,101	2,035	1,200
Deferred revenue	(1,849)	2,895	919
Net cash used in operating activities	<u>(28,721)</u>	<u>(22,106)</u>	<u>(17,742)</u>
Investing activities			
Purchases of property and equipment	(1,518)	(1,132)	(526)
Acquisitions, net of cash acquired	(3,801)	—	(300)
Purchase of Investments	(150)	—	—
Proceeds from sale of assets	15	—	—
Net cash used in investing activities	<u>\$ (5,454)</u>	<u>\$ (1,132)</u>	<u>\$ (826)</u>
Financing activities			
Proceeds from sale of preferred stock, net of issuance costs	—	65,575	—
Proceeds from sale of common stock, net of issuance costs	(20)	8,423	45,428
Proceeds from exercise of stock warrants	—	29	18
Proceeds from stock options exercised	1,871	202	213
Proceeds from the issuance of notes payable and warrants, net of issuance costs	—	(59)	2,954
Payments on notes payable	(1,929)	(921)	(2,697)
Net cash (used in) provided by financing activities	<u>\$ (78)</u>	<u>\$ 73,249</u>	<u>\$ 45,916</u>
Net decrease in cash and cash equivalents	(34,253)	50,011	27,348
Cash, restricted cash, and cash equivalents at beginning of period	79,682	29,671	2,323
Cash, restricted cash, and cash equivalents at end of period	<u>\$ 45,429</u>	<u>\$ 79,682</u>	<u>\$ 29,671</u>
Supplemental cash flow information			
Accretion of redeemable convertible preferred stock to redemption value	\$ —	\$ 4,110	\$ 4,437
Cash paid for interest	\$ 660	\$ 743	\$ 945
Warrants issued to lenders	\$ —	\$ 119	\$ 128
Purchases of property and equipment included in accounts payable	\$ 78	\$ 74	\$ 72
Fair value of common stock warrants exercised and reclassified as shares of common stock	\$ 196	\$ 2,187	\$ 5,257

See accompanying notes.

Quanterix Corporation

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' (Deficit) Equity

	Preferred A stock shares	Preferred A stock value	Preferred B stock shares	Preferred B stock value	Preferred C stock shares	Preferred C stock value	Preferred D stock shares	Preferred D stock value	Common stock shares	Common stock value	Additional paid-in capital	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2015	14,400,001	23,898	5,624,106	15,178	8,605,944	34,369	—	—	1,976,992	2	—	(88,642)	(88,640)
Issuance of Series D preferred stock, net of issuance costs	—	—	—	—	—	—	12,420,262	45,428	—	—	—	—	—
Exercise of preferred stock warrants	1,300,000	3,901	397,530	1,374	—	—	—	—	—	—	—	—	—
Exercise of common stock options	—	—	—	—	—	—	—	—	90,883	—	213	—	213
Vesting of restricted stock	—	—	—	—	—	—	—	—	247,621	—	—	—	—
Accretion of preferred stock to redemption value	—	1,180	—	907	—	2,309	—	41	—	—	(1,141)	(3,296)	(4,437)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	928	—	928
Net loss	—	—	—	—	—	—	—	—	—	—	—	(23,173)	(23,173)
Balance at December 31, 2016	15,700,001	28,979	6,021,636	17,459	8,605,944	36,678	12,420,262	45,469	2,315,496	2	—	(115,111)	(115,109)
Issuance of Series D-1 preferred stock, net of issuance costs	—	—	—	—	—	—	2,113,902	8,423	—	—	—	—	—
Exercise of preferred stock warrants	700,000	2,078	—	—	31,283	138	—	—	—	—	—	—	—
Exercise of common stock options and vesting restricted stock	—	—	—	—	—	—	—	—	289,321	—	204	—	204
Cumulative effect of adoption of ASU No. 2016-09	—	—	—	—	—	—	—	—	—	—	141	(141)	—
Accretion of preferred stock to redemption value	—	1,080	—	840	—	2,140	—	50	—	—	(2,029)	(2,081)	(4,110)
Conversion of preferred stock to common stock	(16,400,001)	(32,137)	(6,021,636)	(18,299)	(8,637,227)	(38,956)	(14,534,164)	(53,942)	14,185,744	15	143,319	—	143,334
Warrant Liability reclassified to equity upon IPO	—	—	—	—	—	—	—	—	—	—	823	—	823
Issuance of common stock in initial public offering, net of \$8,173 in offering costs	—	—	—	—	—	—	—	—	4,916,480	5	65,570	—	65,575
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	2,168	—	2,168
Net loss	—	—	—	—	—	—	—	—	—	—	—	(27,019)	(27,019)
Balance at December 31, 2017	—	—	—	—	—	—	—	—	21,707,041	22	210,196	(144,352)	65,866
Exercise of common stock warrants	—	—	—	—	—	—	—	—	16,718	—	—	—	—
Exercise of common stock options and vesting of restricted stock	—	—	—	—	—	—	—	—	645,277	—	1,871	—	1,871
Common stock issuance offering costs	—	—	—	—	—	—	—	—	—	—	(20)	—	(20)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	4,884	—	4,884
Net loss	—	—	—	—	—	—	—	—	—	—	—	(31,536)	(31,536)
Balance at December 31, 2018	—	—	—	—	—	—	—	—	22,369,036	22	216,931	(175,888)	41,065

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 our 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 is also developing its bead-based technology to detect nucleic acids in biological samples.

The Company currently markets the Simoa HD-1, 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 Analyzer 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 planned for April 2019. This compact instrument has the ability to reach a 10 plex and has custom assay capability. The Company also performs research services on behalf of customers to apply the Simoa technology to specific customer needs. The Company's primary customers are 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 Aushon Biosystems, Inc. (Aushon) in January 2018. With the acquisition of Aushon, the Company acquired a CLIA certified laboratory, as well as Aushon's proprietary sensitive planar array detection technology. Leveraging its proprietary sophisticated Simoa image analysis and data analysis algorithms, the Company further refined this planar array technology to develop the SP-X instrument to provide the same Simoa sensitivity found in its bead-based platform.

Initial Public Offering

In December 2017, the Company completed its initial public offering (IPO) in which the Company sold 4,916,480 shares of its common stock at the initial public offering price of \$15.00 per share. The Company's common stock began trading on The Nasdaq Global Market on December 7, 2017. The aggregate net proceeds received from the IPO, net of underwriting discounts and commissions and offering expenses, was \$65.6 million. Immediately prior to the completion of the IPO, all then outstanding shares of convertible preferred stock were converted into 14,185,744 shares of common stock. The related carrying value of shares of preferred stock and warrants in the aggregate amount of \$143.3 million was reclassified as common stock and additional paid-in capital. Additionally, the Company filed an amended and restated certificate of incorporation with the Secretary of State of the State of Delaware, effective December 11, 2017 to, among other things, change the authorized number of shares of common stock to 120,000,000 and the authorized number of shares of preferred stock to 5,000,000.

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

1. Organization and operations (Continued)

Liquidity

The Company has had recurring losses from operations since inception and has an accumulated deficit of \$175.9 million at December 31, 2018 and the Company incurred a net loss of \$31.5 million, \$27.0 million, and \$23.2 million for the years ended December 31, 2018, 2017, and 2016, respectively. Prior to the IPO the Company had funded its operations principally from issuances of preferred stock, debt financings, grants, product and service sales and development and license agreements. At December 31, 2018, the Company had \$44.4 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.

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification and Accounting Standards Update of the Financial Accounting Standards Board ("FASB"). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company's management evaluates its estimates, which include, but are not limited to, estimates related to revenue recognition, fair value of equity instruments, valuation allowances recorded against deferred tax assets, and stock-based compensation. Actual results could differ from those estimates.

Reverse Stock Split

On December 4, 2017, the Company effected a reverse stock split of its common stock at a ratio of 1-for-3.214. The shares of common stock subject to then outstanding stock options were adjusted accordingly to reflect the reverse stock split. All common stock and related per share amounts presented in these financial statements and related notes have been retroactively adjusted to reflect the 1-for-3.214 reverse stock split.

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 equity instruments and notes receivable, fair

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****2. Significant accounting policies (Continued)**

value of assets acquired and liabilities assumed in acquisitions, valuation allowances recorded against deferred tax assets, and stock-based compensation. Actual results could differ from those estimates.

Revenue recognition

The Company recognizes revenue when (1) persuasive evidence of an arrangement exists, (2) shipment and installation, if applicable, has occurred or services have been rendered, (3) the price to the customer is fixed or determinable and (4) collection of the related receivable is reasonably assured. The Company primarily generates revenue from the sale of products and delivery of services, as well as under license and collaboration agreements. The Company's product revenue includes the sale of instruments as well as assay kits and consumables which are used to perform tests on the instrument. The Company's service revenue is generated from services performed in the Company's Simoa Accelerator Lab under contracts to perform research services on behalf of customers and maintenance and support services.

Product revenue

Revenue for instrument sales is recognized upon installation at the customer's location or upon transfer of title to the customer when installation is not required, which is generally the case with sales to distributors. In sales to end-customers, the Company provides the installation service and often payment is tied to the completion of the installation service. When installation is required, the Company accounts for the instrument and installation service as one unit of accounting and recognizes revenue when installation is completed, assuming all other revenue recognition criteria are met. Instrument transactions often have multiple elements, as discussed below. Included with the purchase of an instrument is a one-year assurance type product warranty assuring that the instrument is free of material defects and will function according to specifications. In addition, the sale of an instrument includes an implied warranty which is promised to the customer during the pre-sales process, at the time that the sales quote is issued to the customer. The implied warranty is provided over the same one-year period as the standard warranty. The services included in the implied warranty are the same as those included in the extended service contracts, and include two bi-annual preventative maintenance service visits, minor hardware updates and software upgrades, additional training and troubleshooting which is beyond the scope of the standard product warranty. The implied warranty has been identified by the Company as a separate deliverable and unit of accounting. Consideration allocated to the implied one year service type warranty is recognized over the one year period of performance as service and other revenue as described below. Consideration allocated to any other elements is recognized as the goods are delivered or the services are performed.

Service and other revenue

Service revenue includes revenue from the implied one-year service type warranty obligation, revenue from extended service contracts, research services performed on behalf of a customer in the Company's Simoa Accelerator Lab, and other services that may be performed. Revenue for the implied one-year service type warranty is initially deferred at the time of instrument revenue recognition and is recognized ratably over a 12-month period starting on the date of instrument installation. Revenue for extended warranty contracts is recognized ratably over the service period. Revenue for research and development services and other services is generally recognized based on proportional performance of the contract, when the Company's ability to complete project requirements is reasonably assured. Most of these services are completed in a short period of time from the receipt of the customer's order.

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

2. Significant accounting policies (Continued)

When significant risk exists in the Company's ability to fulfill project requirements, revenue is recognized upon completion of the contract.

Collaboration and license revenue

Collaboration and license revenue relates to the Joint Development and License Agreement (JDLA) with bioMérieux SA (bioMérieux) as amended and restated in December 2016 by the Amended and Restated License Agreement (the Amended JDLA) and the agreements with a diagnostics company. Refer to "Collaboration and License Agreements (Note 11)" for a description of these arrangements and the Company's revenue recognition policies for these agreements. On September 6, 2018, bioMérieux notified the Company that it was terminating the Amended JDLA, forfeiting any future IVD licensing rights to Quanterix' Simoa technology and enabling Quanterix to consolidate and regain control of all Simoa IVD licensing and IP rights. As a result of the termination the Company recognized \$1.6 million in collaboration and license revenue previously recorded in deferred revenue.

Multiple element arrangements

Many of the Company's instrument sales involve the delivery of multiple products and services. The elements of an instrument sale typically include the instrument installation (when required), an implied one year service type warranty, and in some cases the Company may also sell assays, consumables, or other services. Revenue recognition for contracts with multiple deliverables is based on the individual units of accounting determined to exist in the contract. A delivered item is considered a separate unit of accounting when the delivered item has value to the customer on a stand-alone basis. Items are considered to have stand-alone value when they are sold separately by any vendor or when the customer could resell the item on a stand-alone basis.

The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units. The Company determines the estimated selling price for deliverables within the arrangement using vendor-specific objective evidence (VSOE) of selling price, if available. If VSOE is not available, the Company considers if third-party evidence is available. If third-party evidence of selling price or VSOE is not available, the Company uses its best estimate of selling price for the deliverable.

In order to establish VSOE of selling price, the Company must regularly sell the product or service on a standalone basis with a substantial majority priced within a relatively narrow range. If there are not a sufficient number of standalone sales such that VSOE of selling price cannot be determined, then the Company considers whether third party evidence can be used to establish selling price. Due to the lack of similar products and services sold by other companies within the industry, the Company has not established selling price using third-party evidence.

For product and service sales, the Company determines its best estimate of selling price for instruments, consumables, services and assays using average selling prices over a rolling 12-month period coupled with an assessment of market conditions, as VSOE and third-party evidence cannot be established. The Company recognizes revenue for delivered elements only when it determines there are no uncertainties regarding customer acceptance.

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

2. Significant accounting policies (Continued)

Distributor transactions

In certain markets, the Company sells products and provides services to customers through distributors that specialize in life sciences products. In cases where the product is delivered to a distributor, revenue recognition generally occurs when title transfers to the distributor. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers, except the distributors do not require the Company's services to install the instrument at the end customer and perform the services for the customer that are beyond our standard warranty in the first year following the sale. These transactions are accounted for in accordance with the Company's revenue recognition policy described herein.

Business combinations

Amounts paid for acquisitions are allocated to the assets acquired and liabilities assumed, if any, based on their fair values at the dates of acquisition. The fair value of identifiable intangible assets is based on detailed valuations that use information and assumptions determined by management. Any excess of purchase price over the fair value of the net tangible and intangible assets acquired is allocated to goodwill.

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.

Restricted Cash

Restricted cash represents collateral for a letter of credit issued as security for the lease for the Company's new headquarters. 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, 2018.

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 Labs on behalf of the customers, costs related to instrument maintenance and servicing equipment at customer sites, other direct and overhead.

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

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****2. Significant accounting policies (Continued)****Research and development expenses**

Research and development expenses, including personnel costs, allocated facility costs, lab supplies, outside services, contract laboratory cost 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.

Selling, general, and administrative expense

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 net loss attributable to common stockholders by the weighted-average number of common shares. For purposes of the diluted net loss per share calculations, preferred stock, unvested restricted common stock, and common stock options 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 set 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):

	<u>Year Ended December 31,</u>		
	<u>2018</u>	<u>2017</u>	<u>2016</u>
Series A redeemable convertible preferred stock	—	—	4,884,869
Series B redeemable convertible preferred stock	—	—	1,873,561
Series C redeemable convertible preferred stock	—	—	2,677,649
Series D redeemable convertible preferred stock	—	—	3,864,421
Unvested restricted common stock	361,468	177,192	376,248
Outstanding stock options	2,476,911	2,249,843	1,119,671
Outstanding preferred warrants	—	—	326,374
Outstanding common stock warrants	76,041	86,090	—
Total	<u>2,914,420</u>	<u>2,513,125</u>	<u>15,122,793</u>

As of December 31, 2018, 2017, and 2016 the Company had an obligation to issue warrants to purchase an additional 93,341 shares of common stock, 300,000 shares of Series A-3 Preferred Stock, and 300,000 shares of Series A-3 Preferred Stock, respectively, to a vendor if a contract is terminated prior to a minimum purchase commitment being met. Upon completion of the IPO in December 2017, the warrants to purchase shares of Preferred Stock were converted to warrants to purchase shares of common stock at a one-for-3.214 basis. No amounts are presented in the table above for this obligation to issue a warrant as the issuance of the warrant is not considered probable.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****2. Significant accounting policies (Continued)**

The Company's redeemable convertible preferred stock was entitled to receive dividends based on dividends declared to common stockholders, thereby giving the preferred stockholders the right to participate in undistributed earnings of the Company above the stated dividend rate. However, preferred stockholders did not have a contractual obligation to share in the net losses of the Company. The Company operated in a net loss position for the years ended December 31, 2018, 2017, and 2016 and, therefore the Company's accounting for basic and diluted earnings per share was unaffected by the participation rights of the preferred stockholders.

Cash and Cash equivalents

Cash and Cash equivalents consists 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 consists of the following (in thousands):

	Year Ended December 31,	
	2018	2017
Cash and Cash Equivalents		
Cash	\$ 1,821	\$ 1,500
Money Market funds invested in U.S. Treasury obligations	42,608	78,182
Total cash and cash equivalents	<u>\$ 44,429</u>	<u>\$ 79,682</u>

Restricted cash and deposits

As of December 31, 2018 and 2017, the Company had \$1.4 million and \$0.4 million, respectively, in restricted cash and deposits related to amounts held for a line of credit, amounts held as a security deposit for the Company's facility lease obligation, and a business registration application. \$1.0 million of the \$1.4 million is recorded on a separate line item as restricted cash. The remaining \$0.4 million is included in current and noncurrent assets.

Accounts Receivable and allowance for doubtful accounts

The Company provides credit, in the normal course of business, to customers and does not require collateral. Accounts receivable consist of amounts due to the Company for sales to customers and are recorded net of an allowance for doubtful accounts. The Company reviews accounts receivable on a regular basis to determine if any receivable will potentially be uncollectable and to estimate the amount of allowance for doubtful accounts necessary. Once a receivable is deemed uncollectible, such balance is written off and charged against the allowance for doubtful accounts. The Company has not incurred material write offs in any of the periods presented.

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.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****2. Significant accounting policies (Continued)****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

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.

Investments

During the third quarter of 2016, the Company purchased a minority interest in preferred stock in a privately held company for \$0.3 million. In addition, in the third quarter of 2018, the Company executed a convertible note with a privately held company for \$0.2 million. The investments are recorded on a cost basis in other non-current assets on the accompanying consolidated balance sheets as the Company does not have a controlling investment, does not have the ability to exercise significant influence over the privately held company and the fair value of these equity investments are not readily determinable. The Company performs an impairment analysis at each reporting period to determine if the carrying value of the investment or the note must be reduced due to a decrease in the value of the investment, which includes consideration of whether an event or change in circumstances has occurred that may have a significant adverse effect on the fair value of the investment. The Company determined there was no impairment during the years ended December 31, 2018, 2017, and 2016.

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

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****2. Significant accounting policies (Continued)**

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. The Company has an investment in the preferred stock of a privately held company which is recorded within other non-current assets on a cost basis. This cost method investment's fair value has not been estimated as there are no identified events or changes in circumstances that would indicate a significant adverse effect on the fair value of the investment and to do so would be impractical.

Fair value measurements as of December 31, 2018 are as follows (in thousands):

Description	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Financial Assets				
Cash Equivalents	\$ 42,608	\$ 42,608	—	\$ —
Note receivable	150	—	—	150
Total	\$ 42,758	\$ 42,608	—	\$ 150

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

2. Significant accounting policies (Continued)

Fair value measurements as of December 31, 2017 are as follows (in thousands):

<u>Description</u>	<u>Total</u>	<u>Quoted prices in active markets (Level 1)</u>	<u>Significant other observable inputs (Level 2)</u>	<u>Significant unobservable inputs (Level 3)</u>
Financial Assets				
Cash Equivalents	\$ 78,182	\$ 78,182	—	—
Total	\$ 78,182	\$ 78,182	—	—

As of January 1, 2016, the Company had outstanding warrants to purchase 64,441 shares of Series A-2 redeemable convertible preferred stock (Series A-2 Preferred Stock), 1,300,000 shares of Series A-3 convertible preferred stock (Series A-3 Preferred Stock), 562,488 shares of Series B redeemable convertible preferred stock (Series B Preferred Stock), and 226,733 shares of Series C redeemable convertible preferred stock (Series C Preferred Stock). During the years ended December 31, 2017, and 2016, the Company issued the following warrants:

- On January 29, 2016, the Company issued a warrant to purchase 57,810 shares of Series C Preferred Stock to a lender related to a second amendment to a debt facility (Note 8)
- On November 18, 2016, the Company issued a warrant to purchase 700,000 shares of Series A-3 Preferred Stock to a vendor (Note 7).
- On March 31, 2017, the Company issued a warrant to purchase 38,828 shares of Series D redeemable convertible preferred stock (Series D Preferred Stock) to a lender as part of a third amendment to a debt facility (Note 8).

All of the warrants were initially recorded as a preferred stock warrant liability on the accompanying consolidated balance sheets at fair value. Warrants issued for goods or services are initially accounted for under ASC 505-50 and are recognized over the required performance period in the consolidated statements of operations or consolidated balance sheets at the vesting date or reporting date fair value based on the nature of the underlying arrangement. Warrants issued in connection with a product development contract were recorded to research and development expense. Warrants issued in connection with a revenue arrangement were recorded as a reduction in revenue. Warrants issued in connection with debt arrangements were recorded as a reduction in the carrying value of debt. They are marked to market on each reporting and exercise date with changes in the fair value recorded in other expense (income) on the statement of operations and comprehensive loss. Holders of warrants to purchase 700,000 shares of Series A-3 Preferred stock, and holders of warrants to purchase 111,114 shares of Series C Preferred Stock exercised the warrants during the year ended December 31, 2017. Upon exercise, the fair value of the warrants was reclassified to redeemable convertible preferred stock along with any proceeds received. Upon completion of the IPO, the outstanding warrants to purchase shares of preferred stock were automatically converted into warrants to purchase shares of common stock and are therefore accounted for as equity instruments.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****2. Significant accounting policies (Continued)**

The changes in preferred stock warrant liability measured at fair value for which the Company has used Level 3 inputs to determine fair value are as follows (in thousands):

	<u>Warrant liability</u>
Balance at December 31, 2015	\$ 5,547
Issuance of warrants related to debt facility	128
Issuance of warrants related to a vendor	2,078
Changes in fair value of warrants	307
Warrant exercises	<u>(5,258)</u>
Balance at December 31, 2016	2,802
Issuance of warrants related to debt facility	119
Changes in fair value of warrants	90
Warrant exercises	<u>(2,188)</u>
Conversion to warrants to purchase common stock in connection with IPO	<u>(823)</u>
Balance at December 31, 2017	<u>\$ —</u>

Prior to the completion of the IPO, the warrants were classified as liabilities because they were exercisable for shares of redeemable convertible preferred stock. On each measurement date and immediately prior to the IPO and the resulting change in classification of the warrants to equity instruments, the Company utilized a black-scholes option pricing model to determine the fair value of the warrants and utilized various valuation assumptions based on available market data and other relevant but unobservable factors. Expected volatility for the Company's redeemable convertible preferred stock was determined based on an analysis of the historical volatility of a representative group of guideline public companies because, prior to the IPO, there was no market for the Company's common stock and, therefore, a lack of market-based company-specific historical and implied volatility information. The expected term reflects the remaining contractual term of the warrants. The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future. The risk-free rate is based upon the U.S. Treasury yield curve in effect at the valuation date, commensurate with the remaining contractual life of the warrants. The fair value of the underlying preferred shares was determined by management, with the assistance of a third party valuation specialist, using a hybrid valuation method, which includes a probability weighted analysis of two scenarios. The first scenario was based on the completion of an initial public offering utilizing a market approach and the second scenario was based on the Company remaining privately held utilizing either an income approach or a weighted-average of an income approach and a backsolve to a recent financing event, depending on the proximity of the financing event to the measurement date. The assumption regarding the Company's probability of completing an initial public offering was the primary contributing factor to the changes in fair value of the underlying preferred stock. See "Stock-based Compensation" section of this "Significant Accounting Policies" (Note 2) for discussion of the changes of the probability of completing an initial public offering.

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

2. Significant accounting policies (Continued)

The following assumptions were utilized to determine the fair value of each warrant to purchase preferred stock at each reporting period and as of the change from liability to equity accounting treatment of the warrants in connection with the IPO:

<u>Balance sheet date</u>	<u>Value of underlying Series D preferred stock</u>	<u>Value of underlying Series C preferred stock</u>	<u>Value of underlying Series B preferred stock</u>	<u>Value of underlying Series A-3 preferred stock</u>	<u>Value of underlying Series A-2 preferred stock</u>	<u>Volatility</u>	<u>Probability of an initial public offering</u>
December 7, 2017	\$4.67	\$ 4.67	N/A	\$ 4.67	\$ 4.67	46%	100%

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, 2018 and 2017 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

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****2. Significant accounting policies (Continued)**

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 40% and 34% of the Company's gross trade accounts receivable balance as of December 31, 2018 and 2017 respectively.

At December 31, 2018, no single customer represented 10% of the Company's aggregate accounts receivable, and no single customer represented 10% of the Company's revenue for the year ended December 31, 2018. At December 31, 2017, one customer's accounts receivable balance was 16% of the Company's aggregate accounts receivable no single customer represented 10% of the Company's revenue for the year ended December 31, 2017. At December 31, 2016, one customer's account receivable balance was 26% of the Company's aggregate accounts receivable and represented 11% of the Company's revenue for the year ended December 31, 2016.

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 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.

Net revenue by product and service line are as follows (in thousands):

	Year ended December 31,		
	2018	2017	2016
Product revenue	\$ 23,365	\$ 14,124	\$ 10,601
Service and other revenue	12,117	7,676	5,012
Collaboration and license revenue	2,150	1,074	1,972
Total revenue	<u>\$ 37,632</u>	<u>\$ 22,874</u>	<u>\$ 17,585</u>

The following table reflects total revenue (in thousands) by geography and as a percentage of total revenue, based on the billing address of our customers. North America consists of the United States, Canada and Mexico; EMEA consists of Europe, Middle East, and Africa; and Asia Pacific includes Japan, China, South Korea, Singapore, Malaysia and Australia.

	Year ended December 31,					
	2018		2017		2016	
North America	\$ 22,706	60%	\$ 13,864	61%	\$ 13,018	74%
EMEA	11,742	31%	6,922	30%	3,416	19%
Asia Pacific	3,184	8%	2,088	9%	1,151	7%
Total	<u>\$ 37,632</u>	<u>100%</u>	<u>\$ 22,874</u>	<u>100%</u>	<u>\$ 17,585</u>	<u>100%</u>

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

2. Significant accounting policies (Continued)

Stock-based compensation

The Company accounts for stock-based compensation awards in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 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 adoption of ASU 2016-09 on January 1, 2017, the Company recognized compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. Effective January 1, 2017, the Company ceased utilizing an estimated forfeiture rate and began recognizing 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 Company recognizes compensation costs related to share-based payments granted to non-employees based on the estimated fair value of the awards on the date of grant in the same manner as options for employees; however, the fair value of the stock options granted to non-employees is re-measured each reporting period until the service is complete, and the resulting increase or decrease in value, if any, is recognized as expense or income, respectively, during the period the related services are rendered to the same financial statement line item as any cash consideration would be recognized. There were no material non-employee awards outstanding during the years ended December 31, 2018, 2017, and 2016.

The fair value of stock options granted to employees and directors for their services on the Company's Board of Directors 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,		
	2018	2017	2016
Risk-free interest rate	2.6% - 3.0%	1.8% - 2.1%	1.2% - 1.3%
Expected dividend yield	None	None	None
Expected term (in years)	5.9	6.0	6.0
Expected volatility	32.4% - 36.8%	46.0% - 52.0%	44.9% - 49.0%

Using the Black-Scholes option-pricing model, the weighted-average grant date fair value of options granted for the years ended December 31, 2018, 2017, and 2016 was \$7.19, \$4.52, and \$2.41 per share, respectively. Expected volatility was calculated based on reported volatility data for a representative group of guideline publicly traded companies for which historical information was available. 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. The Company estimates 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 the Company does not expect substantially

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****2. Significant accounting policies (Continued)**

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 life 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. Prior to the completion of the IPO, the fair value of the underlying common shares was determined by management, with the assistance of a third party valuation specialist, using a hybrid valuation method, which includes a weighted analysis of two scenarios. The first scenario is based on the completion of an initial public offering utilizing a market approach and the second scenario is based on the Company remaining privately held utilizing either an income approach or a weighted-average of an income approach and a backsolve to a recent financing event approach, depending on the proximity of the financing event to the measurement date. The initial public offering scenario reflected data gathered from relevant comparable initial public offering transactions and the current value method of equity allocation was used in determining the value of common stock. For the privately held scenario, traditional income methods of business valuation were employed, where the total equity value was then allocated using the option pricing model (OPM). The assumption regarding the Company's probability of completing an initial public offering was the primary contributing factor to the changes in fair value of the common stock. The probability of initial public offering was 40% at December 31, 2016. Since December 31, 2015, the Company had performed the common stock valuations on a quarterly basis. Upon completion of the IPO in December 2017, the Company determines the fair value of the underlying common shares based on the closing price of the common stock on the option grant date.

The probability of completing an initial public offering was based on the facts and circumstances as of each measurement date. During the three months ended December 31, 2016, the Company began initial preparations for completing an initial public offering; including assessing quarterly financial information and holding initial discussions with prospective investment bankers, which resulted in an increase in the probability of completing an initial public offering. Subsequent to March 31, 2017, the Company obtained approval from the Board of Directors to pursue the transaction, selected investment bankers, held an organizational meeting, and performed other procedures necessary to complete an initial public offering. As a result, the probability of completing an initial public offering increased subsequent to March 31, 2017.

The Company is using the straight-line attribution method to recognize stock-based compensation expense for service based awards for employees and non-employees. However, cumulative compensation expense recognized through the end of any period must at least equal the value of vested awards through that period, with compensation expense adjusted accordingly. For the year ended December 31, 2016, the amount of stock-based compensation expense recognized during a period was based on the value of the portion of the awards that were ultimately expected to vest. Prior to January 1, 2017, forfeitures were estimated at the time of grant, and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. During the year ended December 31, 2016, the Company applied an estimate of forfeitures which did not have a material effect on the consolidated financial statements. Effective January 1, 2017, the Company adopted Accounting Standards Update (ASU) 2016-09 *Stock Compensation*, and has elected to account for forfeitures as incurred and therefore no forfeiture estimate is utilized in the years ended December 31, 2018 and 2017. The effect of this adoption has been recorded as a \$0.1 million cumulative effect adjustment to accumulated deficit as of January 1, 2017.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****2. Significant accounting policies (Continued)**

The Company applies an accelerated attribution method to recognize stock-based compensation expense when accounting for performance-based stock awards. The Company records the expense for stock-based compensation awards subject to performance-based milestone vesting over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the expected satisfaction of the performance conditions as of the reporting date. Compensation expense for performance-based stock awards is included in total stock-based compensation expense. There were no material performance-based stock awards outstanding as of December 31, 2018, 2017, and 2016.

Recent accounting pronouncements

The Company is considered to be an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act). The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has elected to avail itself of this extended transition period and, as a result, the Company will not be required to adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies so long as the Company remains an emerging growth company.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (ASC 606). The FASB has issued several updates to the standard which clarify the (i) application of the principal versus agent guidance; (ii) guidance relating to performance obligations and licensing; (iii) assessment of the collectability criterion, presentation of sales taxes, measurement date for non-cash consideration and completed contracts at transition; and (iv) narrows aspects of ASC 606 or corrects unintended application of the guidance (collectively, the Revenue ASUs). The Revenue ASUs provide an accounting standard for a single comprehensive model for recognizing revenue arising from contracts with customers. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In conjunction with the new revenue standard, the FASB also amended the guidance under ASC 340-40, *Other Assets and Deferred Costs—Contracts with Customers*, related to the accounting for costs to obtain or fulfill a contract with a customer. The Company will adopt the new revenue standard as of January 1, 2019 using the modified retrospective method. The Company is still in the process of quantifying the impact of the standard.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). The standard changes how entities measure certain equity investments and present changes in the fair value of financial liabilities measured under the fair value option that are attributable to their own credit. Under the new guidance, entities will be required to measure equity investments that do not result in consolidation and are not accounted for under the equity method at fair value and recognize any changes in fair value in net income unless the investments qualify for the new practicability exception. The Company's assessment is in progress and has not yet concluded on the impact of the standard.

In February 2016, the FASB established Topic 842, *Leases*, by issuing ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****2. Significant accounting policies (Continued)**

arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. The new standard establishes a right-of-use model ("ROU") that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. The new standard is effective for us on January 1, 2020, with early adoption permitted. We expect to adopt the new standard on January 1, 2020 and use the effective date as our date of initial application.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, to address diversity in how certain cash receipts and cash payments are presented and classified in the statements of cash flows. The amendments are effective for the Company for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The amendments should be applied using a retrospective transition method to each period presented. If retrospective application is impractical for some of the issues addressed by the update, the amendments for those issues would be applied prospectively as of the earliest date practicable. As the Company avails itself to the extended transition period as an emerging growth company under the JOBS Act, the new standard is effective for fiscal years beginning after December 15, 2018 and interim periods within fiscal years beginning after December 15, 2019. The Company's assessment is in progress and has not yet concluded on the impact of the standard.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash (ASU 2016-18)*, requiring restricted cash and cash equivalents to be included in the statement of cash flows. As the Company avails itself of the extended transition period as an emerging growth company under the JOBS Act, the new standard is effective for fiscal years beginning after December 15, 2018 and interim periods within fiscal years beginning after December 15, 2019. The Company elected to early adopt this standard in the statement of cash flows for the year ended December 31, 2018.

In January 2017, the FASB issued ASU No. 2017-04 *Intangibles—Goodwill and Other (Topic 350)—Simplifying the Test for Goodwill Impairment*. This ASU eliminates Step 2 from the goodwill impairment test. In addition, income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit should be considered when measuring the goodwill impairment loss, if applicable. The amendments also eliminate the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. This ASU is effective for annual periods beginning after December 15, 2019 and interim periods within those annual periods. Early adoption is permitted, for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company does not expect adoption of this ASU to be material to its financial statements on known trends, demands, uncertainties and events in its business.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820), Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*". This ASU removed the following disclosure requirements: (1) the amount of and reasons for transfers between

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****2. Significant accounting policies (Continued)**

Level 1 and Level 2 of the fair value hierarchy; (2) the policy for timing of transfers between levels; and (3) the valuation processes for Level 3 fair value measurements. Additionally, this update added the following disclosure requirements: (1) the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period; (2) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. For certain unobservable inputs, an entity may disclose other quantitative information (such as the median or arithmetic average) in lieu of the weighted average if the entity determines that other quantitative information would be a more reasonable and rational method to reflect the distribution of unobservable inputs used to develop Level 3 fair value measurements. ASU No. 2018-13 will be effective for fiscal years beginning after December 15, 2019 with early adoption permitted. As of December 31, 2018, the Company has not elected to early adopt this guidance but does not expect that the adoption of this guidance will have a material effect on its consolidated financial statements.

3. Inventory

Inventory consists of the following (in thousands):

	As of December 31,	
	2018	2017
Raw materials	\$ 1,546	\$ 1,032
Work in process	2,331	968
Finished goods	2,068	1,571
Total	<u>\$ 5,945</u>	<u>\$ 3,571</u>

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,	
	2018	2017
Laboratory and manufacturing equipment	\$ 4,127	\$ 2,969
Office furniture and equipment	789	689
Computers and software	786	459
Leasehold improvements	244	180
	<u>5,946</u>	<u>4,297</u>
Less: accumulated depreciation	(3,023)	(2,423)
Total	<u>\$ 2,923</u>	<u>\$ 1,874</u>

The Company incurred depreciation expense of \$0.7 million, and \$0.5 million for the years ended December 31, 2018 and 2017, respectively. Included in Laboratory and manufacturing equipment are

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****4. Property and equipment (Continued)**

27 instruments, which are internally used by the Company. The laboratory & manufacturing equipment balance includes \$1.4 million of cost and \$0.7 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,	
	2018	2017
Accrued inventory	\$ 599	\$ 835
Accrued royalties	323	221
Accrued professional services	723	346
Accrued development costs	795	1,559
Accrued other	689	599
Total accrued expenses	<u>\$ 3,129</u>	<u>\$ 3,560</u>

6. Income Taxes

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

	Year Ended December 31,		
	2018	2017	2016
United States	\$ (31,436)	\$ (27,019)	\$ (23,173)
Foreign	(75)	—	—
	<u>\$ (31,511)</u>	<u>\$ (27,019)</u>	<u>\$ (23,173)</u>

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

6. Income Taxes (Continued)

The following table summarizes the provision for (benefit from) income taxes (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Current:			
United States			
Federal	\$ —	\$ —	\$ —
State	18	—	—
Foreign	—	—	—
Total current income tax provision	<u>18</u>	<u>—</u>	<u>—</u>
Deferred			
United States			
Federal	2	—	—
State	5	—	—
Foreign	—	—	—
Total deferred income tax provision (benefit)	<u>7</u>	<u>—</u>	<u>—</u>
Total income tax provision (benefit)	<u>\$ 25</u>	<u>\$ —</u>	<u>\$ —</u>

During the years ended December 31, 2018 and 2017, the Company recorded an income tax provision of \$25 and \$0 thousand, respectively. During the years ended December 31, 2018, 2017 and 2016, the Company recorded no income tax benefits for any net losses incurred and the tax credits generated in each year, due to its uncertainty of realizing a benefit from those items.

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

	Year Ended December 31,	
	2018	2017
Federal statutory income tax rate	21.0%	34.0%
State taxes, net of federal tax benefit	6.0%	4.8%
Stock compensation	1.1%	0.0%
Permanent items	-1.2%	-1.6%
Tax Credits	2.7%	2.6%
Foreign differential	0.0%	0.0%
U.S. Tax Reform	0.0%	-53.2%
Other, net	0.2%	-1.1%
Valuation Allowance	-29.9%	14.5%
Effective income tax rate	<u>-0.1%</u>	<u>0.0%</u>

The significant reconciling items between the reported amounts of income tax expense for the year to the amount of income tax expense that would result from applying the U.S. statutory tax rate to pre-tax income include state taxes, non-deductible expenses, stock based compensation tax benefits, tax credits, and the valuation allowance maintained against certain of the Company's deferred tax assets.

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

6. Income Taxes (Continued)

During 2018, the Company acquired Aushon Biosystems. The Company analyzed the transaction from an income tax perspective and adjusted the deferred tax assets and liabilities related to the Aushon Biosystems acquisition. Of the total goodwill recorded, approximately \$0.4 million is amortizable related to historical tax basis that Aushon had related to a prior acquisition.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Act") was signed into law, making significant changes to the Internal Revenue Code. Changes included, but were not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, the transition of U.S international taxation from a worldwide tax system to a territorial system, and a one-time transition tax on the mandatory deemed repatriation of cumulative deferred foreign earnings as of December 31, 2017. On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued, which directed taxpayers to consider the impact of the Act as "provisional" when a registrant did not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. During the fourth quarter of 2018 the Company completed its accounting for the tax effects of the Act and recorded no adjustments in its consolidated financial statements.

A valuation allowance is provided when it is more likely than not that all or a portion of the deferred tax asset will not be realized. Realization of deferred tax assets is dependent upon future taxable income, if any, the amount and timing of which are uncertain. The Company maintains a valuation allowance against its net U.S. and foreign deferred tax assets as a result of the negative evidence associated with its history of operating losses.

Deferred tax assets and liabilities reflect the net tax effects of net operating loss carryovers and temporary differences between the carrying amount of assets and liabilities for financial reporting and

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

6. Income Taxes (Continued)

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,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	\$ 35,623	\$ 27,952
Research and development credits	4,678	3,637
Deferred revenue	1,614	1,795
Depreciation	86	629
Amortization	792	—
Stock compensation	541	185
Other deferred tax assets	1,378	614
Total deferred tax assets	44,712	34,812
Valuation allowance	(44,033)	(34,552)
Subtotal	679	260
Section 481(a) Adjustment—Accrued Bonus	(59)	(118)
Amortization	(610)	—
Goodwill	(17)	
Stock-based compensation		(142)
Net deferred tax assets (liability)	\$ (7)	\$ —

As of December 31, 2018, the Company had federal and state net operating loss carryforwards of \$136.8 million and \$108.8 million, respectively. \$0.9 million of the federal net operating loss carryforwards relates to the acquisition of Aushon Biosystems and these losses have been reduced to reflect the limitations on these losses as a result of Section 382 of the Internal Revenue Code. These carryforwards begin to expire in 2026 and 2019, respectively. As of December 31, 2018, the Company had federal and state credit carryforwards of \$3.8 million and \$1.2 million, respectively. These carryforwards begin to expire in 2026 and 2019, respectively. As of December 31, 2018, the Company had foreign net operating loss carryforwards of \$75 thousand. Of this amount, carryforwards of \$75 thousand expire in 2027.

The Company recognizes a deferred tax asset for the future benefit of tax loss carryforwards, tax credit carryforwards, and other deductible temporary differences to the extent that it is more likely than not that these assets will be realized. In evaluating the Company's ability to recover these deferred tax assets, the Company considers all available positive and negative evidence, including its past operating results, taxable income in carryback years, the projected reversal of existing deferred tax liabilities, the availability of tax planning strategies and its forecast of future taxable income. Based on the significant negative evidence, including the three-year cumulative loss position, the Company concluded that its net U.S. deferred tax assets as well as the deferred tax assets in certain foreign subsidiaries were not more likely than not realizable and maintained a full valuation allowance against these deferred tax assets at December 31, 2018.

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

6. Income Taxes (Continued)

The valuation allowance increased by \$9.4 million during the year ended December 31, 2018, primarily as a result of the U.S. operating losses incurred, the research and development tax credit carryforwards generated during the year and acquisition of Aushon Biosystems, Incorporated.

The valuation allowance decreased by \$3.9 million during the year ended December 31, 2017. The decrease in valuation allowance was primarily the result of the impact of the U.S. corporate tax rate reduction enacted during 2017, which resulted in the Company remeasuring its deferred tax assets and liabilities at the lower 21% U.S. federal corporate tax rate and a corresponding reduction in the valuation allowance. This reduction was partially offset by the valuation allowance established in 2017 related to U.S. and foreign operating losses incurred and tax credits generated during the year.

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 net operating loss carryforwards 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. 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 net operating loss carryforwards, or other pre-change tax attributes, to offset U.S. federal and state taxable income and taxes may be subject to significant limitations.

In the ordinary course of business, there is inherent uncertainty in quantifying the Company's income tax positions. The Company assesses income tax positions and records tax benefits for all years subject to examination based upon management's evaluation of the facts, circumstances, and information available at the reporting date. For those tax positions for which it is more likely than not that a tax benefit will be sustained, the Company recorded the largest amount of tax benefit with a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority that has full knowledge of all relevant information. For those income tax positions for which it is not more likely than not that a tax benefit will be sustained, no tax benefit has been recognized in the consolidated financial statements.

The Company accounted for uncertain tax positions using a more likely than not threshold for recognizing and resolving 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 annual 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 part of its provision for income taxes. For the years ended December 31, 2018, 2017 and 2016, there were no accrued interest or penalties in the consolidated statements of operations and comprehensive loss. The Company does not anticipate any significant changes in the next twelve months associated with its liability for unrecognized tax benefits.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****6. Income Taxes (Continued)**

The Company is subject to taxation in the United States as well as the Netherlands and China. At December 31, 2018, the Company is generally no longer subject to examination by taxing authorities in the United States for years prior to 2015. However, net operating loss carryforwards 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 2018 onward.

The Company's foreign subsidiary has incurred losses since inception, and the Company had immaterial undistributed earnings as of December 31, 2018.

7. Redeemable convertible preferred stock

The Company had authorized 47,015,449 shares of preferred stock, \$0.001 par value per share, of which 3,972,415 shares were designated Series A-1 redeemable convertible preferred stock (Series A-1 Preferred Stock), 10,492,027 shares were designated Series A-2 Preferred Stock, 2,000,000 shares were designated Series A-3 Preferred Stock, 6,186,594 shares were designated Series B Preferred Stock, 9,247,089 shares were designated as Series C Preferred Stock, 544,332 shares were designated Series C-1 redeemable convertible preferred stock (Series C-1 Preferred Stock), 12,459,090 shares were designated Series D Preferred Stock and 2,113,902 were designated Series D-1 redeemable convertible preferred stock (Series D-1 Preferred Stock) as of immediately prior to the completion of the IPO.

In February 2016, the Company issued 1,300,000 shares of Series A-3 Preferred Stock to a vendor (Note 8) upon the exercise of Series A-3 Preferred Stock warrants at a purchase price of \$0.001 per share. The fair value of the settled warrant was \$3.9 million at the time of exercise which was reclassified from Preferred Stock Warrant Liability to Series A Preferred Stock.

In March 2016, the Company issued 12,420,262 shares of Series D Preferred Stock at a purchase price of \$3.67 per share. The issuance resulted in cash proceeds of \$45.4 million, net of issuance costs.

In June and July 2016, the Company issued 397,530 shares of Series B Preferred Stock upon exercise of Series B Preferred Stock warrants, which included 312,500 shares of Series B Preferred Stock at a purchase price of \$0.001 per share, 8,330 shares of Series B Preferred Stock at purchase price of \$2.00 per share, and 76,700 shares of Series B Preferred Stock upon a cashless exercise of a warrant. The fair value of the settled warrants was \$1.4 million at the time of exercise which was reclassified from Preferred Stock Warrant Liability to Series B Preferred Stock.

In January 2017, the Company issued 700,000 shares of Series A-3 Preferred Stock to a vendor (Note 8) upon the exercise of Series A-3 Preferred Stock warrants at a purchase price of \$0.001 per share. The fair value of the settled warrant was \$2.1 million at the time of exercise which was reclassified from Preferred Stock Warrant Liability to Series A Preferred Stock.

In June 2017, the Company issued 2,113,902 shares of Series D-1 Preferred Stock at a purchase price of \$4.021 per share. The issuance resulted in cash proceeds of \$8.4 million, net of issuance costs.

In November 2017, the Company issued 31,283 shares of Series C Preferred Stock upon exercise of Series C Preferred Stock warrants, which included 8,474 shares of Series C Preferred Stock at a purchase price of \$3.3299 per share, and 22,809 shares of Series C Preferred Stock upon a cashless exercise of a warrant. The fair value of the settled warrants was \$0.1 million at the time of exercise which was reclassified from Preferred Stock Warrant Liability to Series C Preferred Stock.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****7. Redeemable convertible preferred stock (Continued)**

The Company had a Stock Purchase Agreement (SPA) with bioMérieux, a related party, which required the Company to issue additional shares of Series C Preferred Stock if certain milestones were met in exchange for \$10.0 million in gross proceeds. The milestones were related to activities under a Joint Development and License Agreement (JDLA) (Note 12). bioMérieux also purchased Series C Preferred Stock when the JDLA was entered into in 2012. When the SPA was entered into, the Company evaluated whether the requirement to issue additional shares ("Tranche Feature") required separate accounting. The Company determined that the Tranche Feature was not legally detachable and therefore was an embedded feature in the Series C Preferred Stock that bioMérieux purchased.

During the year ended December 31, 2015, the Company amended the terms of the SPA which restructured the equity milestone from one payment of \$10.0 million to three separate payments (\$5.0 million; \$3.0 million and \$2.0 million) based on components of the initial technical milestones. No other terms of the Series C Preferred Stock changed. The Company achieved the first milestone in January 2015 at which time bioMérieux purchased 1,501,546 shares of Series C Preferred Stock at a price of \$3.3299 for total gross proceeds of \$5.0 million. The Company also achieved the second milestone in May 2015 at which time bioMérieux purchased 600,618 shares of Series C Preferred Stock at a price of \$3.3299 for total gross proceeds of \$2.0 million. In December 2016, the Company further amended the JDLA and SPA which cancelled the third and final milestone (Note 12).

The rights, preferences, and privileges of Series A-1, A-2, A-3, B, C, C-1, D, and D-1 Preferred Stock were as follows:

Conversion

Shares of Series A-1, A-2, A-3, B, C, C-1, D, and D-1 Preferred Stock were convertible into common stock on a 3.214-for-one basis, adjustable for certain dilutive events. Conversion was at the option of the preferred stockholders, although conversion was automatic upon the earlier of the consummation of an initial public offering, resulting in gross proceeds to the Company of at least \$40.0 million and for a minimum per-share amount of \$5.00 per share, or the approval of a Preferred Majority, defined as 60% of the outstanding shares of Series A-1, A-2, B, C, D, and D-1 Preferred Stock voting as a single class.

Dividends

Holder of the Series A-1, A-2, B, C, and C-1 Preferred Stock were entitled to receive, before any cash was paid out or set aside for any common stock, cumulative dividends in arrears at the annual rate of \$0.08, \$0.08, \$0.16, \$0.2664, and \$0.2664 per share, respectively, subject to adjustment for stock splits, stock dividends, combinations and reorganizations. Holders of Series D, and D-1 Preferred Stock were entitled to receive non-cumulative dividends at the rate of \$0.2936, and \$0.3217 per share, respectively, subject to adjustment for stock splits, when and if declared by the Board of Directors of the Company. The cumulative accrued dividends as of immediately prior to the completion of the IPO were \$3.3 million, \$7.8 million, \$5.7 million, \$9.5 million, and \$0.7 million for Series A-1, A-2, B, C and C-1 Preferred Stock, respectively. Holders of Series A-3 Preferred Stock were not entitled to receive any preferred stock dividends. Upon full payment of preferred dividends, additional dividends would have been shared among all preferred stock holders and common stock holders on a pro rata basis.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****7. Redeemable convertible preferred stock (Continued)****Liquidation preference**

Holders of the Series A-1, A-2, A-3, B, C, C-1, D, and D-1 Preferred Stock had preference in the event of a liquidation or dissolution of the Company equal to \$1.0416667, \$1.0416667, \$2.00, \$2.00, \$3.3299, \$3.3299, \$3.67, and \$4.021 per share, respectively, plus any accrued but unpaid dividends. In any liquidation event, Series D and D-1 Preferred Stock holders would receive first priority in liquidation payments. In the event that the amounts available for distribution were insufficient to pay the full amounts, the assets would be distributed ratably among Series D, and D-1 Preferred Stock holders in proportion to their aggregate liquidation preference amounts until such amounts were paid full. Series B, C, and C-1 Preferred Stock holders would receive next priority in liquidation payments after Series D Preferred Stock holders. In the event that the amounts available for distribution were insufficient to pay the full amounts, the assets would be distributed ratably among B, C, and C-1 Preferred Stock holders in proportion to their aggregate liquidation preference amounts. Series A-1, A-2, and A-3 Preferred Stock holders would receive next priority in liquidation preference after Series B, C, and C-1 Preferred Stock holders. In the event that the amounts available for distribution after payment were insufficient to pay the full amounts, the assets would be distributed ratably among A-1, A-2, and A-3 Preferred Stock holders in proportion to their aggregate liquidation preference amounts. Any remaining amounts would be distributed to holders of common stock on a pro rata basis. However, if the holders of any series of preferred stock would receive a greater liquidation preference if they were converted into shares of common stock immediately prior to the liquidation event, then these shares would receive consideration equal to the amount that would be received if the shares had been converted in common stock in lieu of the applicable liquidation preference.

Voting rights

Holders of the Series A-1, A-2, A-3, B, C, D and D-1 Preferred Stock (Voting Preferred) were entitled to vote as a single class with the holders of common stock, and had one vote for each equivalent common share into which the preferred stock was convertible. A Preferred Majority vote was required in order to amend the Certificate of Incorporation or By-Laws, reclassify common stock or establish another class of stock, create or authorize additional shares of preferred stock, effect a sale, liquidation, or merger of the Company, repurchase or redeem any capital stock, or engage in any action which would adversely affect the holders of the preferred stock.

The holders of the Series A-1, A-2 and B Preferred Stock could elect three members to the Board of Directors, voting as a single class. The holders of the Series C Preferred Stock could elect one member to the Board of Directors. The holders of the Voting Preferred could elect one member to the Board of Directors, voting as a single class.

Holders of Series C-1 Preferred Stock had no voting rights.

Prior to the issuance of Series D Preferred Stock in March 2016, a majority vote of the Series B, C and C-1 Preferred Stock holders could elect to redeem all of the outstanding shares of Series B, C and C-1 Preferred Stock at any time on or after November 14, 2016. The Series A-1 and A-2 Preferred Stockholders had the right to elect to redeem all of the outstanding shares at any time after the redemption of the Series B, C and C-1 Preferred Stock shares was made. The preferred stockholders were entitled to the redemption in three equal annual installments.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****7. Redeemable convertible preferred stock (Continued)**

Upon issuance of the Series D Preferred Stock in March 2016, the redemption rights were adjusted. A majority vote of the Series D Preferred Stockholders could elect to redeem all of the outstanding shares of Series D on or after March 18, 2019. Upon issuance of the Series D-1 Preferred Stock in June 2017 the redemption rights were adjusted. A majority vote of the Series D and D-1 Preferred Stockholders, voting as separate classes, could elect to redeem all of the outstanding shares of Series D and D-1 Preferred Stock on or after June 2, 2020. Holders of the Series C-1, C and B Preferred Stock could only redeem their shares following the redemption in full of all shares of Series D and D-1 Preferred Stock and upon a Preferred Majority Vote. Holders of the Series A-1 and A-2 Preferred Stock could only redeem their shares following the redemption in full of the Series D-1, D, C-1, C and B Preferred Stock, and upon a Preferred Majority Vote. Series A-3 Preferred Stock did not have redemption rights other than in certain deemed liquidation scenarios.

The redemption value of the Series A-1, A-2, B, C and C-1 Preferred Stock was equal to the original issuance price of the preferred stock plus any accrued or declared but unpaid cumulative dividends. The redemption price of the Series D and D-1 Preferred Stock was the greater of (i) the fair market value of the common stock which it was convertible into or (ii) the original issuance price plus all declared but unpaid dividends, which were non-cumulative. As of December 31, 2016, the fair market value of the Company's common stock was less than the original issuance price of the Series D Preferred Stock.

Preferred stock was presented in mezzanine equity. The Series A-1, A-2, B, C, C-1, D and D-1 Preferred Stock were redeemable at the option of the holder at a fixed date and therefore the Company was accreting the preferred stock to its redemption value through the earliest possible redemption date for all issuances where the carrying value is less than the redemption value. The Series A-3 Preferred Stock was redeemable only upon certain deemed liquidation scenarios which were outside of the Company's control. The accretion included the accretion of issuance costs and cumulative preferred stock dividends. Series A-3 Preferred Stock was not entitled to dividends. The Company assessed all terms and features of the preferred stock in order to identify any potential embedded features that would require bifurcation or any beneficial conversion features. As part of this analysis, the Company assessed the economic characteristics and risks of its preferred stock, including conversion and liquidation features, as well as dividend and voting rights. The Company determined that all features of the preferred stock were clearly and closely associated with an equity host, and although the preferred stock included conversion features, such conversion features did not require bifurcation as a derivative liability. On the date of issuance, the fair value of common stock into which the Series A-1, A-2, A-3, B, C, C-1, D and D-1 Preferred Stock was convertible was less than the effective conversion price of the Series A-1, A-2, A-3, B, C, C-1, D and D-1 Preferred Stock and as such, there was no intrinsic value of the conversion option at the commitment date.

Upon completion of the IPO on December 7, 2017 all outstanding shares of Preferred Stock were automatically converted into shares of common stock on a 3.214-for-one basis, resulting in the issuance

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****7. Redeemable convertible preferred stock (Continued)**

of 14,185,744 shares of common stock. Details of the shares of Preferred Stock converted to common stock upon the completion of the IPO by class of Preferred Stock is as follows:

<u>Preferred Stock</u>	<u>Shares of Preferred Stock</u>
A-1	3,972,415
A-2	10,427,586
A-3	2,000,000
B	6,021,636
C	8,092,895
C-1	544,332
D	12,420,262
D-1	2,113,902
Total	45,593,028

Pursuant to the amended and restated certificate of incorporation filed in connection with the IPO in December 2017, the Company authorized 5,000,000 shares of preferred stock. The amended and restated certificate of incorporation authorized our board of directors, without any further stockholder action or approval, to issue these shares in one or more classes or series, to establish from time to time the number of shares to be included in each class or series and to fix the rights, preferences and privileges of the shares of each wholly unissued class or series and any of its qualifications, limitations or restrictions. There was no preferred stock issued or outstanding as of December 31, 2017.

The Company has a class of authorized preferred stock amounting to 5,000,000 shares as of December 31, 2018 and December 31, 2017. The authorized preferred stock was classified under stockholders' equity at December 31, 2018 and December 31, 2017.

Prior to the IPO in December 2017, the Company had multiple classes of preferred stock outstanding. These shares of preferred stock were converted to shares of common stock at the time of the IPO on 1-for-3.214 shares basis. The reconciliation of net loss attributable to common shareholders in the consolidated statement of operations for the year ended December 31, 2017 includes an adjustment for accretion of preferred stock to redemption value.

8. Common Stock, warrants, stock-based compensation, stock options, restricted stock and restricted stock units**Common stock reserved**

The Company reserved the following shares of common stock, on a common stock equivalent basis, for the conversion of shares of preferred stock, the exercise of warrants, the exercise of common stock options, and the vesting of restricted common stock.

	<u>Year ended December 31,</u>	
	<u>2018</u>	<u>2017</u>
Common stock warrants	76,041	86,090
Common stock options and unvested restricted common stock	2,838,402	2,427,035
Shares reserved for future awards under compensation plan	2,433,999	3,500,620
	<u>5,348,442</u>	<u>6,013,745</u>

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

8. Common Stock, warrants, stock-based compensation, stock options, restricted stock and restricted stock units (Continued)

Warrants

The following tables summarize the Company's outstanding warrants as of December 31, 2018, and 2017:

	Issued and exercisable	Weighted Average Exercise Price
As of December 31, 2017	86,090	\$ 9.14
Issued	10,000	4.83
Exercised	(16,718)	11.73
Cancelled	(3,331)	\$ 11.73
As of December 31, 2018	<u>76,041</u>	<u>10.10</u>

The Company has an agreement with a vendor (Note 7) where the Company could be obligated to issue warrants to purchase an additional 93,341 shares of common stock to the vendor if the contract is terminated prior to a minimum purchase commitment being met. No shares have been reserved related to these potential obligations to issue warrants in the future. On January 30, 2018, the company issued a warrant to purchase 10,000 of common stock to a consultation company for services rendered.

Stock-based compensation

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

	Year ended December 31,		
	2018	2017	2016
Cost of product revenue	\$ 55	\$ 24	\$ 6
Cost of service and other revenue	173	52	12
Research and development	513	180	59
General and administrative	4,143	1,912	851
Total	<u>\$ 4,884</u>	<u>\$ 2,168</u>	<u>\$ 928</u>

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. At December 31, 2016, the 2007 Plan allowed for the issuance of up to 3,229,935 shares of common stock. During the three months ended March 31, 2017, the 2007 Plan was amended to allow for the issuance of an additional 622,227 shares of common stock for a total issuance of up to 3,852,213 shares of common stock at June 30, 2017. During the three months ended September 30, 2017 the 2007 Plan was further amended to allow for the issuance of an additional 497,822 shares of common stock for total issuance of up to 4,350,035 shares of common stock at September 30, 2017. As of December 31, 2017, under the 2007 Plan, options to purchase 2,249,843 shares of our common stock were outstanding, 571,838 shares of our common stock had been issued and were outstanding pursuant to the exercise of options, 1,128,975 shares of our common stock had been issued and were outstanding pursuant to

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

8. Common Stock, warrants, stock-based compensation, stock options, restricted stock and restricted stock units (Continued)

restricted or unrestricted stock awards, and 399,379 shares of our common stock were available for future awards. In connection with the completion of the IPO, the Company terminated 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 our common stock represented by awards granted under the 2007 Plan that are forfeited, expire 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 becomes effective. As of December 31, 2018 and 2017, there were shares available for grant under the 2017 Plan of 4,393 and 1,042,314, respectively.

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 1, 2019, the number of shares of common stock available for issuance under the 2017 plan was automatically increased by 895,169 shares.

In December 2017, the Company adopted the 2017 Employee Stock Purchase Plan (the 2017 ESPP). As December 31, 2017, the 2017 ESPP allowed for the issuance of up to 208,463 shares of common stock. As of December 31, 2018, 425,533 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 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. The first offering under the 2017 ESPP began on September 1, 2018.

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

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

8. Common Stock, warrants, stock-based compensation, stock options, restricted stock and restricted stock units (Continued)

remaining three years. These options expire ten years after the grant date. Activity under the 2007 and the 2017 Plans was as follows:

	Options	Weighted- average exercise price	Remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2016	1,119,671	\$ 2.99	6.8	5,796
Granted	1,281,135	\$ 8.46		
Exercised	(90,265)	\$ 2.25		
Cancelled or forfeited	(60,698)	\$ 6.16		
Outstanding at December 31, 2017	2,249,843	\$ 6.05	7.8	34,695
Granted	729,224	\$ 18.36		
Exercised	(407,901)	\$ 4.57		
Cancelled or forfeited	(94,255)	\$ 13.16		
Outstanding at December 31, 2018	2,476,911	\$ 9.65	7.733	\$ 22,108
Vested and expected to vest at December 31, 2018	2,476,911	\$ 9.65	7.733	\$ 22,108
Exercisable at December 31, 2018	1,143,480	\$ 5.68	6.514	\$ 14,440

Using the Black-Scholes option pricing model, the weighted-average fair value of options granted to employees and directors during the years ended December 31, 2018, 2017, and 2016 was \$ 7.19, \$4.52, and \$2.41 per share, respectively. The expense related to awards granted to employees was \$2.7 million, \$1.5 million, and \$0.2 million for the years ended December 31, 2018, 2017, and 2016. The intrinsic value of stock options exercised was \$5.3 million, \$1.1 million, and \$0.4 million, for the years ended December 31, 2018, 2017, and 2016, respectively. Activity related to non-employee awards was not material to the years ended December 31, 2018, 2017, and 2016.

At December 31, 2018, there was \$6.8 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over the remaining weighted-average vesting period of 2.23 years.

Restricted Stock Awards

In December 2014, the Company issued 78,912 shares of restricted common stock to a director of the Company under the 2007 Plan. Under the terms of the agreement, shares of common stock issued are subject to a four year vesting schedule. Vesting occurs periodically at specified time intervals and specified percentages. 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

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

8. Common Stock, warrants, stock-based compensation, stock options, restricted stock and restricted stock units (Continued)

performance conditions are not material. No restricted stock awards were granted during the years ended December 31, 2018 or 2017. A summary of restricted stock activity is as follows:

	Shares	Weighted-average grant date fair value per share
Unvested restricted common stock as of December 31, 2015	623,869	3.12
Vested	(247,621)	3.09
Unvested restricted common stock as of December 31, 2016	376,248	3.12
Vested	(199,056)	3.12
Unvested restricted common stock as of December 31, 2017	177,192	3.11
Vested	(137,386)	3.11
Unvested restricted common stock as of December 31, 2018	39,806	3.12

The expense related to awards granted to employees and directors was \$0.4 million, \$0.6 million, and \$0.7 million for the years ended December 31, 2018, 2017, and 2016, respectively.

At December 31, 2018, there was \$0 million of total unrecognized compensation cost related to unvested restricted stock, which is expected to be recognized over the remaining weighted-average vesting period of 0 years.

The aggregate fair value of restricted stock awards that vested during the years ended December 31, 2018, 2017, and 2016, based on estimated fair values of the stock underlying the restricted stock awards on the day of vesting, was \$2.4 million, \$1.9 million and \$1.1 million, respectively.

Restricted stock units

Restricted stock units represent the right to receive shares of common stock upon meeting specified vesting requirements. In the fiscal year ended December 31, 2018, the Company issued 422,027 restricted stock units to employees of the Company under the 2017 Plan. Under the terms of the agreements, 84,637 of the restricted stock units issued are 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, 18,200 of the restricted stock units issued are subject to vesting with 50% vesting on December 31, 2018 and 50% vesting on December 31, 2019, 3,300 of the restricted stock units are subject to a four year vesting schedule with 25% vesting on each anniversary, 15,890 of the restricted stock units vest on December 31, 2018, 50,000 of the restricted stock units vested on

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

8. Common Stock, warrants, stock-based compensation, stock options, restricted stock and restricted stock units (Continued)

August 31, 2018, and 250,000 of the restricted stock units vest evenly over 40 months on the last day of each month starting September 30, 2018. A summary of restricted stock unit activity is as follows:

	Shares	Weighted-average grant date fair value per share
Unvested restricted stock units as of December 31, 2017	—	
Granted	422,027	\$ 15.65
Vested	(99,990)	\$ 15.02
Cancelled or Forfeited	(375)	\$ 18.40
Unvested restricted stock units as of December 31, 2018	<u>321,662</u>	<u>\$ 15.84</u>

The expense related to awards granted to employees and directors was \$1.7 the fiscal year ended December 31, 2018.

At December 31, 2018, there was \$4.9 million of total unrecognized compensation cost related to unvested restricted stock, which is expected to be recognized over the remaining weighted-average vesting period of 0.6 years.

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 Tuft's 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 year ended December 31, 2016, the Company executed a license agreement with a diagnostic company and also amended the bioMérieux agreement (Note 11). During the years ended December 31, 2018, 2017 and 2016, the Company recorded royalty expense of \$0.7 million, \$0.5 million and \$0.3 million, respectively, in cost of product revenue on the consolidated statements of operations and comprehensive loss.

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-sublicenseable 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

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****9. Commitments and contingencies (Continued)**

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. During the year ended December 31, 2018, 2017 and 2016, the Company recorded royalty expense of \$0.4 million, \$0.2 million, and \$0.2 million, respectively, in cost of product revenue on the consolidated statements of operations.

Lease commitments

During the year ended December 31, 2014, the Company entered into a lease agreement for the Company's current corporate headquarters with a lease term that expires in June 2020; however, in November 2018, the Company agreed to terminate the lease with the lessor effective May 2019. The termination of the lease was connected to the Company signing a new lease in Billerica, MA. On October 2, 2018, the Company entered into a 137 month operating lease for the Company's new headquarters in Billerica, MA. The lease is for approximately 92,000 square feet of office and laboratory space, and will commence on or about 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. The amount of the Letter of Credit will be reduced at 41 and 65 months after the commencement date of the lease to \$750,000 and then \$250,000, respectively. The \$1 million Letter of Credit is recorded as restricted cash on the balance sheet.

In connection with the acquisition of Aushon in January 2018, the Company assumed the existing Aushon lease for facilities in Billerica, Massachusetts. In August 2018 the Company terminated the Aushon lease effective September 1, 2019. The Company is required to pay a termination fee no later than July 1, 2019 in consideration for the early termination.

Rent expense is recognized straight-line over the course of the lease term. As of December 31, 2018, \$0.3 million of deferred rent expense was recorded in other non-current liabilities, and less than \$0.1 million was recorded in other accrued expenses. The table below includes committed lease expenditures related to the new lease.

As of December 31, 2018, the minimum future rent payments under the lease agreements are as follows (in thousands):

Years ending December 31:	
2019	\$ 1,172
2020	2,013
2021	3,290
2022	3,372
2023 and Forward	29,207
	<u>\$ 39,054</u>

The Company recorded \$1.6 million, \$1.1 million and \$1.1 million in rent expense for the years ended December 31, 2018, 2017 and 2016, respectively.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****9. Commitments and contingencies (Continued)***Development and supply agreement*

Through the Company's development agreement with STRATEC Biomedical, as amended in December 2016, the parties agreed on additional development services for an additional fee, which is payable when the additional development is completed. A total of \$1.5 million is payable to STRATEC upon completion of the development activities. This amount is being recorded to research and development expense and accrued expenses as the services are performed. The services were completed during the year ending December 31, 2018. Substantive efforts related to these additional development activities started in the first quarter of 2017.

The Company's supply agreement with STRATEC Biomedical requires the Company to purchase a minimum number of commercial units over a seven-year period ending in May 2021. If the Company were to fail to purchase a required number of commercial units, the Company would be obligated to pay termination costs plus a fee based on the shortfall of commercial units purchased compared to the required minimum amount. Based on the number of commercial instruments purchased as of December 31, 2018, assuming no additional commercial units were purchased, this fee would equal \$11.1 million. The amount the Company could be obligated to pay under the minimum purchase commitment is reduced as each commercial unit is purchased. Also, if the Company terminates the Supply Agreement under certain circumstances and has not purchased a required number of commercial units, it would be obligated to issue warrants to purchase 93,341 shares of common stock (the Supply Warrants) at \$0.003214 per share. The Company believes that it will purchase sufficient units to meet the requirements of the minimum purchase commitment and, therefore, has not accrued for any of the potential cash consideration. The Supply Warrants are accounted for at fair value; however, the fair value of the Supply Warrants as of December 31, 2018 and December 31, 2017 was insignificant as there was a low probability of the warrants being issued.

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. Long Term Debt*Loan agreement*

On April 14, 2014, the Company executed a Loan Agreement with a lender, as subsequently amended in March 2015, January 2016, March 2017, August 2018, and October 2018. As of December 31, 2018, there were no additional amounts available to borrow under the debt facility. The interest rate on this term loan is variable based on a calculation of the prime rate less 5.25% with a minimum interest rate of 8%. 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 in 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.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****10. Long Term Debt (Continued)**

In connection with the Loan Agreement, the Company granted the lender warrants to purchase shares of either Series C Preferred Stock or shares of preferred stock in the next financing round. Following the completion of the IPO, these warrants became exercisable for shares of the Company's common stock. Therefore, additional warrants will be issued if the Company draws on any of the remaining debt facility. The warrants issued in connection with the initial borrowing were initially recorded at fair value of \$0.1 million as a preferred stock warrant liability in the accompanying consolidated balance sheets and a corresponding debt discount was recorded. The Company has not further drawn on the remaining debt facility.

The Company also incurred debt issuance costs of \$0.1 million. As a result of the debt discounts recorded related to the warrants and the debt issuance costs, the debt was initially recorded at less than its face value. The debt, including the end of term charge, is being accreted over the life of the loan using the effective interest method.

The Loan Agreement also provided the lender with a right to invest up to \$1.0 million or, subject to Company approval and consent, to convert up to \$1.0 million of outstanding principal into shares of preferred stock in the next financing round at the same price as all other investors. The lender invested \$1.0 million in March 2016 as part of the Series D Preferred Stock financing.

Amendment 1 to loan agreement

On March 4, 2015, the Company executed Amendment 1 to the Loan Agreement (Amendment 1) and borrowed the remaining \$5.0 million that was available under the loan facility. The terms of Amendment 1 allowed the Company to defer the commencement of principal payments to December 1, 2015 and extended the loan maturity date to February 1, 2018. If the Company obtained at least \$10.0 million in equity financing before December 1, 2015, the commencement of principal payments could be further deferred until March 1, 2016 and the loan maturity date could be extended to May 1, 2018. As the financing milestone was not achieved, the Company made the first principal payment of \$0.3 million on December 1, 2015 and the loan maturity date was February 1, 2018 under Amendment 1.

The additional \$5.0 million borrowed included an additional \$0.2 million end of term charge. The end of term charge on this borrowing is being accreted over the life of the loan as additional interest expense. The additional borrowing also resulted in the issuance of additional warrants with a grant date fair value of \$0.1 million. The fair value of the additional warrants were initially recorded at fair value as a preferred stock warrant liability in the accompanying consolidated balance sheets and a corresponding debt discount was recorded. The debt, including the end of term charge, is being accreted over the remaining life of the loan using the effective interest method.

Amendment 2 to loan agreement

In January 2016, the Company executed Amendment 2 to the Loan Agreement (Amendment 2). Amendment 2 increased the total facility available by \$5.0 million to a total of \$15.0 million and further delayed the commencement of principal payments to July 1, 2016. Under Amendment 2, following the Series D Preferred Stock financing (Note 8), the Company could have elected to further delay the commencement of principal payments until January 1, 2017, however the Company voluntarily began paying principal on July 1, 2016. Upon signing Amendment 2, the Company drew an additional \$3.0 million under the debt facility. The remaining \$2.0 million available under the facility

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

10. Long Term Debt (Continued)

expired unexercised in April 2016, which reduced the amounts available under the facility to \$13.0 million.

The additional \$3.0 million borrowed included an additional \$0.1 million end of term charge. The end of term charge on this borrowing is being accreted over the life of the loan. The additional borrowing also resulted in the issuance of additional warrants with a grant date fair value of \$0.1 million. The fair value of the additional warrants were initially recorded at fair value as a preferred stock warrant liability in the accompanying consolidated balance sheets and a corresponding debt discount was recorded. The debt, including the end of term charge, is being accreted to over the remaining life of the loan using the effective interest method.

Amendment 3 to loan agreement

In March 2017, the Company signed Amendment 3 to the Loan Agreement (Amendment 3). Amendment 3 increased the total facility available by \$5.0 million to a total of \$18.0 million. Additionally, the lender may provide an additional optional term loan, solely at the lender's discretion, for an incremental \$5.0 million, increasing the total potential facility to \$23.0 million. As of December 31, 2017, the Company has not drawn any of this additional facility. The terms of Amendment 3 allowed the Company to defer the commencement of principal payments to March 1, 2018 and extended the loan maturity date to March 1, 2019. Amendment 3 did not change the due date of the existing end of term fees of \$0.05 million which remained due on February 1, 2018. Upon signing Amendment 3, the Company did not draw any of the additional amounts available under the amended debt facility and no amounts have been subsequently drawn under the facility. The Company has until September 3, 2018 to draw the additional amounts.

Amendment 4 to loan agreement

In July 2017, the Company signed Amendment 4 to the Loan Agreement (Amendment 4). Amendment 4 instituted a cap of 10% with respects to the "Term Loan Interest Rate".

Amendment 5 to loan agreement

In August 2018, the Company signed Amendment 5 to the Loan Agreement (Amendment 5). Amendment 5 instituted a 2018 End of Term Charge of \$0.08 million. Additionally, the Term Loan Maturity Date was amended to be extended until March 1, 2020. Amendment 5 additionally, changed the due date of the End of Term Charge to, the earlier of (i) the Term Loan Maturity Date, (ii) the date that Borrower prepays the outstanding Secured Obligations or (iii) the date that the Secured Obligations become due and payable. The Company incurred a cost of \$0.05 million in relation to the execution of Amendment 5. In connection with the extension of the due date of the Loan, the deferral of principal payments (Amendment 3) was further deferred until the new Term Loan Maturity Date.

Amendment 6 to loan agreement

In October 2018, we signed Amendment 6 to the Loan agreement, which amends the Loan Agreement's collateral clause to exclude the \$1 million certificate of deposit associated with the lease on our new headquarters in Billerica, MA.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****10. Long Term Debt (Continued)**

End of term charges related to the facility of \$0.5 million, and principal payments of \$1.4 million were paid during the fiscal year ended December 31, 2018. Under the terms of the August 2018 amended agreement, principal payments were delayed until March 2020. The Company accounted for the August 2018 amendment as a modification as it was determined that no material change occurred as a result of the modification. The Company voluntarily made principal payments in the months of March, April, and May, 2018. No principal payments were made in June, July or August, 2018. Under the amended Loan Agreement, the remaining outstanding principal will be paid upon maturity of the note in March 2020. As of December 31, 2018, the remaining loan balance is classified as a long term liability since all principal payments are due greater than twelve months after the balance sheet date.

Debt payment obligations due based on principal payments are as follows (in thousands):

Years ending December 31:	
2019	\$ 0
2020	7,763
	<u>\$ 7,763</u>

The balance sheet contains \$0.1 million of unamortized debt issuance costs which nets the Long Term Debt balance to \$7.6 million. Non-cash interest expense related to debt discount amortization and accretion of end of term fees was \$0.2 million, \$ 0.2 million, and \$0.4 million for the year ended December 31, 2018, 2017, and 2016, respectively.

The Company assessed all terms and features of the Loan Agreement and the subsequent amendments in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the debt. The Company determined that all features of the Loan Agreement and the subsequent amendments are either clearly and closely associated with a debt host or have a de minimis fair value and, as such, do not require separate accounting as a derivative liability. The Company assessed each amendment under ASC 470-50 and concluded that all of the amendments constituted modifications. In this analysis, consideration was given to the fact that Amendments 4, 5, and 6 were executed within one year of each other. The Company also assessed whether the amendments represented a troubled debt restructuring and concluded they did not. The Company accounted for each of the amendments to the Loan Agreement as a modification of its debt and the unamortized discount and issuance costs related to the prior debt are amortized over the modified term of the new debt.

The Loan Agreement and the subsequent amendments contain negative covenants restricting the Company's activities, including limitations on dispositions, mergers or acquisitions, incurring indebtedness or liens, paying dividends or making investments and certain other business transactions. There are no financial covenants associated with the Loan Agreement and the subsequent amendments. The obligations under the Loan Agreement and subsequent amendments are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in the Company's business, operations or financial or other condition. The Company has determined that the risk of subjective acceleration under the material adverse events clause is not probable and therefore has classified the outstanding principal in current and long-term liabilities based on scheduled principal payments.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****11. Collaboration and license arrangements**

In November 2012, the Company entered into the JDLA with bioMérieux, a related party. As discussed below, the JDLA has been subsequently amended. Under the terms the JDLA, the Company granted bioMérieux an exclusive, royalty-bearing license, without right to sublicense, to manufacture and sell instruments and assays using our Simoa technology exclusively for in vitro diagnoses used in clinical lab applications, food quality control testing, and pharma quality control testing, and co-exclusively in certain related fields, as defined in the contract. As part of the JDLA, the Company was also to develop and manufacture instruments to bioMérieux's specifications for bioMérieux's use or for sale by bioMérieux. The Company retained rights to sell the instrument in the co-exclusive fields and any other fields not licensed exclusively to bioMérieux. bioMérieux was to develop and sell diagnostic assays to be used in conjunction with the Company's instruments.

Upon execution of the JDLA, the Company received \$10.0 million in consideration and was entitled to receive two additional payments of \$5.0 million each upon the achievement of certain developmental criteria. Neither of these criteria have been achieved. The Company was also entitled to receive royalty payments on the sale of assays and payments for the manufacture and delivery of instruments based on a contractual rate subject to future adjustments.

At the inception of the JDLA, the Company determined that the deliverables were as follows: (1) licenses to the Company's technology and trademarks, training, completion and delivery of a prototype instrument per contractual specifications (License and Prototype), (2) various activities to assist bioMérieux in the development of the initial assay and an instrument that is IVD compliant (Initial Assay Assistance), (3) various activities to assist bioMérieux in the development of a benchtop instrument (Benchtop Assistance), and (4) joint steering committee participation (JSC). Each of these deliverables were considered separate units of accounting, and the License and Prototype unit of accounting was determined to have standalone value as the License and Prototype unit of accounting could be utilized by bioMérieux without the related services included in the other units of accounting.

The Company allocated the allocable arrangement consideration based on the relative selling price of each unit of accounting. For all units of accounting, the Company determined the selling price using the best estimate of selling price (BESP). Management's best estimate of the selling price of the License and Prototype unit of accounting was based on a discounted cash flow analysis to support the estimated selling price of the license. The Company determined the BESP of the other units of accounting based on internal estimates of the costs to perform the services, adjusted to reflect a reasonable profit margin as well as based on market prices for similar instruments and services.

Revenue related to the License and Prototype unit of accounting of \$8.3 million was recognized in 2013 upon delivery of both the license which was delivered at inception, and the first prototype instrument, which was required for bioMérieux to make use of the license. Prior to the effect of the 2016 Amendment described below, revenue for the other units of accounting were recognized over an estimated period of performance.

Amendments to the JDLA

In May 2014 and January 2015, the parties executed a First and Second Amendment to the JDLA, respectively. These amendments addressed revised timelines related to completing the development activities under the JDLA and enacted additional governance protocols to monitor those activities.

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

11. Collaboration and license arrangements (Continued)

These amendments did not change the deliverables under the JDLA or the total arrangement consideration. The Company revised its estimates of the remaining period of performance for the remaining undelivered units of accounting and these revisions did not have a material effect on revenue recognition.

On December 22, 2016, the Company entered into the 2016 Amendment which ended the ongoing joint development efforts between the parties, and modified the rights and obligations of both parties accordingly, as follows:

- For a period of not more than three years from the date of the 2016 Amendment bioMérieux has the ability to evaluate independently whether it will develop a new, smaller in vitro diagnostic instrument using the Simoa technology for use in clinical lab applications, food quality control testing, and pharmaceutical quality control testing benchtop (the "Feasibility Period") and has the sole right to determine whether or not to develop such a new instrument during the Feasibility Period. If bioMérieux does elect to pursue development of such a new instrument, they will have a set number of years to complete development within a specified period, which contains various development milestones which must be accomplished.
- bioMérieux received a license to the source and object code of the Company's Level 1 Data Reduction (L1DR) software. The L1DR software the Company's proprietary image processing algorithms that convert images of microscopic beads associated with biomarker molecules in microwells. Also, the Company must provide to bioMérieux access to any know how and intellectual property associated with the L1DR software, including any updates and upgrades to the L1DR software during the Feasibility Period. If bioMérieux exercises its right to develop an instrument independently, this right will continue throughout the development period to the end of the term of the agreement related to independently developed instruments.
- It was clarified that the Company can engage a collaboration partner (IVD Partner), subject to restrictions as to the particular parties with which the Company could elect to partner and the assays that can be developed, in the field of in vitro diagnostics used in Clinical Lab Applications. The Company shall pay bioMérieux a mid-double-digit percentage of royalties received from the IVD Partner based on assays sales by the IVD Partner.
- bioMérieux's licenses include all patents and know-how owned or controlled by the Company related to the Company's Simoa technology and upgrades thereto that are necessary for the development, manufacture, use or sale of instruments and assays or consumables on such instruments over the Feasibility Period. If bioMérieux exercises its right to develop an instrument independently, this right will continue throughout the development period to the end of the term of the 2016 Amendment related to independently developed instruments.
- bioMérieux retains an option (the Option) to obtain worldwide distribution rights to the HD-1 floor standing instrument in the applicable fields. The Option is exercisable over a three year period and upon exercise, the Company and bioMérieux are required to negotiate, in good faith, a distribution agreement that would include a specified upfront payment.

The 2016 Amendment included a cash payment of \$2.0 million from bioMérieux which was paid in January 2017.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****11. Collaboration and license arrangements (Continued)**

On September 6, 2018, bioMérieux notified the Company that it was terminating the Amended JDLA, forfeiting any future IVD licensing rights to the Company's Simoa technology and enabling the Company to consolidate and regain control of all Simoa IVD licensing and IP rights.

Accounting assessment

Prior to the execution of the 2016 Amendment, the Company was recognizing revenue over the estimated period of performance of the ongoing units of accounting (Initial Assay Assistance, Benchtop Assistance, and JSC). As a result, the Company recognized \$0.2 million and \$0.2 million in revenue for the years ended December 31, 2015 and 2016, respectively. At the date of the execution of the 2016 Amendment, the Company had \$1.2 million in deferred revenue related to the JDLA. Upon the execution of the 2016 Amendment, all undelivered elements and contingent consideration of the JDLA were cancelled. The Company determined the 2016 Amendment should be accounted for as a modification to the JDLA and the balance of deferred revenue prior to the 2016 Amendment should be included as allocable consideration under the 2016 Amendment resulting in total allocable consideration of \$3.2 million. The Company recorded an increase to deferred revenue upon receipt of the \$2.0 million during the three months ended March 31, 2017.

The Company has determined that the deliverables included under the 2016 Amendment are rights to the L1DR software, training and rights to future technology improvements for L1DR Software, rights to all future technological improvements related to the Simoa technology, and participation on joint committees.

The Company determined that the L1DR and rights to unspecified technology improvements (the "L1DR Unit of Accounting") includes the sale of software and software related elements and therefore should be accounted for under ASC 985-605—*Software Revenue Recognition*. The Company cannot demonstrate Vendor Specific Objective Evidence (VSOE) of fair value for the ongoing obligation to provide unspecified technology improvements. Therefore, the deliverables in the L1DR Unit of Accounting cannot be separated. The Company has applied the combined service approach and the consideration allocated to this unit of accounting is being recognized ratably over the estimated period of performance, which has initially been determined to be estimated to be the three year Feasibility Period. This will be reevaluated each period to determine if there are any changes to the estimated period of performance.

The Company concluded that the rights to future technology improvements for the Simoa technology and the participation on joint committees represented a second unit of accounting (the "Instrument Know How Unit of Accounting"). The deliverables in the Instrument Know How Unit of Accounting are considered non-software deliverables that are subject to ASC 605-25 and will be delivered over time on a when and if available basis. Revenue is being recognized on a straight line basis over the estimated period of performance, which has initially been determined to be the three year Feasibility Period. This period will be reevaluated each period to determine if there are any changes to the period of performance.

The Option is considered substantive as the Company is at risk with regard to whether bioMérieux will exercise the Option. In addition, the Option exercise payment payable by bioMérieux upon exercise is not priced at a significant and incremental discount. Accordingly, the Option is not considered a deliverable at the inception of the arrangement and the associated Option exercise payment is not included in allocable arrangement consideration.

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

11. Collaboration and license arrangements (Continued)

Under the 2016 Agreement the Company is eligible to receive royalties on net sales of assays sold by bioMérieux in the mid to high single digits, and to receive low double digit royalties on sales of instruments by bioMérieux based on manufactured cost. No royalties have been recognized through December 31, 2018.

Upon termination of the agreement, the Company no longer held an obligation to bioMérieux related to the initial agreement or the amendment to the agreement. As such, the Company immediately recognized all remaining deferred revenue related to the agreements as of the date of termination.

The Company recognized revenue of \$2.1 million and \$1.1 million for the years ended December 31, 2018 and 2017, respectively, as collaboration revenue.

Evaluation and option agreements and license agreement

In 2015, the Company entered into three agreements, for three separate fields, with a diagnostic company for the evaluation of the Company's Simoa technology. These agreements each allowed for the option to negotiate a license agreement. In return, the Company received non-refundable payments totaling \$2.0 million. In December 2016, the diagnostic company exercised one of its options and the parties entered into a license agreement in one of the fields. This agreement has a one-time non-refundable license fee of \$1.0 million and the right to receive running low single digit royalties on licensed products. The negotiation periods for the other two agreements were extended and the negotiations remain ongoing.

For each of the three fields, the right to evaluate the technology, the right to negotiate a license to the technology, and the undelivered license to the technology represents a combined unit of accounting, and the licenses to each of the three fields each have standalone value. The Company has allocated the allocable arrangement consideration based on the relative selling price of each unit of accounting. The BESP of each of the three options was determined to be representative of the contractual amount paid for each option. The Company defers the amounts allocated to each of the three options until the corresponding license is delivered or, if no license agreement is executed and delivered, when the negotiations for each option terminates.

Upon execution of the license in one of the fields in December 2016, the \$1.0 million license fee, in addition to the \$0.8 million allocated to the option for this field, resulted in a total of \$1.8 million of consideration being recognized as revenue as there were no remaining undelivered performance obligations. Because the negotiations remain ongoing with respect to the other two fields, the consideration allocated to these options of \$1.2 million has been deferred and is recorded as deferred revenue as of December 31, 2017.

In December 2018 the Company entered into an option agreement for the rights to negotiate an exclusive agreement with the diagnostic company. In exchange for the rights to negotiate an exclusive agreement, the Company will receive \$0.5 million in consideration. As the right to negotiate with the Company has not been executed, the consideration from this agreement is deferred until the sooner of the execution of the contract or the end of the option period.

12. Employee benefit-plans

The Company sponsors a 401(k) savings plan for our employees. The Company may make discretionary contributions for each 401(k) plan year. During the year ended December 31, 2018 the Company made contributions of \$0.1 million and during the year ended December 31, 2017 and 2016 did not make any contribution.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****13. Business combinations**

On January 30, 2018, the Company completed the acquisition of Aushon pursuant to an Agreement and Plan of Merger dated January 30, 2018 (the "Aushon Acquisition"). The Company acquired Aushon to complement its existing product line, improve its existing research and development capabilities in assay development and software engineering, and expand its customer base. The Aushon Acquisition has been accounted for as a business combination and the Company has recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date.

In connection with the closing of the Aushon Acquisition, the Company paid \$3.2 million at closing, and an additional \$0.8 million in July 2018, the six-month anniversary of the acquisition date.

The following table presents the allocation of the purchase consideration for the transaction as of January 30, 2018 including the allocation of the purchase consideration (in thousands):

Fair value of consideration transferred:	
Cash	\$ 3,200
Obligation to issue cash	800
Total acquisition consideration	<u>\$ 4,000</u>
Fair value of assets acquired and liabilities assumed:	
Cash and cash equivalents	\$ 199
Accounts receivable	210
Inventory	828
Prepaid expenses	71
Property and equipment and other non-current assets	180
Intangible Assets	2,950
Goodwill	<u>1,308</u>
Total assets acquired	5,746
Contractual obligations	(1,155)
Accounts payable and accrued liabilities	<u>(591)</u>
Net assets acquired	<u>\$ 4,000</u>

The intangible assets identified in the purchase price allocation discussed above include developed technology, tradenames and customer relationships. Tradenames are amortized over the useful life on a straight-line basis, while developed technology and customer relationships are amortized over their respective useful lives on an accelerated basis reflecting the period of expected derived benefits of the underlying assets. Developed technology consists of products that have reached technological feasibility and trade names represent acquired company and product names. To value the developed technology and trade name assets, the Company utilized a relief from royalty method. Under the methodology, fair value is calculated as the discounted cash flow savings accruing to the owner for not having to pay the royalty. Key assumptions included expected revenue attributable to the assets, royalty rates, discount rate and estimated asset lives. Customer relationships represent the underlying relationships with certain customers to provide ongoing services and continued product sale opportunities. The Company utilized excess earnings methodology to derive the fair value of the customer relationships. Key assumptions included expected attrition of customer's rates, operating income margins and discount

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****13. Business combinations (Continued)**

rate. The Company used a risk-adjusted discount rate of 14.4% in determining the fair value of the intangible assets.

The goodwill recorded as a result of the Aushon Acquisition represents the strategic benefits of growing the Company's product portfolio and the expected revenue growth from increased market penetration from future products and customers. The goodwill was recorded as an asset (Note 14). None of the goodwill recorded is tax deductible for income tax purposes.

The Company incurred a total of \$0.1 million in transaction costs in connection with the transaction, which were included in selling, general and administrative expense within the consolidated statement of operations for the twelve months ended December 31, 2018.

14. Goodwill and Intangible Assets

As of December 31, 2018 the carrying amount of goodwill was \$1.3 million. The following is a rollforward of our goodwill balance (in thousands):

	<u>Goodwill</u>
Balance as of December 31, 2017	\$ —
Goodwill acquired	1,308
Balance as of December 31, 2018	<u>\$ 1,308</u>

Intangible assets consist of the following (dollars in thousands):

	Estimated Useful Life (in years)	December 31, 2018			Weighted average life remaining
		Gross Carrying Value	Accumulated Amortization	Net Carrying Value	
Developed technology	7	\$ 1,650	\$ (378)	\$ 1,272	6.08
Customer relationships	10	1,250	(208)	1,042	9.08
Tradenames	3	50	(15)	35	2.08
Total		<u>\$ 2,950</u>	<u>\$ (601)</u>	<u>\$ 2,348</u>	

The Company recorded amortization expense of \$0.6 million for the fiscal year ended December 31, 2018. No amortization expense was recognized in the fiscal year ended December 31, 2017 and 2016 as the intangible assets are a result of the purchase of Aushon BioSystems in January 2018. Amortization relating to developed technology is recorded within research and development expense, amortization of customer relationships is recorded within sales and marketing expenses, and amortization of tradenames is recorded within general and administrative expenses.

Quanterix Corporation**Notes to Consolidated Financial Statements (Continued)****14. Goodwill and Intangible Assets (Continued)**

As of December 31, 2018, the Company expects to record the following amortization expense (amounts in thousands):

<u>For the Years Ended December 31,</u>	<u>Estimated Amortization Expense</u>
2019	\$ 582
2020	500
2021	403
2022	320
2023	238
2024 and thereafter	305

15. Related party transactions

As described in Notes 11 and 7, bioMérieux is a customer through its Joint Development and License Agreement and also a holder of the Company's common stock. bioMérieux formerly also had a designee on the Company's Board of Directors. The Company recognized revenue related to the JDLA with bioMérieux of \$2.1 million, \$1.1 million, and \$0.2 million, in the years ended December 31, 2018, 2017, and 2016 respectively, from bioMérieux. They also had no deferred revenue as of December 31, 2018 and had deferred revenue of \$2.1 million at December 31, 2017. As described in Note 8, bioMérieux purchased shares of our Series C Preferred Stock totaling \$7.0 million in the year ended December 31, 2015.

As described in Note 7, in March 2016, the Company issued an aggregate of 12,420,262 shares of Series D Preferred Stock for an aggregate purchase price of \$45.6 million. Of the amount issued, \$22.9 million was purchased by the Company's existing principal stockholders, officers and directors.

As described in Note 7, in June 2017, the Company issued an aggregate of 2,113,902 share of Series D-1 Preferred Stock for an aggregate purchase price of \$8.5 million. Of the amount issued, \$1.0 million was purchased by a director of the Company.

As described in Note 9, 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 Tuft's 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, 2018, 2017, and 2016 the Company recorded royalty expense of \$0.7 million, \$0.5 million, and \$0.3 million, respectively, in cost of product revenue on the consolidated statements of operations and comprehensive loss. During the year ended December 31, 2016, the Company recognized \$0.4 million as cost of license revenue associated with a payment made to Tufts.

During the year ended December 31, 2017 Harvard University became a related party. Revenue recorded from sales to Harvard University were less than \$0.1 million for each of the years ended December 31, 2018 and December 31, 2017.

On November 28th, the Company entered into a sponsor agreement with 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 commits a maximum of \$120,000 in funds and services to be provided to PPH for the term of the agreement. The agreement is terminable by either party and does not bind the

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

15. Related party transactions (Continued)

Company to beyond the term of the agreement. As of the year ended December 31, 2018, the Company had a total contributed amount less than \$0.1 million.

16. Restricted Cash

The Company's restricted cash consists of cash that the Company is contractually obligated to maintain in accordance the terms of the Letter of Credit in the lease agreement. The \$1.0 million Letter of Credit drawable by the lessor under specifically outlined conditions within the lease, which are primarily related to rent payments. The amount of the Letter of Credit will be reduced at 41 and 65 months after the commencement date of the lease to \$750,000 and then \$250,000, respectively.

17. Quarterly Data (Unaudited)

(In thousands, except per share data)

2018	Q1	Q2	Q3	Q4	Total Year
Product revenue	\$ 4,745	\$ 5,200	\$ 5,962	\$ 7,458	\$ 23,365
Service and other revenue	2,507	3,174	3,017	3,419	12,117
Collaboration and license revenue	269	269	1,612	—	2,150
Total revenue	7,521	8,643	10,591	10,877	37,632
Operating expenses:					
Cost of product revenue	2,773	2,945	3,277	3,734	12,729
Cost of services and other revenue	1,576	1,725	1,719	1,935	6,955
Research and development	3,644	3,705	4,411	4,045	15,805
Selling, general and administrative	6,691	7,579	8,846	10,577	33,693
Total operating expenses	14,684	15,954	18,253	20,291	69,182
Loss from operations	(7,163)	(7,311)	(7,662)	(9,414)	(31,550)
Interest expense, net	(24)	16	30	24	46
Other (expense) income, net	(15)	(48)	(25)	81	(7)
Tax expense	—	—	—	(25)	(25)
Net loss	\$ (7,202)	\$ (7,343)	\$ (7,657)	\$ (9,334)	\$ (31,536)
Reconciliation of net loss to net loss attributable to common stockholders:					
Net loss	(7,202)	(7,343)	(7,657)	(9,334)	(31,536)
Net loss attributable to common stockholders	(7,202)	(7,343)	(7,657)	(9,334)	(31,536)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.33)	\$ (0.34)	\$ (0.35)	\$ (0.42)	\$ (1.43)
Weighted-average common shares outstanding, basic and diluted	21,788,605	21,890,978	22,670,786	22,221,305	21,994,317

Quanterix Corporation

Notes to Consolidated Financial Statements (Continued)

17. Quarterly Data (Unaudited) (Continued)

2017	Q1	Q2	Q3	Q4	Total Year
Product revenue	\$ 3,425	\$ 3,337	\$ 3,293	\$ 4,069	\$ 14,124
Service and other revenue	1,644	1,608	2,172	2,252	7,676
Collaboration and license revenue	269	268	269	268	1,074
Total revenue	5,338	5,213	5,734	6,589	22,874
Operating expenses:					
Cost of product revenue	1,834	1,834	1,905	2,169	7,742
Cost of services and other revenue	1,144	1,198	1,264	1,539	5,145
Research and development	4,250	3,903	4,224	3,927	16,304
Selling, general and administrative	4,166	4,747	4,728	6,047	19,688
Total operating expenses	11,394	11,682	12,121	13,682	48,879
Loss from operations	(6,056)	(6,469)	(6,387)	(7,093)	(26,005)
Interest expense, net	(255)	(240)	(240)	(216)	(951)
Other (expense) income, net	(80)	77	13	(73)	(63)
Tax Expense	—	—	—	—	—
Net loss	\$ (6,391)	\$ (6,632)	\$ (6,614)	\$ (7,382)	\$ (27,019)
Reconciliation of net loss to net loss attributable to common stockholders:					
Net loss	(6,391)	(6,632)	(6,614)	(7,382)	(27,019)
Accretion of preferred stock to redemption value	(1,090)	(1,099)	(1,112)	(809)	(4,110)
Accrued dividends on preferred stock	(16)	(16)	(16)	(11)	(59)
Net loss attributable to common stockholders	(7,497)	(7,747)	(7,742)	(8,202)	(31,188)
Net loss per share attributable to common stockholders, basic and diluted	\$ (3.18)	\$ (3.21)	\$ (3.13)	\$ (1.06)	\$ (8.30)
Weighted-average common shares outstanding, basic and diluted	2,357,503	2,416,984	2,475,166	7,731,514	3,756,954



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October 22, 2018

Jackson Streeter

Dear Jackson:

Quanterix Corporation (the "Company") is pleased to offer you the full-time position of SVP, Corporate Development and Strategy, reporting to me, pending Board approval. Your effective date of hire will be November 12, 2018. We are excited about the prospect of you joining our team.

Salary: The Company will pay you a salary at an annual rate of \$300,000, paid at a bi-weekly rate of \$11,538.46 (subject to periodic review and adjustment at the discretion of the Company).

Bonus: You will be eligible to receive an annual performance bonus. The Company will target the bonus at up to 50% of your annual base salary earnings. The actual bonus percentage is discretionary and will be subject to your achievement of the metrics and goals established by and agreed to with Kevin Hrusovsky. The bonus also will be subject to your employment for the full period covered by the bonus, approval by and adjustment at the discretion of the Company and Company's Board of Directors, and the terms of any applicable bonus plan. You must be actively employed by Quanterix on the date the bonus is paid to receive a performance bonus.

Benefits: You will be eligible to participate in the employee benefits and insurance programs generally made available to its full-time employees, including medical insurance, dental insurance, 401K Plan and match, ESPP, Flexible Spending Account, term life insurance, and short and long term disability insurance. Details of these benefits programs, including mandatory employee contributions, will be made available to you when you start. You



also will be eligible to receive paid vacation time. You will be eligible for up to 20 days of paid vacation per year, which shall accrue on a prorated basis. Other provisions of the Company's vacation policy are set forth in the policy itself.

Stock Options & RSUs: You will be eligible to participate in the Company's stock option program, subject to approval by the Compensation Committee. We will recommend to the Compensation Committee to approve that you be granted 28,441 Restricted Stock Units (RSUs) and an option to purchase 66,143 shares of the Company's common stock at the stock's then fair market value. The RSUs and options will vest over four years, with 25% vesting on the first anniversary of your start date, and the remaining vesting ratably on a monthly basis over the next three years. Your eligibility for stock options will be governed by the Quanterix 2017 Employee, Director and Consultant Equity Incentive Plan and any associated stock option agreement required to be entered into by you and the Company.

Representation Regarding Other Obligations: This offer is conditioned on your representation that you are not subject to any confidentiality, non-competition agreement or any other similar type of restriction that may affect your ability to devote full time and attention to your work at the Company. If you have entered into any agreement that may restrict your activities on behalf of the Company, please provide me with a copy of the agreement as soon as possible.

Other Terms: Your employment with the Company shall be on an at-will basis. In other words, you or the Company may terminate employment for any reason and at any time, with or without notice. Similarly, the terms of employment outlined in this letter are subject to change at any time. You also will be required to sign the Company's standard "Employee Non-Solicitation, Confidentiality and Assignment Agreement" as a condition of your employment. A copy of that Agreement is enclosed. In addition, as with all employees, our offer to you is contingent on your submission of satisfactory proof of your identity and your legal authorization to work in the United States.

We are excited about the opportunity to work with you at Quanterix. If you have any questions about this information, please do not hesitate to call. Otherwise, please confirm your acceptance of this offer of employment by signing below and returning a copy to me no later than October 23, 2018.

We are confident that with your background and skills, you will have an immediate positive impact on our organization.

Sincerely,

/s/ Kevin Hrusovsky

Kevin Hrusovsky
CEO and Executive Chairman

Offer accepted:

/s/ Jackson Streeter
Jackson Streeter

10/25/18
Date

Quanterix Corporation
2018 Non-Employee Director Compensation Policy

Effective as of January 1, 2018

I. Overview

The Board of Directors (the “Board”) of Quanterix Corporation (the “Company”) has approved this 2018 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 (“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	\$	35,000
Additional Lead Director/Non-Employee Board Chairman Retainer	\$	20,000
Additional Audit Committee Chairman Retainer	\$	20,000
Additional Compensation Committee Chairman Retainer	\$	12,000
Additional Nominating and Governance Committee Chairman Retainer	\$	10,000
Additional Audit Committee Member Retainer	\$	7,500
Additional Compensation Committee Member Retainer	\$	6,000
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 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, (A) a non-qualified stock option (the “Options”) to purchase 7,900 shares of Common Stock at an exercise price equal to the Fair Market Value as of such grant date and (B) 2,270 restricted stock units (each RSU relating to one (1) share of Common Stock) (“RSUs”) (collectively, the “Annual Awards”). 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, (A) 15,800 Options at an exercise price equal to the Fair Market Value as of such grant date and (B) 4,540 RSUs (collectively, the "Initial Awards"). 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.

QUANTERIX CORPORATION

NON-EMPLOYEE DIRECTOR COMPENSATION ELECTION FORM

In accordance with the Director Compensation Policy, effective January 1, 2018 (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

SUBSIDIARIES

<u>Company Name</u>	<u>Jurisdiction of Incorporation</u>
Aushon Biosystems, Inc.	Delaware
Quanterix Security Corporation	Massachusetts
Quanterix Netherlands B.V.	The Netherlands

QuickLinks

[Exhibit 21.1](#)

[SUBSIDIARIES](#)

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-223771) pertaining to 2007 Stock Option and Grant Plan, as amended, 2017 Employee Stock Purchase Plan, and 2017 Employee, Director and Consultant Equity Incentive Plan of our report dated March 18, 2019, 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, 2018.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 18, 2019

QuickLinks

[Exhibit 23.1](#)

[Consent of Independent Registered Public Accounting Firm](#)

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 18, 2019

/s/ E. KEVIN HRUSOVSKY

E. Kevin Hrusovsky
Chairman, President and Chief Executive Officer (principal executive officer)

QuickLinks

[Exhibit 31.1](#)

[CERTIFICATIONS UNDER SECTION 302](#)

CERTIFICATIONS UNDER SECTION 302

I, Joseph Driscoll, 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 18, 2019

/s/ JOSEPH DRISCOLL

Joseph Driscoll
Chief Financial Officer
(principal financial officer and principal accounting officer)

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[Exhibit 31.2](#)

[CERTIFICATIONS UNDER SECTION 302](#)

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, 2018 (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 18, 2019

/s/ E. KEVIN HRUSOVSKY

E. Kevin Hrusovsky
Chairman, President and Chief Executive Officer

Dated: March 18, 2019

/s/ JOSEPH DRISCOLL

Joseph Driscoll
Chief Financial Officer

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[Exhibit 32.1](#)

[CERTIFICATIONS UNDER SECTION 906](#)