UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2019

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: 001-38957

ADAPTIVE BIOTECHNOLOGIES CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Washington	**27-0907024**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1551 Eastlake Avenue East, Suite 200	
Seattle, Washington	**98102**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (206) 659-0067

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.0001 per share	ADPT	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the 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 15(d) of the 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The NASDAQ Global Select Market on June 28, 2019 (the last business day of the Registrant's most recently completed second fiscal quarter), was approximately $2,009,000,000.

As of February 21, 2020, the Registrant had 126,317,893 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Annual Report on Form 10-K, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Shareholders to be held in 2020.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. Some of the statements in the "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections and elsewhere in this Annual Report on Form 10-K contain forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe we have a reasonable basis for each forward-looking statement contained in this Annual Report on Form 10-K, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the success of our significant investments in our continued research and development of new products and services;
- the success of developing, commercializing and achieving commercial market acceptance of clonoSEQ, immunoSEQ Dx, our TCR-Antigen Map, TCR-based cellular therapies and additional products and services beyond our current portfolio;
- the potential for our identified research priorities to advance our proprietary immune medicine platform or our future products and services;
- the success, cost and timing of our research development activities, preclinical and clinical studies and, in certain instances, clinical trials and clinical validations;
- the potential benefits of collaborations, our ability to enter into collaborations or arrangements, and our ability to attract collaborators with development, manufacturing, regulatory and commercialization expertise;
- the ability and willingness of our collaborators to continue development, manufacturing, distribution and commercialization activities relating to our jointly developed products and services;
- our ability to identify research priorities and apply a risk-mitigated strategy to efficiently discover and develop products and services;
- our ability to obtain and maintain regulatory approval of our products and services;
- our ability, and that of our collaborators, to commercialize our products and services;
- our ability to generate revenue and obtain funding for our operations, including funding necessary to complete further development of our current and future products and services, and if successful, commercialization;
- the size and growth potential of the markets for our products and services, and our ability to serve those markets, either alone or in combination with others;
- the rate and degree of market acceptance of our products and services;
- our financial performance;
- the pricing and reimbursement of our products and services following approval where required;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our immune medicine platform, products, services and related technologies and the direction of such protection;
- regulatory developments in the United States and foreign countries;
- the success of competing products or services that are or may become available;
- developments relating to our competitors and our industry;
- our ability to attract and retain key scientific or management personnel;
- the impact of laws and regulations; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

In addition, you should refer to the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of other important factors that may cause actual results to differ materially from those expressed or implied by the forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report on Form 10-K will prove to be accurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements herein represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

In this Annual Report on Form 10-K, unless the context requires otherwise, all references to "we," "our," "us," "Adaptive" and the "Company" refer to Adaptive Biotechnologies Corporation.

PART I

Item 1. Business

Overview

We are advancing the field of immune-driven medicine by harnessing the inherent biology of the adaptive immune system to transform the diagnosis and treatment of disease. We believe the adaptive immune system is nature's most finely tuned diagnostic and therapeutic for most diseases, but the inability to decode it has prevented the medical community from fully leveraging its capabilities. Our immune medicine platform applies our proprietary technologies to read the diverse genetic code of a patient's immune system and understand precisely how it detects and treats disease in that patient. We capture these insights in our dynamic clinical immunomics database, which is underpinned by computational biology and machine learning, and use them to develop and commercialize clinical products and services that we are tailoring to each individual patient. We have two commercial products and services and a robust pipeline of clinical products and services that we are designing to diagnose, monitor and enable the treatment of diseases such as cancer, autoimmune conditions and infectious diseases. Since our inception in 2009, we have characterized over 37 billion immune receptors, established partnerships and commercial relationships with over 165 biopharmaceutical companies and launched two product lines. Our goal is to understand the adaptive immune system and translate it into new products with unprecedented scale, precision and speed.

Our immune medicine platform is the foundation for our expanding suite of products and services. The cornerstone of our platform and core immunosequencing product, immunoSEQ, serves as our underlying research and development engine and generates revenue from academic and biopharmaceutical customers. Our first clinical diagnostic product, clonoSEQ, is the first test authorized by the Food and Drug Administration ("FDA") for the detection and monitoring of minimal residual disease ("MRD") in patients with multiple myeloma ("MM") and B cell acute lymphoblastic leukemia ("ALL") and is being validated for patients with other blood cancers. Leveraging our collaboration with Microsoft Corporation ("Microsoft") to create a map of the interaction between the immune system and disease ("TCR-Antigen Map"), we are also developing a diagnostic product, immunoSEQ Dx, that may enable early detection of many diseases from a single blood test. We have established proof of concept for immunoSEQ Dx in acute Lyme disease, such that we can proceed to clinical validation, and continue to pursue signals for other disease states. Our therapeutic product candidates, being developed under our collaboration agreement with Genentech Inc. ("Genentech"), leverage our platform to identify specific immune cells to develop into cellular therapies in oncology. We believe this approach has the potential to be applicable to patients across a wide range of cancers.

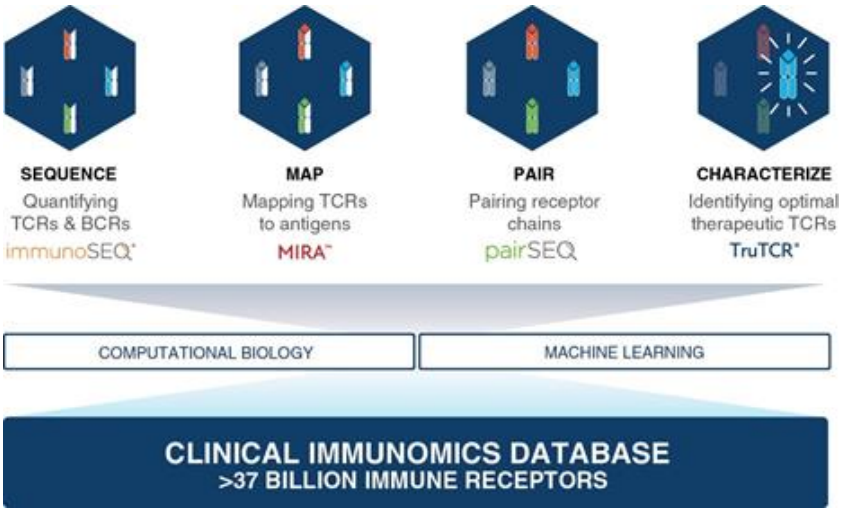
Immune-driven medicine is one of the largest global addressable markets in healthcare. We estimate the potential market opportunity for our portfolio to be $48.7 billion, including $1.0 billion for research products, $16.3 billion for clinical diagnostics and $31.4 billion for cellular therapy in oncology. We use multiple sources and assumptions to estimate the total addressable market for immune-driven medicine. While we believe them to be reasonable, these sources and assumptions may be incorrect or subject to change due to any number of factors. In particular, our drug discovery initiatives are still in the early stages of development, which may make our assumptions and estimates more uncertain. Despite the novelty of this area, we believe we are uniquely positioned to develop and commercialize a pipeline of immune-driven diagnostic and therapeutic products across multiple disease states by leveraging the cumulative learning from our immune medicine platform.

Our Immune Medicine Platform

The adaptive immune system is comprised of specialized cells, called T cells and B cells, which hold the instructions for diagnosing and treating most diseases. These instructions enable these cells to identify, bind and destroy pathogens or human cells presenting foreign signals of disease ("antigens") using receptors on their cell surface. Unlike all other genes in the human genome, the genetic sequences of T cell receptors ("TCRs") and B cell receptors ("BCRs") rearrange over time creating massive genetic diversity. The resulting diversity of the adaptive immune repertoire, which consists of over 100 million different genes in a healthy adult compared to approximately 30,000 genes in the static human genome, gives the immune system the ability to detect and respond to millions of different antigens associated with human disease.

Our immune medicine platform combines a suite of proprietary technologies, bioinformatics, software and machine learning to generate clinical immunomics data to decode the adaptive immune system. It extracts and interprets insights from the adaptive immune system with the scale, precision and speed required to enable the design of clinical products tailored to the specific genetics of each patient's immune system.

Our Immune Medicine Platform



Our immune medicine platform performs the following key functions related to immune receptors:

- *Sequence.* immunoSEQ sequences single chains of "Y-shaped" TCRs or BCRs using next generation sequencing ("NGS"), enabling us to understand the quantity and diversity of T and B cells in a biological sample. This provides deep insights into individual and collective immune responses at a scale that is thousands of times greater than was previously possible.
- *Map.* MIRA (Multiplexed Identification of T cell Receptor Antigen Specificity) maps millions of TCRs to thousands of clinically relevant antigens. Combined with immunoSEQ, MIRA elucidates what potential diseases a patient's immune system has been exposed to or is actively fighting.
- *Pair.* pairSEQ builds on immunoSEQ by using a combinatorial strategy to accurately pair both chains of Y-shaped immune cell receptors at high-throughput, which is challenging to do at scale using other methods because the two chains of the Y-shaped receptors are located on different chromosomes. The ability to accurately pair both chains of the receptors in a sample enables us to reconstruct receptors for therapeutic purposes.
- *Characterize.* TruTCR characterizes binding, cytotoxicity and safety properties of antigen-specific, paired TCRs to identify a subset that is therapeutic-grade, enabling the discovery and development of optimal clinical candidates to be engineered into TCR-mediated cellular therapies.

The massive amount of data generated by our immune medicine platform is stored in our dynamic clinical immunomics database of over 58 billion immune receptors, of which we have data rights to over 37 billion. We believe the application of machine learning, supported by our collaboration with Microsoft, has the potential to exponentially accelerate our ability to derive novel insights from this database and use them to inform our robust product development efforts.

Our Current Products and Pipeline

Our current portfolio includes commercial products and services in life sciences research and clinical diagnostics, and we are developing products and services in both clinical diagnostics and drug discovery. Our commercial research product, immunoSEQ, primarily serves as our underlying research and development engine to develop and validate our clinical pipeline. We plan to continue to invest in our immune medicine platform to develop additional clinical products, which we prioritize based on clinical actionability, unmet medical need and commercial viability.

Life Sciences Research

Our immunoSEQ research service and kit are used to answer translational research questions and discover new prognostic and diagnostic signals. Our technology has been used for research purposes by over 2,200 academic researchers and more than 165 biopharmaceutical companies and incorporated into over 600 clinical trials since our inception in 2009. We have completed development of a next generation, sample-type agnostic research use only ("RUO") kit that is now available. Our goal is to achieve global distribution of our research product. We are working to analytically validate the improved version of immunoSEQ so that all research data generated using immunoSEQ can be used for clinical validation of potential diagnostic applications.

Clinical Diagnostics

Our clonoSEQ diagnostic test detects and monitors the remaining number of cancer cells that are present in a patient's body during and after treatment, known as MRD. In September 2018, clonoSEQ was granted marketing authorization from the FDA, under the *de novo* process, for patients with MM and ALL to monitor their MRD from bone marrow samples. clonoSEQ is also available for use in other lymphoid cancers as a laboratory developed test ("LDT"). In January 2019, clonoSEQ received Medicare coverage aligned with the FDA label and National Comprehensive Cancer Network ("NCCN") guidelines for longitudinal monitoring in MM and ALL. In 2019, we secured payor coverage for clonoSEQ aligned with our FDA label with Medicare, five national private payors and several large regional plans for a total of over 175 million covered lives. Most recently, Medicare coverage has also been extended to include patients with chronic lymphocytic leukemia ("CLL"). clonoSEQ testing has been ordered by clinicians for over 10,000 unique patients and used by more than 40 biopharmaceutical companies in over 190 clinical trials. We continue to deepen our commercial investments to expand clinical adoption of clonoSEQ and have increased the size of our specialized sales organization and infrastructure in the United States while exploring partnerships in other parts of the world. We believe clonoSEQ has broad applicability across all lymphoid malignancies and we are pursuing FDA clearance to expand the clonoSEQ label to multiple additional indications. Specifically, we recently submitted a 510(k) premarket notification for CLL from blood samples in December 2019 and are actively validating the test for patients with non-Hodgkin's lymphoma ("NHL") disease types. Importantly, we are validating the use of clonoSEQ to monitor MRD in patients with ALL and MM also from blood samples, which is less invasive than bone marrow samples, and may facilitate more frequent monitoring and broader physician adoption.

Leveraging Microsoft's machine learning capabilities to create the TCR-Antigen Map, we are developing a diagnostic product, immunoSEQ Dx, that may enable early detection of many diseases from a single blood test. Initially, we are validating early detection testing for a set of discrete diseases for which there is a significant unmet medical need for better diagnostic testing and early intervention, and where antigen specificity is well-known. These include certain prevalent cancer types, infectious diseases and autoimmune disorders. In the third quarter of 2019, we established proof of concept in acute Lyme disease from two independent, retrospective cohorts of over 200 patients. In both of these studies, we compared to standard of care, two-tiered serology testing. Our data shows a reduction in both false positive and false negative rates compared to standard of care, as well as an overlap of TCRs specific for Lyme disease between the two patient cohorts. The signal in Lyme establishes proof of concept of the science behind immunoSEQ Dx by demonstrating that machine learning can be leveraged to develop diagnostic signals, even without the large cohorts of prospective patient data often required for diagnostics development. We also continue to progress toward identifying signals for other disease states, such as celiac disease. In addition to continually assessing retrospective patient cohort analyses, in the third quarter of 2019, we opened a research study for 1,000 volunteers who believe they may have celiac disease. We have already enrolled over 400 people, with a projected study close in the second half of 2020. We plan to sponsor several other such studies in additional disease states in the near future.

We believe we are uniquely positioned to rapidly identify signals for early detection across many disease states simultaneously because our immune medicine platform works with retrospective sample sets, and uses machine learning and computational statistics to continuously improve our detection and accuracy. Data generated from multiple sources, including retrospective patient cohorts, Adaptive-sponsored trials and machine learning applied to our clinical immunomics database, will all be used in ongoing discussions with the FDA to demonstrate the concept and potential of immunoSEQ Dx in early 2020, with a planned submission for one indication by the end of 2020.

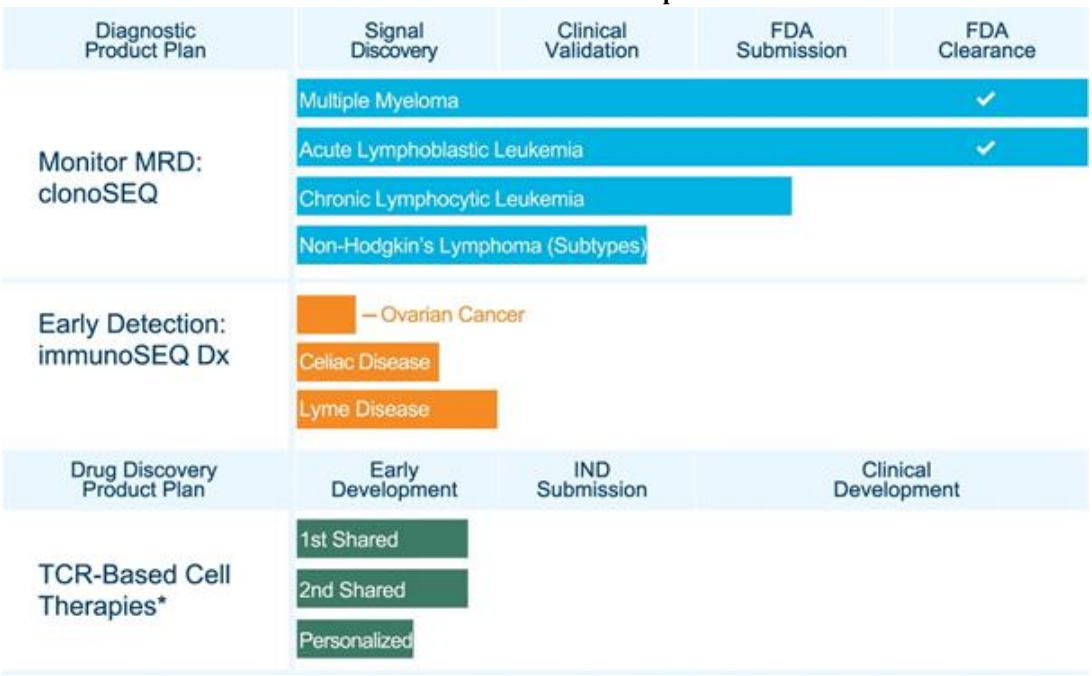
Drug Discovery

Our TruTCR process characterizes TCRs against shared antigens for use in the development of therapeutics. In December 2018, we entered into an exclusive collaboration with Genentech to leverage this capability for the development of cellular therapies in oncology. We are pursuing two product development pathways for novel T cell immunotherapies in which Genentech intends to use TCRs screened by our immune medicine platform to engineer and manufacture cellular medicines:

- *Shared Products.* The shared products will use "off-the-shelf" TCRs identified against cancer antigens shared among patients ("Shared Products"). We are on track for a planned investigational new drug ("IND") submission by Genentech for the first shared product targeting a selected shared cancer antigen by the end of 2020.
- *Personalized Product.* The personalized product will use patient-specific TCRs identified by real-time screening of TCRs against cancer antigens in each patient ("Personalized Product").

In parallel, we plan to evaluate an investment in facilities for the screening of patient-specific TCRs to shorten the time from patient blood draw to infusion of the Personalized Product. We believe this investment would position us to potentially pursue additional opportunities outside of this collaboration, including cellular therapy in other disease states and cancer vaccines.

Our Clinical Portfolio and Pipeline



* Product candidates in development as part of our worldwide collaboration and license agreement with Genentech. The "1st Shared" and "2nd Shared" product candidates refer to the two lead clinical product candidates selected from our library of TCRs that target cancer antigens present in many cancer patients. Genentech will determine the timing of discussions with, and submissions to, the FDA.

Our Competitive Strengths

We aim to harness the inherent biology of the adaptive immune system to develop clinical products and services that improve human health by leveraging our core competitive strengths.

- *Our immune medicine platform is uniquely capable of supporting clinical products.* We have developed a platform that is capable of reading and translating the massive genetic diversity of the adaptive immune system and its selective response to disease. Specifically, our platform *sequences* immune receptors and *maps* them to antigens for diagnostic applications, *pairs* receptor chains and *characterizes* antigen-specific, paired receptors to identify optimal clinical targets for therapeutic use. We are the only company that can perform all of these functions—and we do so at an unprecedented scale to develop novel clinical diagnostic and therapeutic products.
- *Our clinical immunomics database provides a robust product development engine.* Our dynamic clinical immunomics database of over 37 billion immune receptors, now being annotated with antigens using machine learning, drives our ability to rapidly discover and develop potential diagnostic and therapeutic applications. Our aim is to translate the natural capabilities of the immune system into the clinic by capturing the millions of diverse unique receptors present in a patient's blood.
- *Clinical applicability spans diagnostic and therapeutic product potential.* Our ability to accumulate, synthesize and process billions of immunomic datapoints to generate multiple clinical diagnostic and therapeutic applications across disease areas provides optionality to our commercial pipeline. Each of our products also has broad applicability, enabling robust product lifecycle extensions.
- *Regulatory and reimbursement expertise will help inform future clinical product development.* Having successfully obtained FDA marketing authorization, and coverage for clonoSEQ from Medicare and five national private payors, we believe we have developed valuable core capabilities that will facilitate future product development through to regulatory approval and reimbursement. We believe this capability will inform future development of other clinical products, including early detection tests.

- *Transformational collaborations with industry leaders validate our platform.* Our collaborations with industry-defining leaders such as Genentech and Microsoft validate our unique approach to advancing the promise of immune-driven medicine. We will continue to seek opportunities to optimize our ever-growing clinical immunomics database to drive product development and commercial success and facilitate efficient use of capital.
- *Strong intellectual property protects our immune medicine platform and its applications.* As of December 31, 2019, we had filed 368 patent applications, 283 of which had issued as of that date, covering improvements in sequencing methods and new ways to leverage adaptive immune receptors for life sciences research, clinical diagnostic and drug discovery applications.

Our Strategy

Our focus is to leverage our immune medicine platform and competitive strengths to develop transformative clinical solutions accessible to patients around the world.

- *Advance the promise of immune-driven medicine.* We facilitate the development of the immune medicine field by providing a platform to encourage generation of immunomics data to facilitate a deeper understanding of, and biological discovery from, the adaptive immune system. We leverage the unique capability of our platform to translate the genetics of a patient's immune system with the scale, precision and speed required to enable the development of Personalized Products, including clinical diagnostic tests for disease monitoring and early detection, as well as immune-based therapeutics.
- *Rapidly identify and advance new products, leveraging foundational technology.* Integrate proven chemistry into our clinical products in development, avoiding the need to re-engineer new products for every clinical application. We do this by serially identifying new applications of immunoSEQ Dx for early detection of disease using retrospective datasets without requiring live cells from large cohorts of patients, and by characterizing TCRs for therapeutic use. As our platform expands into new indications across cancer, autoimmune conditions and infectious diseases, we believe we will benefit from economies of scale and drive margin improvement over time.
- *Entrench our products and services in clinical drug development with biopharmaceutical collaborators.* Position our platform as the gold standard for the validation of potential immune-driven clinical discoveries in late-stage clinical trials. Since inception, our products and services have been used by more than 165 biopharmaceutical companies and incorporated into over 600 clinical trials, and clonoSEQ has proven to be the MRD test of choice for select registrational trials. To deepen our established position as a partner of choice, we provide end-to-end support, including hypothesis-driven trial design, extensive data analyses, parallel regulatory support, compliant data transfers and novel target screening. These synergistic relationships advance the development and adoption of our own clinical products and also inform drug development for our partners.
- *Drive the commercial adoption of distributed, reimbursed and regulated clinical products.* Expand distribution and drive usage of our products and services, including the possibility of developing clinical *in vitro* diagnostic ("IVD") kits. Leverage the commercial infrastructure built for clonoSEQ to submit clinical data for regulatory clearance of our products and services, expand current payor coverage and provide robust billing and patient access infrastructure for multiple clinical applications.
- *Maintain an entrepreneurial, scientifically rigorous, data-driven and inclusive corporate culture.* Fuel the promise and potential that our platform offers to help patients better manage their disease by translating insights from our world-class team, which includes 98 people with medical or doctoral degrees with expertise in biology, chemistry, bioinformatics, software, drug discovery, development and commercialization, into clinical products and services. We plan to continue to expand our team to advance the promise of immune-driven medicine.

A Primer: The Adaptive Immune System

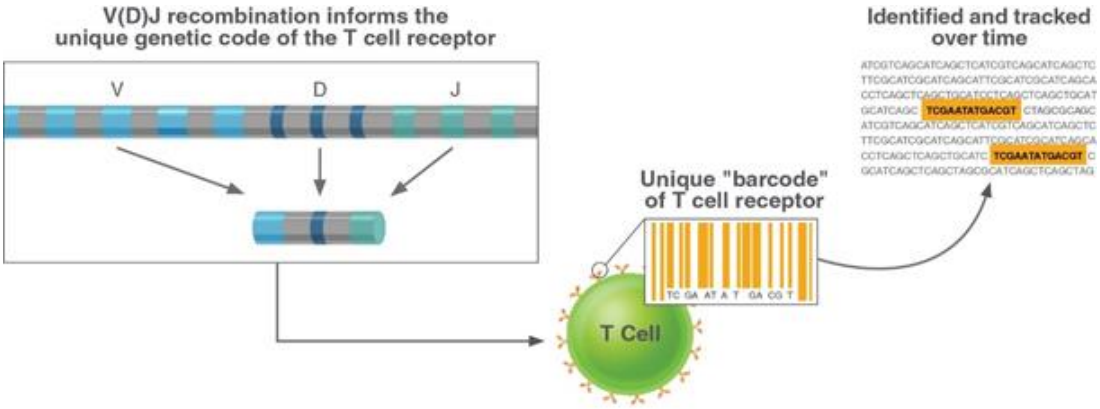
Over millions of years, the adaptive immune system has evolved an elegant solution to keeping people healthy. It recognizes and responds to most antigens, whether they come from outside the body, such as a virus, or inside the body, such as mutations that drive cancer.

The innate and adaptive immune systems both play a role in human immunity, but only the adaptive immune system provides a specific response to signals of disease, or antigens. These disease specific antigens are primarily fragments of proteins that are recognized as foreign, such as proteins from a virus. However, antigens can be recognized as foreign even if they are not from a pathogen. In cancer cells, antigens are generated from neoantigens, which are derived from mutations specific only to the cancer, or tumor associated antigens ("TAAs"), which are from aberrantly expressed normal proteins. For autoimmune disorders, the immune system mistakenly recognizes normal protein fragments as foreign antigens and attacks otherwise healthy tissue.

The Adaptive Immune Response

The key cells of the adaptive immune system that enable our bodies to mount responses against antigens are called T cells and B cells. T cells can destroy target cells directly, and B cells secrete antibodies, activating other parts of the immune system to destroy targets.

Each T and B cell has a unique Y-shaped receptor, which can recognize one or a small number of the millions of antigens to which our bodies are continuously exposed. When an adaptive immune response is initiated against a particular disease, the T cells and B cells encoding the disease-specific targeting receptors rapidly multiply through clonal expansion, allowing for a powerful immune response. Some of these expanded cells directly attack the disease, and others form long-term memory to allow rapid recognition of the same antigens in the future and protect against reinfection. Unlike all other genes in the human genome, the genetic sequences of TCRs and BCRs rearrange over time through a complex biological process resulting in massive diversity. The diversity of these receptors is made possible by a unique reshuffling of their genetic code known as V(D)J recombination (V=Variable, D=Diversity, J=Joining). This recombination process only occurs in T cells and B cells, and it results in each cell clone having a unique receptor-associated deoxyribonucleic acid ("DNA") sequence. This unique DNA sequence acts like a barcode that can be used to identify and track an individual receptor over time, as shown in the figure below:



The adaptive immune response requires millions of these unique receptors to be widely distributed and present in the blood at all times in order to have the ability to rapidly respond to many different diseases simultaneously. Even after a specific TCR binds to an antigen and clonally expands, the frequency of these expanded T cell clones containing the TCR remains relatively low in relation to the estimated trillions of other T cells that are circulating. We have demonstrated this by sequencing thousands of healthy individuals for control cohorts for our research and development efforts. We now know that disease-specific TCRs that are clonally expanded in a patient's blood are present, on average, at less than 1 cell out of 100,000 cells. Despite their relatively low abundance, disease-specific TCRs can mount a systemic, persistent response to most perturbations because of the highly specialized properties of the immune response summarized in the table below:

PROPERTY	DESCRIPTION
High sensitivity	The adaptive immune system identifies even a very small amount of antigen in the body.
High specificity	TCRs and BCRs specifically bind to this antigen or pieces of this antigen presented on cells, respectively, but normally avoid binding to features on healthy cells.
Natural amplification	Upon binding, the disease-specific T cells and B cells expand, or multiply exponentially. So, even when the amount of antigen is small, the number of disease-specific T cells can become quite large and more easily measurable.
Systemic expansion	These expanded T cells and B cells then circulate throughout the body to identify and protect the body systemically, making them readily accessible in blood and other tissues.
Persistence	A fraction of these disease-specific T cells, and the B cells that they direct, move into long-term memory and can be found in the blood decades after the disease is cleared.

In order to fully leverage these inherent properties of the immune system to develop clinical products, this enormous diversity and scale must be taken into consideration to be able to reliably and repeatedly measure the relative frequency of each disease-specific T cell in the blood. For example, cancer-specific TCRs circulating in the blood of a cancer patient are only present at 1 out of 100,000 cells. Auto-reactive T cells specific to any given autoimmune disorder circulating in the blood are only present at 1 out of 1,000,000 cells. Accordingly, the ability to detect disease-specific T cells requires a technology that can quantitatively probe a minimum of hundreds of thousands to millions of blood cells from each sample.

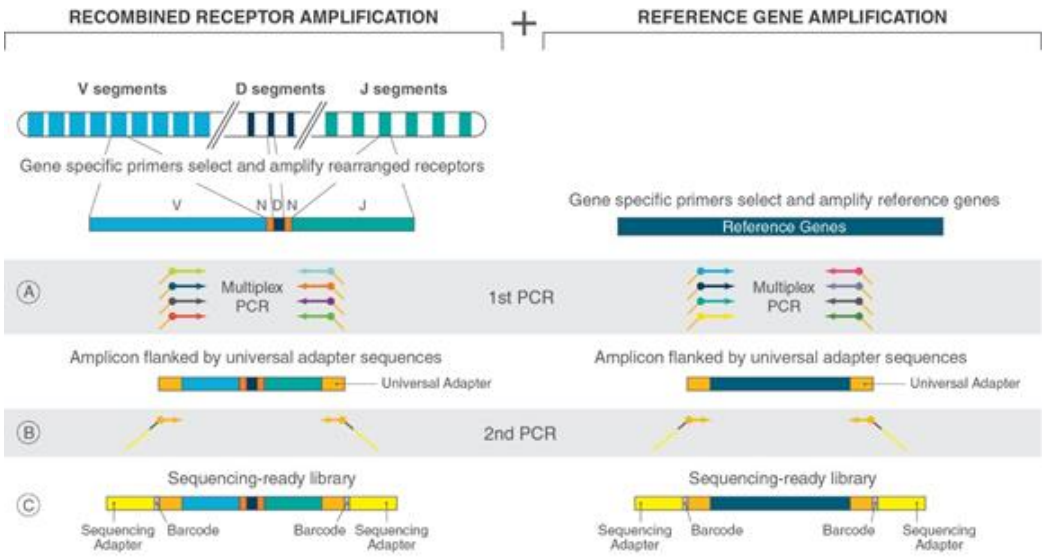
Our Immune Medicine Platform

We built a platform that can reveal and translate these properties of the adaptive immune system with the scale, precision and speed required to enable the development of Personalized Products, including disease monitoring, clinical diagnostic tests for early detection and immune-based therapeutics. Our immune medicine platform combines a suite of proprietary technologies, bioinformatics, software and machine learning to generate clinical immunomics data to decode the adaptive immune system and transform the diagnosis and treatment of disease.

The massive amount of data generated by our immune medicine platform is stored in our dynamic clinical immunomics database of over 58 billion immune receptors, of which we have data rights to over 37 billion. We believe the application of machine learning with Microsoft has the potential to exponentially accelerate the growth of novel insights from this database, which we expect will further inform our product development efforts, as demonstrated by our clinical signal which establishes of proof of concept in acute Lyme disease.

Sequence with immunoSEQ

immunoSEQ sequences single chains of Y-shaped TCRs and BCRs using NGS. NGS generally describes several modern sequencing technologies that enable more efficient DNA and ribonucleic acid ("RNA") sequencing than prior technologies. The key innovation in the development of immunoSEQ, pioneered by Dr. Harlan Robins and a team of leading immunologists at the Fred Hutchinson Cancer Research Center ("Fred Hutch"), was a novel approach utilizing a two-step multiplex polymerase chain reaction ("PCR") amplification process, hybridization and sequencing of rearranged TCRs to determine the sequences in millions of rearranged TCR genes, as shown in the figure below. We apply a similar approach for BCR sequencing. All of the data generated by immunoSEQ is uploaded to our clinical immunomics database and accessed through our proprietary cloud-based visualization and analytic tool called the immunoSEQ Analyzer.



Note: V, D, and J gene segments are recombined on the human TCRB locus. A) Multiplex PCR to capture the highly variable reference gene (autosomal loci). B) PCR to add barcodes and adapter sequences for high-throughput sequencing. C) Sequencing-ready libraries.

One of the biggest challenges of any multiplex PCR technique is controlling for PCR amplification bias, which is critical for accuracy. We solved for this problem by creating a synthetic immune repertoire that mimics rearranged immune receptor loci for all V and J genes. By identifying specific primers that are either under or over amplified, titrating the primer concentrations and computationally adjusting residual bias, we optimize quantitation. The accuracy and reproducibility of our bias control methodology was demonstrated in our lab and independently in a multi-center, lab-to-lab concordance study using our immunoSEQ RUO kit. The ability to generate an unbiased TCR or BCR sequencing read-out is paramount for any clinical product and will be required for the utility and reliability of clinical kits.

immunoSEQ enables us to observe the majority of receptors involved in a real human immune response, providing deep insights into a complex biological system that was previously challenging to understand.

Map with MIRA

Our proprietary MIRA technology enables the identification of TCRs specific to thousands of antigens simultaneously. The MIRA technology leverages a multiplexed, combinatorial approach to mapping TCRs to antigens in four steps:

1. Identify and query antigens of interest which can include neoantigens, tumor-associated, viral, infectious, autoimmune or other antigens.
2. Pool the antigens of interest and incubate them with immune cells from multiple donors whereby antigen specificities are determined based on the antigen pool design.
3. Sort T cells by marker of interest.
4. Match T cell clones to specific antigens based on the presence of specific sequences in designated pools.

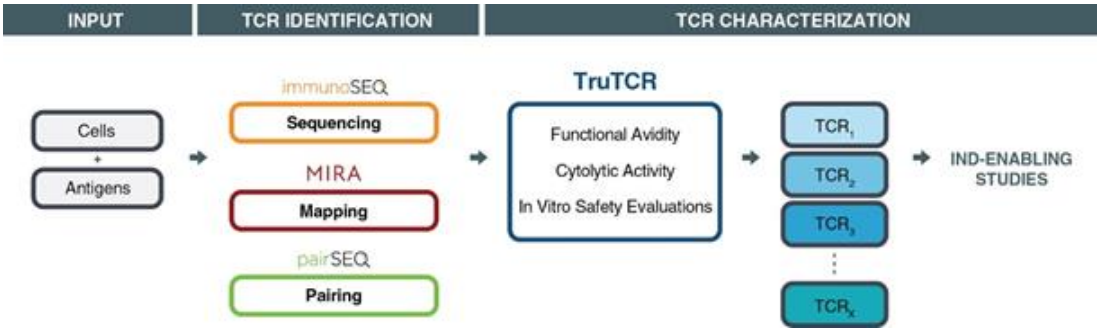
Combined with immunoSEQ, MIRA elucidates what diseases a patient's immune system has been exposed to or is actively fighting at a scale that is one thousand times more sensitive than standard immunological techniques such as ELISPOT, or enzyme-linked immunospot.

Pair with pairSEQ

Our proprietary pairSEQ technology builds on immunosequencing by using a combinatorial strategy to accurately pair the two chains of Y-shaped immune cell receptors at higher throughput than can be achieved with single cell sequencing. Pairing is difficult because the two chains of the Y-shaped receptor are located on different chromosomes, which get separated when DNA is extracted from a cell for sequencing. By pairing TCRs, we rapidly detect thousands of complete chain sequences to develop new TCR-mediated cellular therapies. Additionally, this technology may be used for downstream target discovery for novel therapies. pairSEQ has also been developed for BCRs which may enable improvements to current methods of antibody development and engineering.

Characterize with TruTCR

TruTCR characterizes binding, cytotoxicity and safety properties of antigen-specific, paired TCRs to identify a select subset that are therapeutic-grade, enabling the development of optimal clinical candidates to be engineered into TCR-mediated cellular therapies. Our comprehensive TCR characterization process utilizes advanced cellular immunology to measure TCRs against a variety of metrics to determine the optimal clinical candidates. Antigen-specific, paired TCRs undergo evaluation for avidity, cytokine release, cytotoxicity and safety. Those TCRs that pass the first safety filter are then evaluated for TCR reactivity against T cell lines and primary cells. To date, we have identified and characterized to different stages more than 3,000 unique antigen-specific TCRs against 600 different clinically relevant targets, constituting our pipeline of possible clinical candidates. TCR characterization using TruTCR is summarized in the figure below:



In collaboration with Genentech, we plan to apply a similar process to screen, identify and characterize in real-time what we believe are the most promising patient-specific TCRs targeting the patient's specific cancer antigens, advancing the next generation of cellular therapy in oncology.

Clinical Immunomics Database

We are developing a large, dynamic clinical immunomics database, which currently contains over 58 billion immune receptors, of which we have data rights for over 37 billion. We use our proprietary software and core competency in computational biology to structure and store data and to create tools for rapid analysis and easy visualization. All immunosequencing data is processed and uploaded to a secure cloud-based database.

The record of diseases a person has encountered, both past and present, is recorded in their TCR repertoire. This comprehensive disease information is contained in the immunosequencing data that we generate from each sample, which we believe will be revealed over time by our TCR-Antigen Map. We plan to map, both directly and through machine learning, an estimated 10^{15} TCRs to thousands of clinically relevant antigens, which we believe will allow us to annotate this immunosequencing data with information about disease states, increasing the value of the data over time.

We leverage our database to fuel our pipeline of immune-driven medicine products. With data rights for over 37 billion immune receptors, our platform enables us to work with retrospective samples which serve as training sets to which our Microsoft collaborators apply machine learning and computational statistics to improve the accuracy of certain of our clinical products and services.

Our Products and Services

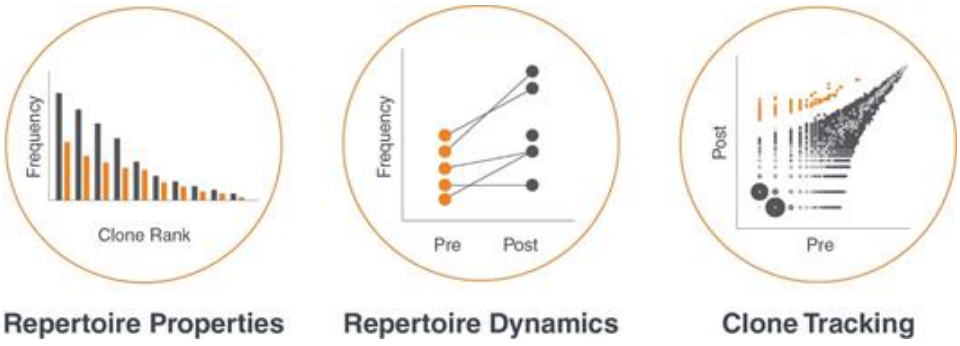
Our current portfolio includes commercial products and services in life sciences research and clinical diagnostics, and we are developing products and services in both clinical diagnostics and drug discovery. Our commercial research product, immunoSEQ, primarily serves as our underlying research and development engine to develop and validate our clinical pipeline. The technologies underlying our current research and diagnostic products, immunoSEQ and clonoSEQ, respectively, leverage the sequencing and tracking capabilities of our immune medicine platform and comprise our sequencing revenue. Our pipeline of clinical diagnostics for early detection and our TCRs for drug discovery are informed by the mapping function of our platform, which we are optimizing with Microsoft's machine learning capabilities. The selection of TCRs for drug discovery also leverages the pairing and characterization components of our platform. We have strategically scaled our drug discovery efforts in 2019 to expedite the path to the clinic for the cellular therapy product candidates we are developing in collaboration with Genentech, which generates most of our development revenue. We plan to continue to invest in our platform to develop additional clinical applications, which we prioritize based on rigorous data requirements for clinically actionability, unmet medical need and commercial viability.

Life Sciences Research

immunoSEQ for Research Use Only

Our immunoSEQ technology, which we offer to customers as a service and a kit, is the core of our immune medicine platform. immunoSEQ utilizes multiplex, bias-controlled PCR to accurately and quantitatively sequence millions of immune receptors at high-throughput directly from DNA. We believe immunoSEQ is positioned to become the global standard for immunosequencing due to the quality and reliability of our data and the analytics and data visualization tools that are easily accessible to customers in the immunoSEQ Analyzer, whether sequenced as a service or a kit.

Since inception, immunoSEQ has been used for research purposes by over 2,200 academic researchers and more than 165 biopharmaceutical companies and incorporated into over 600 clinical trials to answer translational research questions relating to the adaptive immune system, monitor response to therapies and discover new prognostic and diagnostic signals. These research questions are answered by using the data generated by immunoSEQ and uploaded to the immunoSEQ Analyzer to study different properties and dynamics of all of the sequences in an immune repertoire, such as frequency or abundance, and by tracking specific sequences over time in clinical trials. Graphical representations of the Analyzer output are shown in the figure below:



immunoSEQ provides a growing revenue stream. However, we also use immunoSEQ as the foundational technology for our clinical diagnostic and therapeutic products. To fuel innovation, we also provide immunoSEQ to select research and development collaborators who gain access to immunoSEQ and significant computational and analytical support, co-share and co-publish the data with us, and contribute to the validation of potential clinical diagnostic discoveries. For example, we work closely with our collaborators to conduct translational research to explore the use of immunosequencing to predict responders to novel immunotherapies such as checkpoint inhibitors.

Our immunoSEQ Analyzer is housed on a secure cloud-based database and is the visualization gateway to our clinical immunomics database that currently has billions of TCR and BCR sequences which are often annotated and accompanied by samples with associated metadata. We offer computational services to assist our customers in realizing the power of their data and to compare their data to other publicly available datasets in our clinical immunomics database. We contribute some of our own research and development sequences into the publicly available datasets and customers are offered the option to make their data public using one of our tools on our immunoSEQ Analyzer, called immuneACCESS, through which researchers can expedite and streamline the peer-review process by sharing their data with reviewers prior to manuscript submission. The ongoing analysis of immune receptor data from an expanding database tagged with clinical metadata, when possible, has led to over 460 peer-reviewed publications referencing immunoSEQ and potential clinical signals to explore.

We recently launched an improved version of immunoSEQ to our research customers. We incorporated these chemistry improvements into a new RUO kit, which was completed in the fourth quarter of 2019 and is now available. We expect this service and kit offering to become the technology upon which we clinically validate the early detection diagnostics we are developing using our TCR-Antigen Map. The kit improvements will further enhance the quantitation of the data and allow for any sample type to be used, including stored cancer tumor tissue sections, which is more readily available globally amongst researchers in the field of cancer immunotherapy.

Clinical Diagnostics

We aim to be a global leader in immune-driven diagnostics for early detection, prognosis and monitoring of disease. To achieve this long-term goal, we are focused on leveraging the sequencing and mapping functions of our immune medicine platform to develop diagnostic tests that meet regulatory standards, are widely reimbursed and are accessible to patients all around the world.

Monitoring MRD with clonoSEQ

Our first diagnostic product, clonoSEQ, is an FDA-authorized test for the detection and NGS-based monitoring of MRD in bone marrow samples in patients with MM and ALL. In these blood cancers and others, such as CLL and NHL, the malignant cell is derived from a T cell or B cell. MRD refers to the presence and number of these malignant T or B cells that may remain in a patient’s body during and following treatment. Because our technology quantifies the frequency of every T cell or B cell in a sample, we can monitor MRD accurately at a sensitivity of 1 out of 1,000,000 cells, given sufficient sample input. By taking a baseline measurement prior to starting therapy and then tracking the number of cells at several time points following therapy initiation, hematologists can improve their ability to detect relapse early, help predict patient outcomes and monitor response to therapy.

NCCN Guidelines recommend using a validated test to measure MRD to define the burden of disease and assess response to therapy in MM and ALL after each treatment stage. NGS-based MRD testing has been added to these guidelines and we plan to seek expansion of the recommendations to include additional time points in each disease state and to incorporate clonoSEQ specific data.

MRD monitoring is becoming increasingly important in the hematologic oncology field because highly effective new therapies are extending survival. This has created a need for more sensitive tools to monitor the disease status of patients over longer periods of time and has introduced the potential for MRD to be included as a surrogate or primary endpoint in registrational clinical trials. We believe we are uniquely positioned to benefit from these industry dynamics with both our clinical and biopharmaceutical customers.

clonoSEQ testing has been ordered by clinicians for over 10,000 unique patients. We believe increased adoption of clonoSEQ will now be possible due to the extensive coverage policies granted in 2019 by Medicare to assess MRD at multiple time points throughout therapy in MM, ALL and CLL, and five national private payors, and several large regional payors, together representing over 175 million total covered lives. We are in active discussions with other large private national and regional payors. Additionally, we believe clonoSEQ will remain the preferred commercial test among biopharmaceutical companies using MRD in their registrational trials. To that end, clonoSEQ is now being used by more than 40 biopharmaceutical companies in over 190 clinical trials. To continue demonstrating clinical utility across disease settings and lines of therapy, clonoSEQ is also being used in 40 ongoing prospective investigator-led clinical trials, and our MRD data have been included in over 66 peer-reviewed publications.

clonoSEQ is also currently available as an LDT for use across lymphoid malignancies and sample types, including those which are not yet authorized by the FDA. We continue to pursue FDA clearance to expand the clonoSEQ label to multiple additional indications. Specifically, we recently submitted a 510(k) premarket notification for CLL from blood samples in December 2019 and are actively validating the test for patients with NHL disease types. Importantly, we are validating the use of clonoSEQ to monitor MRD in patients with ALL and MM also from blood samples, which is less invasive than bone marrow samples, and may facilitate more frequent monitoring and broader physician adoption.

The Technology

clonoSEQ is our FDA-authorized, NGS-based MRD technology that is designed to sequence all rearranged receptor sequences in a tumor in parallel to ensure accurate, sensitive and robust MRD monitoring.

A summary of the steps for FDA-authorized usage is as follows:

1. gDNA is extracted from bone marrow.
2. Extracted DNA quality is assessed, and rearranged immune receptors are amplified using a multiplex PCR.
3. Reaction-specific index barcode sequences for sample identification are added to the amplified receptor sequences by PCR.
4. Sequencing libraries are prepared from barcoded amplified DNA which are then sequenced by synthesis using NGS.
5. Raw sequence data are uploaded from the sequencing instrument to our analysis pipeline.
6. Sequence data is analyzed in a multi-step process, where a sample's sequence data is first identified using the sample index sequences and the data is then processed using a proprietary algorithm with in-line controls to remove amplification bias.
7. Following completion of these data processing steps, a report is issued.

Adaptive Assist: Patient support program

Adaptive Assist is our patient support program to facilitate access to clonoSEQ testing services for patients who could benefit from the clinical insights provided by NGS-based MRD testing. Patients can call to discuss their individual circumstances with one of our dedicated patient support representatives in order to better understand their coverage prior to clonoSEQ testing and to navigate the insurance process, including appeals for denied claims. We also offer financial assistance for qualified uninsured and under-insured patients who cannot afford their patient financial responsibility for clonoSEQ.

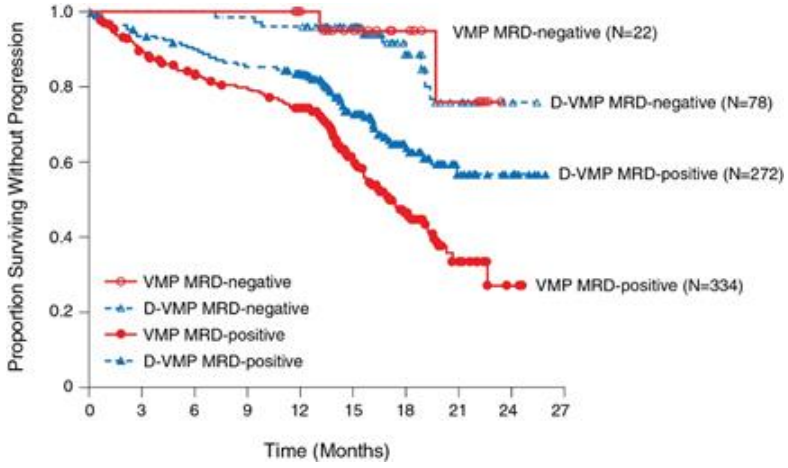
Clinical Validation in FDA Filing for MM and ALL

Our clonoSEQ test has been shown to help better predict patient outcomes and add insight to the evaluation of disease response to therapy because we have clinically validated clonoSEQ's ability to detect MRD at a sensitivity greater than the current recommended clinical standard for all lymphoid malignancies. clonoSEQ has demonstrated sensitivity of 1 out of 1,000,000 cells (10^{-6}), given sufficient sample input, which is a deeper resolution than the current accepted standard of 1 out of 100,000 cells (10^{-5}) or 1 out of 10,000 cells (10^{-4}) for MM and ALL, respectively. Based on these results, as further illustrated below, we believe clinical standards for MRD sensitivity may be increased to 10^{-6} to better predict patient outcomes.

Clinical validation in MM was demonstrated in two studies. The first study, a 720 patient, randomized phase III trial conducted at the Dana Farber Cancer Institute (DFCI 10-106), evaluated the ability to predict progression-free survival ("PFS") and disease-free survival in patients who achieved complete response ("CR") and the ability to predict PFS in all evaluable patients. This study demonstrates that MRD negativity for patients in CR significantly predicts PFS.

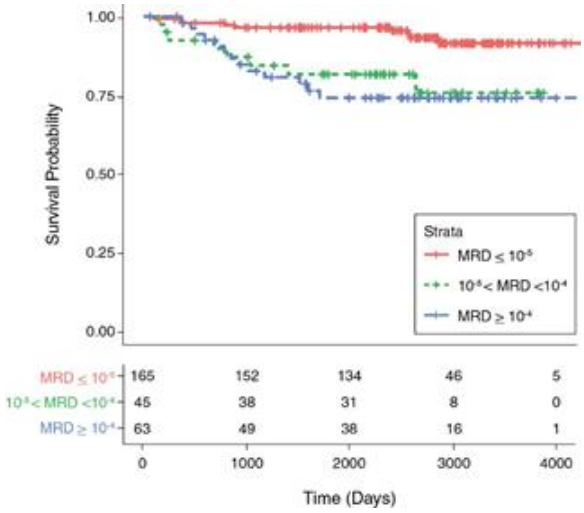
The second study, a 706 patient, randomized phase III trial sponsored by Janssen Biotech, Inc. ("ALCYONE"), evaluated Darzalex in patients with newly diagnosed MM who were transplant ineligible and served as the basis of the approval of Darzalex in combination with Bortezomib, Melphalan and Prednisone ("VMP") in this patient population. This study provides evidence that our clonoSEQ diagnostic test is predictive of PFS, regardless of treatment received. Patients who were MRD negative at less than or equal to 10^{-5} had longer PFS and the group with persistent MRD negativity had the longest PFS overall.

Patients who were MRD negative by the clonoSEQ Assay had longer PFS compared to MRD positive patients regardless of treatment.



Clinical validation in ALL was demonstrated in two Children's Oncology Group studies, AALL0232 (high risk) and AALL0331 (standard risk) by evaluating the ability of clonoSEQ to predict event-free survival ("EFS") at a primary cutoff of 10^{-4} and across a continuous MRD measure. Results demonstrate that patients with the lowest levels of MRD have better outcomes than patients with higher disease burden regardless of risk stratification.

Patients with lower levels of MRD (less than 1/100,000 cells), using the increased sensitivity of clonoSEQ, have a higher probability of EFS.



Strategy to Achieve Market Leadership

We aim to drive adoption and achieve market leadership for MRD monitoring with clonoSEQ for all lymphoid malignancies. To do so, we are executing against the following strategic initiatives:

- *Expand reimbursement with public and private payors.* We are working with payors to develop appropriate coverage policies, generate healthcare economic information and provide robust billing and patient access infrastructure. In 2019, we secured payor coverage for clonoSEQ aligned with our FDA label with Medicare, five national private payors and several large regional plans for a total of over 175 million covered lives. Most recently, Medicare coverage has also been extended to include patients with CLL. We expect to seek broader coverage in line with our planned FDA label expansions and we continue to invest in health economic research and real-world evidence to demonstrate the benefits of including MRD testing across indications.
- *Entrench clonoSEQ in biopharmaceutical clinical trials.* As the industry pursues the inclusion of MRD as a potential surrogate or primary endpoint in clinical trials for lymphoid malignancies, having a standardized and highly accurate and sensitive method for MRD testing to guide clinical decisions in late stage trials, including registrational trials, is valuable. Our goal is to position clonoSEQ for use by our biopharmaceutical collaborators as the MRD test of choice for these clinical trials.
- *Validate clonoSEQ in additional indications for use.* With the end goal of clonoSEQ becoming a universal MRD test for all lymphoid malignancies, we have developed a robust lifecycle development plan to generate sufficient clinical evidence to support the extension of the FDA label beyond ALL and MM. We submitted for label expansion to include CLL in December 2019, and are actively generating clinical validation data to support a future submission in NHL.
- *Validate clonoSEQ in blood to offer a minimally invasive alternative.* Our CLL 510(k) submission is based on data generated from blood samples and we expect to also submit data to the FDA in 2020 to add blood as a validated sample type to our FDA label for MM and ALL, which may enable more frequent monitoring of patients over longer periods of time. Testing with blood is less invasive for patients and less expensive as compared to MRD testing from bone marrow samples, and it may only be possible because of the deep sensitivity of our clonoSEQ diagnostic test.
- *Invest in an experienced, specialty salesforce.* We are expanding our sales organization to target key customer segments, including academic centers, integrated health networks and community clinicians, in a tiered manner based on patient volume. In 2019, we focused on Tier 1 and Tier 2 accounts, which we estimate to drive 75% of the market potential. As adoption increases, we will drive uptake in Tier 3 and Tier 4 accounts.
- *Develop a decentralized testing solution.* We continue to explore options to service the MRD opportunity in institutions and markets where local testing is needed or required. One way to achieve this goal is to develop, in partnership with Illumina, Inc. (“Illumina”), a clonoSEQ IVD kit which could be sold to trained high complexity molecular labs.
- *Expand internationally.* We have expanded our technology transfer program to select centers to conduct investigational studies that further demonstrate the value of clonoSEQ and are essential for reimbursement submissions. We have already completed successful technology transfer labs in Toulouse, France in 2017 and Bologna, Italy and Heidelberg, Germany in 2019. Additionally, we are in the process of selecting additional select sites in Europe in 2020. In 2019, we obtained a Conformité Européene (“CE”) mark for our clonoSEQ reagents, which is intended to support our reimbursement efforts in Europe. We expect these market development activities to enhance our commercialization efforts and accelerate international market acceptance over the next three to five years.

Early Detection with immunoSEQ Dx

By learning to read the antigen specificity of a patient’s immune system, we are developing the immunoSEQ Dx diagnostic test for early detection across a broad range of diseases, including certain prevalent cancer types and autoimmune disorders. We believe the adaptive immune system presents an ideal model for diagnostic tools for early detection of disease. Treatment is typically most effective early in the course of a disease, when there is a minimal amount of disease-specific antigen present. TCRs recognize this very small amount of antigen before it is detectable by conventional methods and then they expand exponentially. Given this large response in proportion to the amount of antigen present, we believe we will be able to see this signal of disease much sooner than is possible with other methods of early disease detection.

We are leveraging our existing immunoSEQ technology to develop immunoSEQ Dx for the early detection of many diseases simultaneously. This is possible because our platform works with retrospective sample sets and uses machine learning and computational statistics to continuously improve accuracy without requiring large cohorts of prospective patients. Before pursuing broad population screening tests, however, we are initially developing immunoSEQ Dx for the early detection of specific disease states that meet the following criteria:

- Clinically relevant antigens are known and understood.
- High unmet medical need for diagnosis.

- Potential to improve patient outcomes with early intervention.
- Availability of sample sets with patient outcomes.

We have initially chosen to pursue a small subset of indications that meet these criteria. In the third quarter of 2019, we established proof of concept in acute Lyme disease, as we continue to progress toward identifying signals for other disease states. Our goal is to make a submission in the fourth quarter of 2020 and to run analytical validation studies for the technology in parallel. We plan to repeat this process for additional disease states as we expand our knowledge about the antigen specificity of millions of TCRs in our clinical immunomics database. Using these clinical signals and validation studies, we then plan to pursue FDA clearance, authorization or approval of immunoSEQ Dx in one or more of these initial indications as an IVD conducted in our Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified, College of American Pathologists ("CAP") accredited, ISO 13485-certified laboratory. We believe the same blood test will ultimately be able to be used to detect multiple diseases simultaneously.

The TCR-Antigen Map

In order to detect disease from a blood sample, the TCRs sequenced by immunoSEQ must be annotated with their disease-specific antigens by cross-referencing our TCR-Antigen Map in the cloud. We are building our TCR-Antigen Map as part of our strategic collaboration with Microsoft established in December 2017. Together we are using immunosequencing, proprietary computational modeling and machine learning to map TCR sequences to the antigens they bind. Using these data, we aim to translate the natural diagnostic capability of the immune system into the clinic.

Proof of Concept

For proof of concept of the ability of our technology to detect infectious disease exposure in patients, our researchers profiled the T cell repertoire of more than 660 subjects with known cytomegalovirus ("CMV") status and identified a set of TCRs across that population that are specific for CMV. This set of CMV-specific TCRs was then tested as a method for CMV diagnosis in a new cohort of 120 people. Using this TCR set, we were able to confirm CMV infection in up to 93% of blood samples evaluated. These data represent a significant step forward for the potential use of TCR sequences to detect exposure to pathogens or other diseases with distinct T cell profiles.

By combining the power of our clinical immunomics database with a machine learning technique known as pseudo-labeling, we are rapidly scaling the identification and validation of antigen-specific TCRs for diagnostic applications. For example, we have already iteratively scaled the identification of additional CMV-specific TCRs to improve the diagnostic accuracy in our proof of concept study to 98% with a minimal false positive rate. We believe this approach has the potential to significantly reduce the time and number of individuals, and ultimately the cost, required to accurately validate our clinical diagnostics across different diseases.

In the third quarter of 2019, we established proof of concept in acute Lyme disease from two independent, retrospective cohorts of over 200 patients. In both of these studies, we compared to standard of care, two-tiered serology testing. Our data shows a reduction in both false positive and false negative rates compared to standard of care, as well as an overlap of TCRs specific for Lyme disease between the two patient cohorts. The signal in Lyme establishes proof of concept of the science behind immunoSEQ Dx by further demonstrating that machine learning can be leveraged to develop diagnostic signals, even without the large cohorts of prospective patient data often required for diagnostics development.

Strategic Plan to Evolve Early Detection of Disease

To achieve our goal of developing a diagnostic test for early detection across a broad range of diseases, we are pursuing the following strategic plan:

- Apply machine learning to high-throughput mapping to generate the TCR-Antigen Map.
- Demonstrate clinical signals for early detection using mapped TCRs in select indications.
- Launch one TCR sequencing technology, immunoSEQ Dx, for initial indications.
- Broaden utility to a wide range of diseases without requiring large prospective trials.

Drug Discovery

Our aim is to develop immune-mediated therapies in oncology and other disease areas by using the full functionality of our immune medicine platform, including TruTCR for TCR characterization. We are currently working to leverage our TCR discovery capabilities to enable commercialization of novel therapies by collaborators. In the future, we may explore expanding our end-to-end capabilities for the development of cellular therapies and vaccines.

TCR Discovery for Cellular Therapy

We have developed a high-throughput TCR screening process that allows for the discovery of antigen-specific TCRs that occur in low frequencies in healthy individuals. We believe this provides a set of naturally-occurring TCRs with a more favorable safety profile in comparison to engineered TCRs. We then further characterize these naturally-occurring TCRs for binding avidity and cytotoxic potency. To date, we have identified and characterized to different stages more than 3,000 unique antigen-specific, paired TCRs against 600 different clinically relevant targets, constituting our pipeline of possible clinical candidates. We complete a data package for each characterized TCR that we believe meets the thresholds for therapeutic evaluation. These thresholds are divided into a series of seven key steps covering antigen specificity, functional avidity, cytolysis and safety assessment. A package is considered complete when the TCR meets the rigorous criteria for all seven steps and the data are compiled to support an IND package. As a proof of concept, we compared our fully characterized TCR against WT-1, a TAA often overexpressed in various cancers, to a benchmark WT-1 TCR. A gold standard for testing TCR efficacy is killing of cells that naturally express the target antigen at low levels. Using a cancer cell line that is known to express low levels of WT-1, our candidate WT-1 TCR was over four times more effective at killing cancer cells than the benchmark TCR. The complete data package for our lead WT-1 TCR candidate demonstrates improved avidity, cytolysis and a promising safety profile.

Our high-throughput screening technologies enable us to discover TCRs against any type of antigen which opens up the potential to develop novel TCR-mediated cellular therapies for any type of cancer. As compared to cellular therapies that target T cell surface antigens that are not specific to cancer, we believe our approach to TCR cellular therapies may mitigate the risk of off-target side effects. Therefore, we believe our approach may be applicable to the vast majority of solid tumors, even those where the tissue of origin is vital to survival such as lung or renal.

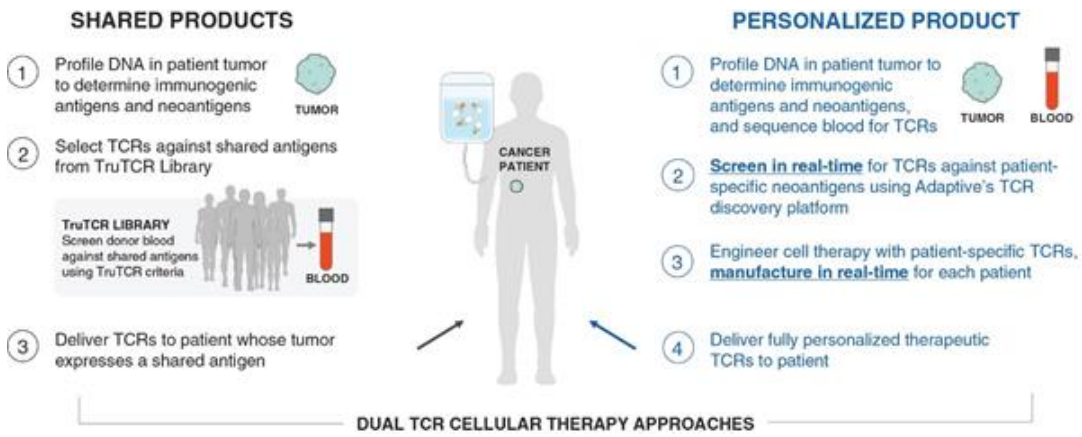
In December 2018, Genentech selected our platform to develop, manufacture and commercialize novel neoantigen directed T cell therapies for the treatment of a broad range of cancers. Our ultimate goal is to harness the vast majority of therapeutically relevant, patient-specific TCRs against neoantigens and advance the next generation of cellular therapies in oncology. We believe our TCR discovery capabilities may also facilitate the development of cellular therapies in disease areas beyond cancer, which we can commercialize outside of the Genentech collaboration.

In addition to cellular therapy applications, we believe our TCR screening capabilities can guide the design and development of next generation vaccines by characterizing the immunogenicity of hundreds of antigens at a time. Our platform can also be used to then monitor early signs of antigen-specific immune response in patients treated with novel vaccines.

Strategic Collaboration with Genentech

Through our worldwide collaboration and license agreement with Genentech, we plan to develop, manufacture and commercialize novel neoantigen directed T cell therapies for the treatment of a broad range of cancers to advance the next generation of cellular therapies in oncology. We are pursuing two product development pathways for novel T cell immunotherapies in which Genentech intends to use TCRs screened by our immune medicine platform to engineer and manufacture cellular medicines:

- *Shared Products.* The Shared Products will use “off-the-shelf” TCRs identified against cancer antigens shared among patients. We are on track for a planned IND submission by Genentech for the first shared product targeting a selected shared cancer antigen by the end of 2020.
- *Personalized Product.* The Personalized Product will use patient-specific TCRs identified by real-time screening of TCRs against cancer antigens in each patient.



Under the terms of the agreement, we received a $300.0 million initial upfront payment in February 2019, and we may be eligible to receive approximately $1.8 billion in aggregate milestone payments upon achievement of specified development, regulatory and commercial milestones. Additionally, we may receive royalties on sales of products commercialized under that agreement. Genentech will be responsible for clinical, regulatory and commercialization efforts. We will be responsible for the screening and identification of TCRs that can most effectively recognize and directly target specific cancer antigens, including neoantigens.

In parallel, we plan to evaluate an investment in facilities for the screening of patient-specific TCRs to shorten the time from patient blood draw to infusion of the Personalized Product. We believe this investment would position us to potentially pursue additional opportunities outside of this collaboration, including developing and commercializing cancer vaccines and cellular therapies in other disease states.

Our People and Culture

Our employees, internally referred to as "Adapters," are passionate about immune-driven medicine, empowered by scientific discipline and fueled by our foresight and curiosity about the adaptive immune system.

As of December 31, 2019, we had 453 full-time employees of which 189 had advanced degrees, including 98 who hold medical or doctoral degrees. None of our employees are subject to a collective bargaining agreement and we have not experienced any work stoppages. We believe relations with our employees are good.

Our talented employees drive our mission and share core values that both stem from and define our culture, which plays an invaluable role in our execution at all levels in our organization. Our core values are used in candidate screening and in employee evaluations to help reinforce their importance in our organization:

- *Make it happen.* Individual ownership and accountability keep us moving forward.
- *Innovate fearlessly.* Push against boundaries and think boldly to achieve world-changing results.
- *Debate openly.* Value discussions inspired by different points of view.
- *Work together.* Demonstrate you care about the success of others. The same goes for our partners and customers—together we can achieve more.
- *Follow True North.* Show up with integrity and do the right thing.
- *Have fun.* Fun makes everything better.

We believe our employees are highly engaged, and we were recognized consecutively in 2018 and 2019 by the Puget Sound Business Journal as one of Washington State's Best Places to Work.

Strategic Collaborations and Other Agreements

Genentech Agreement

In December 2018, we entered into the Genentech Agreement to develop, manufacture and commercialize novel neoantigen directed T cell therapies for the treatment of a broad range of cancers. Pursuant to the Genentech Agreement, we are responsible for the screening and identification of TCRs that can most effectively recognize and directly target specific neoantigens, while Genentech is responsible for clinical, regulatory and commercialization efforts. During the term of the Genentech Agreement, we have agreed to certain defined exclusivity obligations or restrictions with respect to the development and commercialization of certain cell therapies.

In February 2019, we received a $300.0 million upfront payment from Genentech. We also may be eligible to receive approximately $1.8 billion over time, including payments of up to $75.0 million upon the achievement of specified regulatory milestones, up to $300.0 million upon the achievement of specified development milestones, and up to $1.4 billion upon the achievement of specified commercial milestones. Genentech will also pay us tiered royalties at a rate ranging from the mid-single digits to the mid-teens on aggregate worldwide net sales of the Shared Products and the Personalized Product arising from the strategic collaboration, subject to certain reductions, with aggregate minimum floors. For the year ended December 31, 2019, the Genentech Agreement accounted for approximately 41.3% of our revenue.

The Genentech Agreement will continue until the expiration of all royalty payments, but may be terminated by mutual agreement, upon an uncured material breach by either party, upon insolvency of either party, or by Genentech for convenience upon prior written notice.

Microsoft Agreement

In December 2017, we entered into a strategic collaboration agreement with Microsoft ("Microsoft Agreement") to map TCR sequences to the antigens they bind with the goal of developing diagnostic tests for early detection of many diseases from a single blood test.

Pursuant to the Microsoft Agreement, Microsoft applies machine learning and computational statistics to our clinical immunomics data in order to produce predictive models that allow us to map TCR sequences to the antigens they bind. Under the Microsoft Agreement, we retain all rights to these predictive models and the data underlying our TCR-Antigen Map, including the right to commercialize clinical products using our TCR-Antigen Map. We and Microsoft have granted each other certain licenses to one another's intellectual property rights and have agreed to certain defined exclusivity obligations with respect to collaborations and projects that are substantially similar to the Microsoft Agreement.

During the term of the Microsoft Agreement, we have agreed to exclusively use Microsoft's Azure cloud services at standard volume pricing with a minimum Azure consumption requirement. We have also agreed to host each diagnostic product developed as a direct result of the Microsoft Agreement on Azure throughout the term of the Microsoft Agreement and for a period of five years thereafter. In addition, we have agreed to exclusively use Microsoft's immunomics artificial intelligence services for TCR-antigen mapping in connection with all of our technology, products and services developed as a direct result of our collaboration with Microsoft throughout the term of the Microsoft Agreement.

The Microsoft Agreement has a seven-year term and may be terminated by mutual agreement or by either party upon an uncured material breach. Concurrently with entry into the Microsoft Agreement, Microsoft purchased shares of our Series F-1 convertible preferred stock which were converted into common stock upon the closing of our initial public offering in July 2019.

Illumina Agreement

In September 2019, we entered into a non-exclusive development and supply agreement with Illumina for the development and commercialization of IVD kits for clonoSEQ and immunoSEQ Dx ("Illumina Agreement"). Pursuant to the Illumina Agreement, Illumina will develop custom software for us to support use of the IVD kits and provide regulatory and related support for the custom software and the Illumina components of the IVD kits. Illumina will retain ownership of the custom software, subject to an exclusive license to us, and we will retain ownership of the IVD kits. Each party will be responsible for distributing and otherwise commercializing its respective products to end users.

We have agreed to pay Illumina two technology access milestone payments related to the development of the custom software modules, payable upon our acceptance of a verified custom software module that meets the specification requirements set forth in the development plan for the first IVD kit, and the installation of the custom module at a clinical trial site. We have also agreed to pay Illumina tiered revenue share payments on net sales of the IVD kits, subject to certain customary reductions, ranging from a low to mid-single digit percentage of future net sales. During the development phase of the Illumina Agreement, we will purchase instruments and consumables from Illumina as needed to support the pre-commercial development of the IVD kits.

The Illumina Agreement has a six-year term, but may be earlier terminated by either party in the event of an uncured material breach by the other party, the bankruptcy or insolvency of the other party or if at any time after the second anniversary of the effective date of the agreement there are no active development plans in place.

Processing and Manufacturing

We process both clinical and research use samples in our laboratory in Seattle, Washington. Our Seattle laboratory is CLIA-certified, CAP-accredited and ISO 13485-certified. After we intake samples sent to us from healthcare providers or research and biopharmaceutical customers, we extract DNA from the sample if required, amplify it and otherwise prepare it for our sequencing and data analysis. Throughout our processes, we apply a rigorous quality management system, which is designed to comply with the Quality System Regulation ("QSR") and the requirements of CLIA, CAP and other applicable state licensing and accreditation requirements.

In order to process samples submitted to us using immunoSEQ or clonoSEQ, we utilize a combination of proprietary primer mixes and commercial materials, including a multiplex PCR master mix, enzymes, high throughput multi-cycle sequencing reagents and other materials, which we obtain and assemble as needed from various third-party vendors on customary terms. A number of our processing steps utilize automated equipment to help ensure consistency and efficiency. Sequencing is performed using the Illumina NextSeq System, which we have appropriately qualified for the intended uses of our products and services. We also work with a third-party vendor to manufacture our immunoSEQ RUO kit using our proprietary primer mix and other materials.

For our TCR-Antigen Map and drug discovery initiatives, we conduct our current operations at our laboratories in Seattle, Washington and South San Francisco, California. These laboratories have cell sorting, tissue culture and other processing equipment.

We use a limited number of suppliers, or in some cases single suppliers, for our laboratory equipment and materials. We manage this concentration risk by targeting levels of surplus stock that, we believe, would allow us to locate alternative suppliers if needed. However, if one of our suppliers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers and may face delays in processing samples or developing and commercializing our products and services. In particular, we have purchased the Illumina NextSeq System, and Illumina also supplies us with reagents that have been designed for use solely with this sequencer. While we acquire these reagents from Illumina on customary terms, if we had to replace the reagents we use we may also need to acquire and qualify a replacement sequencer, validate the reagents and potentially revalidate aspects of our existing assays.

Distribution

We processed our first immunoSEQ samples in 2011 and issued our first clonoSEQ report in 2013. Since then, we have focused on expanding our customer base. We sell our products and services primarily through our own internal sales force. Our sales and marketing efforts are targeted at department heads, laboratory directors, principal investigators, core facility directors, clinicians, payors and research scientists and pathologists at leading academic institutions, biopharmaceutical companies, research institutions and contract research organizations. We seek to increase awareness of our products and services among our target customers through direct sales calls, trade shows, seminars, academic conferences, web presence and other forms of internet marketing. Our drug discovery efforts are focused on large biopharmaceutical companies.

We have completed an improved RUO kit that can be used with various sample types, which we expect to enable global distribution of our research product. We plan to utilize a third-party global distributor. We may not be able to engage a distributor in a timely manner or on commercially reasonable terms.

Intellectual Property

We have an extensive global portfolio of intellectual property rights to protect our immune medicine platform, the products and services that draw on it and our reputation in the industry.

As of December 31, 2019, we owned or controlled 336 active patents and patent applications whose claims are intended to cover what we do, what we plan to do and what others might do to compete with us. From our earliest patent filings in 2009, our portfolio has been tailored to reflect our efforts to harness the adaptive immune system for research, diagnostic and therapeutic applications. Our patent claims extend to not only adaptive immune receptor molecules, but also to uniquely powerful techniques for sequencing immune cell receptors, determining clonality and immune competency, diagnosing disease, predicting responses to immunotherapy and identifying new drug candidates. Our patent protections generally expire in years ranging from 2029 to 2038.

Critical know-how we develop is protected by a trade secrecy program to ensure against inappropriate disclosure or use. Encompassed in our know-how is our proprietary database of coding sequences, antigen reactivities and safety profiles for immune receptors, which is vast and growing. Even with collaborators, access to our immune medicine platform technology is limited and tightly controlled through contracts and careful communication. We own our immune medicine platform, including improvements we or collaborators make to it, and retain rights in data resulting from its use.

We also pursue trademark registration for our product and service names and promotional slogans in our existing and projected markets.

Intellectual Property Portfolio by the Numbers

As of December 31, 2019, our intellectual property portfolio consisted of the following:

- 368 patent applications filed worldwide directly or in conjunction with a co-owner or licensor since 2009;
- 104 pending patent applications;
- 283 issued patents across our immune medicine platform;
- 24 patent families directed to methods and tools useful in our immune medicine platform for non-target specific immunosequencing and research, including immunoSEQ;
- 14 patent families directed to methods and tools useful in diagnosis, prognosis and disease monitoring, including clonoSEQ and the TCR-Antigen Map;

- 12 patent families directed to methods and tools useful in drug discovery, including TruTCR, MIRA and pairSEQ; and
- 19 trademarks registered and pending registration worldwide.

Patent Portfolio

We have developed an expansive patent portfolio in commercially important markets with claims to critical aspects of our technology, beginning with our first patent applications exclusively licensed from Fred Hutch in 2009. Our ongoing patent strategy is to generate a return on our patenting investments, which values substantive quality over volume to build a defensible moat around technology we use as well as what others might develop to design around our position.

We prioritize pursuing patent claims with a reasonable likelihood of being granted. Where patentability for a particular invention is questionable, we often choose to protect it as a trade secret instead. In some instances, however, we may seek to push the patentability envelope when the state of the applicable patent laws are in flux, such as patent eligibility for naturally occurring molecules, including TCRs, in the United States.

Methods of Measuring Adaptive Immunity

In 2009, a U.S. provisional patent application was filed to pursue protection for immunosequencing by our Co-Founder, Dr. Harlan Robins. The invention broadly relates to methods for assessing the adaptive immune system status of individuals. Rearranged V and J segment genes of TCRs or BCRs are targeted as biomarkers for assessing the status of the immune system at one or more points in time. Granted claims extend to the use of particular sets of amplification primers, while pending claims are being pursued to capture additional assessment techniques. Licensed exclusively to us by Fred Hutch, the application has since spawned 31 additional patent applications, from which 12 patents have been granted as of December 31, 2019, including U.S. Patent No. 9,809,813.

Optimizing Nucleic Acid Amplification Reactions

Amplification of nucleic acids can result in over- or under-representation of the amplified molecules, misrepresenting the number present in the source material, such as a blood sample. Dr. Robins invented a method to correct for such bias, thereby improving the precision of PCR-based quantification of TCR and BCR coding sequences in a sample. The claimed approach utilizes synthetic templates, reflecting nucleic acid sequences for rearranged V and J receptor segments in the sampled cells. Twenty-eight related patent applications have since been filed, from which 16 patents have been granted as of December 31, 2019, including U.S. Patent Nos. 9,371,558 and 10,214,770.

Diagnosing and Monitoring Disease

In connection with our acquisition (“Sequenta Acquisition”) of Sequenta, Inc (“Sequenta”) in 2015, we purchased Sequenta’s extensive patent portfolio. The portfolio includes 124 patent applications which disclose and claim methods to identify and quantify T cell-based immune responses to antigen exposure using NGS. TCR and BCR DNA, RNA or cell-free DNA from samples, including blood and bone marrow, are used to detect, prognose and monitor disease, including autoimmune disease, infection and cancer. One hundred twelve patents have been granted in the portfolio as of December 31, 2019, including U.S. Patent Nos. 8,628,927 and 8,236,503.

Our diagnostic methods also apply to the detection of MRD, the target of our clonoSEQ diagnostic test for assessing how disease burden changes in response to treatment or during remission. Nine patents have been granted from additional applications filed by us, including U.S. Patent No. 9,824,179.

TCR-Antigen Map

In connection with our Microsoft collaboration, we are developing a diagnostic product to detect cancer and other diseases at their earliest stage by learning the signals and responses of the activated immune receptors in a patient’s blood. Pre-collaboration, we filed 10 related patent applications for methods to produce antigen-exposed enriched T cell populations and identify their antigen specificities by comparison to a pre-exposure population of cells or by use of an algorithm. We have filed additional patent applications relating to TCRs and algorithmic-based methods to characterize antigen specificities and will continue to do so as our work proceeds with Microsoft.

MIRA

We developed and are pursuing patent protection for bioinformatic-based methods to determine the antigen specificity of TCRs by exposing T cells to a panel of multiple antigens. Antigen exposure can be performed by incubation or presentation; for example, it can be performed via recombinant expression in another cell. These methods may also be used to pair the two TCR chains as well as to identify high avidity TCRs. Eight related patent applications have been filed, from which three patents have been granted as of December 31, 2019, including U.S. Patent No. 10,066,265.

pairSEQ

In nature, TCRs and BCRs exist as a heterodimer of paired chains, each of which is encoded on a different chromosome. Immunosequencing reveals the nucleotide structure of each individual chain, but not which chains match as cognate pairs. We developed and are pursuing patent protection for multiple bioinformatic-based approaches to pairing the two chains of TCRs and BCRs, including one deployed in our pairSEQ technique. Our methods also allow for identification of receptor chain pairs which are specific to particular antigen targets. Fifty-four related patent applications have been filed, from which 21 patents have been granted as of December 31, 2019, including U.S. Patent No. 10,077,478.

Assessing Responsiveness to Immunotherapy

Leveraging our immunosequencing technologies, we developed methods for predicting responses to immunotherapy, vaccines and infection. To those ends, rearranged TCR or BCR sequences are quantified and their levels or frequencies compared at different points in time. Twenty-three related patent applications have been filed, from which 15 patents have been granted as of December 31, 2019, including U.S. Patent No. 10,221,461.

In-Licensed and Acquired Intellectual Property Rights

While we have developed the majority of our immune medicine platform, products and services, we occasionally license or acquire third-party owned inventions to bolster the strength of our patent estate and ensure freedom to operate.

Early work by Dr. Robins with Fred Hutch led to discoveries around immunosequencing methods and tools covered by 128 patents and patent applications in the United States and abroad which we exclusively licensed. Our rights are for all fields of use worldwide and are sublicensable. To the extent any licensed granted patent rights extend to products or services sold by us, we pay Fred Hutch a royalty rate of 0.75% of net sales on licensed products.

Through our Sequenta Acquisition, we also obtained an exclusive paid-up license, with rights to sublicense, to patents filed in the United States, Europe, Australia and China owned by iRepertoire, Inc. The license is for worldwide use in diagnosis, prognosis, treatment and monitoring of any proliferative disorder for which rearranged nucleic acids capable of encoding an immune receptor, whether productive or unproductive, or functional or nonfunctional, of a cell, excluding tumor infiltrating lymphocytes, of the proliferative disorder can be used as markers for the disorder, including, but not limited to, lymphoid and myeloid proliferative disorders, such as ALL, CLL, acute myeloid leukemia, chronic myelogenous leukemia, Hodgkin's and non-Hodgkin's lymphomas, plasma cell neoplasms, such as MM, monoclonal gammopathy of undetermined significance, monoclonal B cell lymphocytosis and myelodysplastic syndromes.

In addition to the patent estate acquired from Sequenta, we also acquired ownership of immunosequencing-related patent portfolios from Imdaptive, Inc. and ImmunID S.A.S.

Trademarks

We own various trademarks, applications and unregistered trademarks in the United States and other commercially important markets, including our company name, product and service names and other trade or service marks. Our trademark portfolio is designed to protect the brands for our products and services, both current and in the pipeline.

Trade Secrecy Program

We have a trade secrecy program to prevent disclosure of our trade secrets to others, except under stringent conditions of confidentiality when disclosure is critical to our business. Our trade secrets include the composition of certain reagents, assay protocols and immunosequencing-related data, such as immune receptor sequences. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements provide that all confidential information developed or made known during the course of an individual or entities' relationship with us must be kept confidential during and after the relationship. These agreements also provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Accordingly, we may not be able to meaningfully protect our trade secrets. For more information regarding the risks related to our intellectual property, see "*Risk Factors—Risks Related to Our Intellectual Property*."

Competition

The biotechnology and pharmaceutical industries, including the fields of life sciences research, clinical diagnostics and drug discovery, are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. Given the breadth and promise of immune medicine, we face substantial competition from many different sources, including life sciences tools, diagnostics, pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions across various components of our platform and product and service offerings. Due to the significant interest and growth in immune-driven medicine more broadly, we expect the intensity of the competition to increase. However, we believe our scale, precision and speed, and the resulting clinical applicability, distinguish us from our competitors. In life sciences research, immunoSEQ faces competition from a number of companies.

In clinical diagnostics, clonoSEQ faces competition primarily from institutions performing flow cytometry in-house, particularly outside of the United States. We may also face competition from companies developing early cancer detection testing products for indications that do not currently compete with clonoSEQ.

In drug discovery, clinical trials in the field of immune-driven medicine are being pursued by a number of industry and academic players.

Immune medicine is being pursued by several biotechnology companies as well as by large-cap biopharmaceutical companies. Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, regulatory approval and compliance, and sales and distribution than we do. Mergers and acquisitions involving life sciences research, clinical diagnostics or drug discovery companies in the immune medicine space may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize research or diagnostic products or services that are more accurate, more convenient to use or more cost-effective than our products or services. Competitor therapeutic products could also prove safer, more effective, more convenient to administer or more cost-effective than any therapeutic products we may develop with our collaborators. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the relevant market.

Government Regulation

Life Sciences Research Use Only Technologies

Our core research product, immunoSEQ, is an RUO tool in the United States that provides data to third parties such as biopharmaceutical companies that are themselves engaged in the research and development of potential diagnostic and therapeutic products and services for which they may later pursue investigation and clearance, authorization or approval from regulatory authorities, such as the FDA.

RUO products belong to a separate regulatory classification under a long-standing FDA regulation. From an FDA perspective, products that are intended for research use only and are labeled as RUO are not regulated by the FDA as *in vitro* diagnostic devices and are therefore not subject to the regulatory requirements discussed below for clinical diagnostic products. Thus, RUO products may be used or distributed for research use without first obtaining FDA clearance, authorization or approval. The products must bear the statement: "For Research Use Only. Not for Use in Diagnostic Procedures." RUO products cannot make any claims related to safety, effectiveness or diagnostic utility, and they cannot be intended for human clinical diagnostic use. Accordingly, a product labeled RUO but intended or promoted for clinical diagnostic use may be viewed by the FDA as adulterated and misbranded under the Federal Food, Drug, and Cosmetic Act ("FDCA") and subject to FDA enforcement action. The FDA will consider the totality of the circumstances surrounding distribution and use of an RUO product, including how the product is marketed and to whom, when determining its intended use. If the FDA disagrees with a company's RUO status for its product, the company may be subject to FDA enforcement activities, including, without limitation, requiring the company to seek clearance, authorization or approval for the products.

Clinical Diagnostics in the United States

Our first diagnostic product, clonoSEQ, was granted marketing authorization by the FDA for the detection and monitoring of MRD in bone marrow samples in patients with MM and ALL under the *de novo* process, which classified clonoSEQ and future DNA-based tests to measure MRD in hematological malignancies as Class II devices, as explained further below. We recently submitted a 510(k) premarket notification seeking clearance of clonoSEQ for CLL in blood samples.

In the United States, medical devices are subject to extensive regulation by the FDA under the FDCA and its implementing regulations, and other federal and state statutes and regulations. The FDA regulates the design, development, preclinical, analytical and clinical testing, manufacture, safety, effectiveness, clearance, authorization or approval, record-keeping, packaging, labeling, storage, adverse event reporting, advertising, promotion, marketing, sales, distribution and import and export of medical devices. IVDs are a type of medical device and include reagents and instruments used in the diagnosis or detection of diseases, conditions or infections, including, without limitation, the presence of certain chemicals, genetic information or other biomarkers. Predictive, prognostic and screening tests can also be IVDs.

Devices must undergo premarket review by and receive clearance, authorization or approval from the FDA prior to commercialization, unless the device is of a type exempted from such review by statute, regulation or pursuant to the FDA's exercise of enforcement discretion. For example, the FDA, to date, has generally exercised enforcement discretion over most LDTs, which are tests that are designed, manufactured, validated and used within a single laboratory, subject to certain other limitations such as the LDT not being offered directly to consumers.

Pursuant to the FDCA, medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the controls the FDA determines necessary to reasonably ensure their safety and effectiveness. Class I devices are deemed to be low risk. Class II devices are deemed to be moderate risk. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the devices' safety and effectiveness.

Class I devices are those for which reasonable assurance of safety and effectiveness can be provided by adherence to the FDA's "general controls" for medical devices. General controls apply to all classes of devices and include FDA's QSR, labeling requirements, premarket review, establishment registration and device listing, the medical device reporting ("MDR") regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur, and the Reports of Corrections and Removals regulation, which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA. Most Class I devices are exempt from premarket regulation; however, some Class I devices require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are subject to the FDA's general controls, and any other "special controls," such as performance standards, post-market surveillance and the FDA guidelines, deemed necessary by the FDA to provide reasonable assurance of the devices' safety and effectiveness. Premarket review and clearance by the FDA for Class II devices are accomplished through the 510(k) premarket notification pathway, although some Class II devices are exempt from the 510(k) requirements. Premarket notifications are subject to user fees, unless a specific exemption applies. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is "substantially equivalent" to a legally marketed predicate device, which is usually a previously 510(k)-cleared device. In determining substantial equivalence, the FDA assesses whether the proposed device has the same intended use as the predicate device, and the same technological characteristics as the predicate device, or, if the proposed device has different technological characteristics, that the information submitted in the premarket notification demonstrates the proposed device is as safe and effective as and does not raise different questions of safety and effectiveness than the predicate device. Premarket notifications typically include bench, analytical, and preclinical data, and sometimes include clinical data. The 510(k) pathway usually takes from three to nine months from the time of submission to the FDA, but it can take longer, particularly for a novel type of product. If the FDA determines that a device is substantially equivalent to a predicate device, the subject device may be marketed. However, if the FDA makes a not substantially equivalent determination, then the device would be regulated as a Class III device, discussed below. If a manufacturer obtains a 510(k) clearance for its device and then makes a modification that could significantly affect the device's safety or effectiveness or constitutes a major change or modification in the intended use of the device, a new clearance, authorization or approval may be required.

Class III devices are deemed by the FDA to pose the greatest risk, such as those for which reasonable assurance of the device's safety and effectiveness cannot be assured solely by the general controls and special controls described above and that are life-sustaining or life-supporting. Some pre-amendment Class III devices, for which the FDA has not yet required a Premarket Approval Application ("PMA"), require the FDA's clearance of a premarket notification in order to be marketed. However, most Class III devices are required to undergo the PMA process in which the manufacturer must demonstrate reasonable assurance of the safety and effectiveness of the device for its proposed intended use to the FDA's satisfaction. The PMA pathway is costly, lengthy and uncertain. A PMA must provide valid scientific evidence, typically extensive preclinical, analytical and clinical trial data and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMAs and supplemental PMAs are subject to significantly higher user fees than are 510(k) premarket notifications. Some PMAs are exempt from a user fee, such as a small business' first PMA. As part of its PMA review process, the FDA will typically inspect the manufacturer's facilities for compliance with QSR requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. The PMA review process typically takes one to three years from submission but can take longer.

Novel devices are placed in Class III by default if the device type was not previously classified by the FDA and has no predicate. Manufacturers of such novel devices may request that the FDA reclassify the device to Class II or Class I via a *de novo* request. The Food and Drug Administration Modernization Act of 1997 established a 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. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act ("FDASIA") in July 2012, 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. FDASIA sets a review time for the FDA of 120 days following receipt of the *de novo* application, but the FDA does not routinely meet this timeline and has publicly only committed to a review of 150 days for 55% of applications. 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. 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 and special controls would be inadequate to ensure the safety and effectiveness of the device. If the FDA agrees with the down-classification, the FDA will grant the device market authorization and establish a classification regulation for the device type. The device can then be used as a predicate device for future 510(k) submissions by the manufacturer or a competitor. In December 2018, the FDA issued proposed regulations to govern the *de novo* classification process, which include requirements beyond what has historically been required in *de novo* submissions. If finalized, these regulations could further impact this path to market.

A clinical trial may be required in support of a 510(k) or *de novo* submission and generally is required for a PMA. These trials require an Investigational Device Exemption ("IDE") approved by the FDA for a specified number of patients and sites, unless the product is exempt from IDE requirements or deemed a non-significant risk device eligible for more abbreviated IDE requirements. Most clinical studies of IVDs are exempt from the IDE requirements, if certain requirements are met. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in or on humans and that the testing protocol is scientifically sound. Clinical trials may begin 30 days after the submission of the IDE application unless the FDA disapproves the IDE or places the trial on clinical hold. Additionally, clinical trials may not begin until their protocol and informed consent receive approval from the appropriate ethical review boards, including institutional review boards ("IRBs"). Unless an exemption applies, clinical trials intended to assess the safety or efficacy of a device must be conducted in accordance with the FDA's IDE requirements. Clinical investigations that are not assessing safety and effectiveness but are being used to generate other data to support FDA submissions are subject to the more broadly applicable informed consent and IRB regulations.

Even if regulatory clearance, authorization or approval of a device is granted, the FDA may impose limitations on the uses and indications for which the device may be labeled and promoted, and the device remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared, authorized or approved.

After a device, including a device exempt from FDA premarket review, is placed on the market, numerous post-market regulatory requirements apply. These requirements are as discussed above in the general controls. Some manufacturers also may be subject to post-market surveillance regulations. Facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include, among other things: untitled letters, public warning letters, fines, injunctions, civil or criminal penalties, recall or seizure of products, operating restrictions, partial suspension or total shutdown of production, delays in or refusals of 510(k), *de novo* or PMA submissions, withdrawing existing clearance, authorization and approval, and a recommendation by the FDA to disallow a device manufacturer from entering into government contracts. If certain conditions are met, the FDA also has the authority to order manufacturers to repair, replace or refund the cost of any devices that present an unreasonable risk of substantial harm to the public health. In the event that a supplier fails to maintain compliance with FDA or the device manufacturer's quality requirements, the manufacturer may have to qualify a new supplier and could experience manufacturing delays as a result.

Position in the European Union

In the EU, IVDs can be placed on the market by obtaining a "CE mark," which demonstrates conformity with the *In vitro* Diagnostic Medical Device Directive ("IVDD"). The requirements under the Directive include:

- *Essential Requirements*. The IVDD specifies "essential requirements" that all medical devices must meet to demonstrate the product is safe and effective under normal conditions of use. The requirements are similar to those adopted by the FDA relating to quality systems and product labeling.
- *Conformity Assessment*. The requirements to obtain a CE mark are risk-based, and follow a similar classification system as in the United States. However, unlike the United States, which requires virtually all devices to undergo some level of premarket review by the FDA, the IVDD currently allows manufacturers to bring many devices to market using a process in which the manufacturer self-certifies that the device conforms to the applicable essential requirements.
- *Vigilance*. The IVDD specifies requirements for post market reporting similar to those adopted by the FDA.

On May 26, 2017, the EU released a new regulatory framework, the *In vitro* Diagnostic Medical Device Regulation ("IVDR"), which will replace the IVDD. Our products in the EU will have to comply with the IVDR requirements after May 26, 2022, subject to the applicable transitional provisions before full compliance is required. The IVDR is considerably stricter in regulatory oversight than the IVDD and will require more IVD devices to be reviewed by a notified body before being placed on the market. Until that time, our products must continue to meet the requirements of IVDD for commercialization in the EU.

Laboratory Developed Tests in the United States

clonoSEQ is available as an LDT for use in assessing MRD for other lymphoid malignancies, including CLL and NHL, at our Seattle, Washington laboratory. LDTs have generally been considered to be tests that are designed, developed, validated and used within a single laboratory. The FDA has taken the position that it has authority to regulate such tests as medical devices under the FDCA, but the FDA has historically exercised enforcement discretion and has not required clearance, authorization or approval of LDTs prior to marketing. Laboratories certified as "high complexity" under CLIA may develop, manufacture, validate and run LDTs. The CLIA requirements are discussed below in " *—U.S. Federal and State Regulation of Laboratories*."

Although we believe we are within the scope of the FDA's policy on enforcement discretion for LDTs, the initial commercialization and continued commercial availability of an LDT is subject to uncertainty given the FDA's latitude in interpreting and applying its laws and policies. For example, the FDA does not consider tests to be subject to its LDT enforcement discretion if they were or are designed or manufactured completely, or partly, outside of the laboratory that offers and uses them, or if they are offered "over-the-counter," as opposed to being available to patients only when prescribed by a healthcare provider. Even for tests that appear to fall within the FDA's previously stated enforcement discretion, the FDA may decide to take action against certain LDTs on a case-by-case basis at any time if the FDA views them as presenting a risk to patients. The FDA Commissioner and the Director of the CDRH have expressed significant concerns regarding potential disparities in accuracy and quality between some LDTs and IVDs that have been reviewed and cleared, authorized or approved by the FDA. In addition, the U.S. Congress has been considering various legislative proposals that would reform the FDA's regulation of laboratory tests, and such legislation might lead to heightened FDA scrutiny of LDTs, particularly new LDTs, in the future. Whether such legislation will pass and, if so, what effect it may have on how the FDA regulates laboratory tests, including LDTs, is unknown. If the FDA disagrees with a laboratory test's LDT status, the FDA may consider the test to be an unapproved medical device, may subject us to FDA enforcement action, including, without limitation, requiring us to seek clearance, authorization or approval for the laboratory test.

On October 3, 2014, the FDA issued two draft guidance documents proposing a new regulatory paradigm for oversight of LDTs. These draft guidance documents proposed more active review of LDTs. The draft guidance documents were the subject of considerable controversy, and in November 2016, the FDA announced that it would not be finalizing the 2014 draft guidance documents. On January 13, 2017, the FDA issued a discussion paper which laid out elements of a possible revised future LDT regulatory framework, but did not establish any regulatory requirements.

The FDA's recent efforts to regulate LDTs have prompted the drafting of legislation governing diagnostic products and services that seeks to substantially revamp the regulation of both LDTs and IVDs. The U.S. Congress may act to provide further direction to the FDA on the regulation of LDTs and substantially modify the regulation of IVDs, which might result in heightened FDA scrutiny of LDTs, particularly new LDTs, in the future.

U.S. Federal and State Regulation of Laboratories

Given that aspects of our business at certain facilities involve acting as a clinical laboratory, we are required to hold certain federal and state licenses, certifications and permits to conduct our business.

As to federal certifications, CLIA establishes rigorous quality standards for all laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health. As a clinical laboratory, we must obtain a CLIA certificate based on the complexity of testing performed at the laboratory, such as a Certificate of Compliance for high-complexity testing. CLIA also mandates compliance with various operational, personnel, facilities administration, quality and proficiency requirements, intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. CLIA compliance and certification is also a prerequisite to be eligible to bill for services provided to government payors and for many private payors. Furthermore, we are subject to survey and inspection every two years to assess compliance with program standards, and may be subject to additional unannounced inspections. Laboratories performing high-complexity testing are required to meet more stringent requirements than laboratories performing less complex tests.

In addition to CLIA requirements, we elect to participate in the accreditation program of the CAP. The U.S. Centers for Medicare & Medicaid Services ("CMS"), the agency that oversees CLIA, has deemed CAP standards to be equally or more stringent than CLIA regulations and has approved CAP as a recognized accrediting organization. Inspection by CAP is performed in lieu of CMS inspections for accredited laboratories. Therefore, because we are accredited by the CAP Laboratory Accreditation Program, we are deemed to also comply with CLIA.

CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory requirements. Select states, including Washington, have laboratory regulations that have been deemed by the federal government to be at least as stringent as CLIA, and thus laboratories licensed under those state regimes are exempt from CLIA and the state Department of Health is permitted to issue a CLIA number, along with a state Medical Test Site license, rather than a certificate being issued by CMS. Our laboratory holds the required Washington license. State laws may require that laboratory personnel meet certain qualifications, specify certain quality control procedures, facility requirements or prescribe record maintenance requirements.

Several states additionally require the licensure of out-of-state laboratories that accept specimens from those states. For example, New York requires a laboratory to hold a permit which is issued after an on-site inspection and approval of each LDT offered by a laboratory, and has various, more stringent requirements than CLIA and CAP, including those for personnel qualifications, proficiency testing, physical facility and equipment and quality control standards. Our laboratory holds the required licenses for Maryland, Rhode Island, Pennsylvania, New York and California.

From time to time, other states may require out-of-state laboratories to obtain licensure in order to accept specimens from the state. If we identify any other state with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

If a clinical laboratory is found to be out of compliance with CLIA certification, CAP accreditation or a state license or permit, the applicable regulatory agency may, among other things, suspend, restrict or revoke the certification, accreditation, license or permit to operate the clinical laboratory, assess civil monetary penalties and impose specific corrective action plans, among other sanctions.

In December of 2018, Congress released draft legislation to establish a framework for overseeing in vitro clinical tests ("IVCTs"), such as test kits and LDTs, the Verifying Accurate Leading-edge IVCT Development Act ("VALID Act"). The draft legislation would establish a risk-based approach to IVCT regulation, prioritizing FDA resources for the highest-risk tests that expose patients to serious or irreversible harm. The legislation, if passed in its current form, also would establish a precertification program for lower-risk tests that are not otherwise required to go through premarket review. Precertification would allow the FDA to establish standard validity requirements, while also lowering the burden on labs and developers and protecting continued innovation. High-risk tests, such as novel tests, would be required to undergo premarket review to verify analytical and clinical validity. The FDA could require that any test undergo premarket review after providing the developer an opportunity to address issues identified by the agency. The VALID Act is a priority focus for the FDA, as well as certain members of Congress, and they have been working with industry to understand potential issues around the discussion draft. To date, a revised draft of the discussion draft has not been publicly communicated nor has any legislation been introduced.

Federal and State Privacy, Security and Breach Notification Laws

Many state and federal laws govern the processing of personally identifiable information or individually identifiable health information. At the federal level, under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), the U.S. Department of Health and Human Services ("HHS") issued regulations that establish standards for protecting the privacy and security of "protected health information" used or disclosed by certain healthcare providers and other "covered entities" and their "business associates." Three principal data protection-related regulations with which we are required to comply have been issued in final form under HIPAA and HITECH: privacy regulations, security regulations and security breach notification regulations.

The privacy regulations govern the use and disclosure of "protected" health information by covered healthcare providers, as well as health insurance plans. They also set forth certain rights that an individual has with respect to his or her protected health information maintained by a covered health care provider, including the right to access or amend certain records containing protected health information or to request restrictions on the use or disclosure of protected health information. The security regulations establish requirements for safeguarding the confidentiality, integrity and availability of protected health information that is electronically transmitted or electronically stored. HITECH, among other things, established certain health information security breach notification requirements. A covered entity must notify HHS and each affected individual of a breach of unsecured protected health information as well as the media if the breach involves more than 500 individuals.

HIPAA violations are subject to civil and criminal penalties. Additionally, to the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied. Although there is no private right of action, HIPAA has been used as the standard of care in negligence actions brought under state law.

Section 5(a) of the Federal Trade Commission Act ("FTCA") has also been used to regulate data privacy and security at the federal level. According to the U.S. Federal Trade Commission ("FTC"), failing to take appropriate steps to keep consumers' personal information secure or using or disclosing personal information in violation of a company's privacy notice may constitute unfair or deceptive acts or practices in or affecting commerce in violation of the FTCA. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities.

In addition, certain state laws govern the privacy and security of health information, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. In addition, there are state breach notification laws in every state. The HIPAA regulations establish a federal "floor" of protection and do not supersede state laws that may be more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to their records containing health information. Failure to comply with these laws, where applicable, can result in the imposition of significant civil or criminal penalties and private litigation. For example, California recently enacted legislation, the California Consumer Privacy Act ("CCPA"), which went into effect January 1, 2020 and will be enforceable as of July 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach.

Alastair Mactaggart, the founder and board chair of Californians for Consumer Privacy (which backed the ballot initiative that led to the enactment of the CCPA), announced a new initiative that he hopes to get on the November 2020 ballot in California. Mactaggart filed the initiative with the California Attorney General on September 25, 2019. The initiative is called the California Privacy Rights and Enforcement Act, which is being referred to as "the moat" around the CCPA or CCPA 2.0. If the law is approved by voters in November 2020, most provisions would be operative on January 1, 2021. Certain provisions, however, would be operative within days after enactment, giving businesses little time to prepare for the stringent new requirement in addition to the CCPA. The law would provide some clarity as to health data that the CCPA is lacking.

General Data Protection Regulation in the EU

The General Data Protection Regulation ("GDPR") is a legal framework that sets requirements for the collection and processing of personal information of individuals within the European Economic Area ("EEA"). The GDPR sets out the principles for data management and the rights of the individual, while also imposing very significant fines that can be revenue-based. It applies to U.S. companies that process personal information of persons in the EEA in connection with the offer of products or services to those persons, or the monitoring of such persons' behavior. It may also apply when a U.S. company processes personal information in the context of the activities of an entity established in the EEA. The GDPR became enforceable on May 25, 2018. The regulation applies to the human resources record of employees and even the Internet Protocol addresses of people using online services. The GDPR builds upon data rights that the EU had previously advocated, such as the right of an individual to be forgotten and the right to data portability.

Federal, State and Foreign Fraud and Abuse Laws

In the United States, there are various fraud and abuse laws with which we must comply and we are subject to regulation by various federal, state and local authorities, including CMS, other divisions of HHS, such as the Office of Inspector General ("OIG"), the U.S. Department of Justice ("DOJ") and individual U.S. Attorney offices within the DOJ, and state and local governments. We also may be subject to foreign fraud and abuse laws.

In the United States, the Anti-Kickback Statute ("AKS") prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for patient referrals for, or purchasing, leasing, ordering or arranging for the purchase, lease or order of, any healthcare item or service reimbursable under a governmental payor program. Courts have stated that a financial arrangement may violate the AKS if any one purpose of the arrangement is to encourage patient referrals or other federal healthcare program business, regardless of whether there are other legitimate purposes for the arrangement. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, meals, travel, credit arrangements, payments of cash, consulting fees, waivers of co-payments, ownership interests and providing anything at less than its fair market value. Recognizing that the AKS is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, the OIG issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain provisions, which, if met, will assure healthcare providers and other parties that they will not be prosecuted under the AKS. The failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the AKS will be pursued. In those instances, arrangements will be evaluated on a case-by-case basis to determine whether enforcement will be pursued. Penalties for AKS violations are severe and can include imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. The regulations establishing safe harbor protection are subject to change and could affect future operations. Many states also have anti-kickback statutes, some of which may apply to items or services reimbursed by any third-party payor, including commercial insurers as well as patient self-pay. A violation of the AKS may be grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The civil monetary penalties statute is another potential statute under which a clinical laboratory may be subject to enforcement. Among other things, the civil monetary penalties statute imposes fines against any person who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent. The civil monetary penalties statute also prohibits a person from offering or providing remuneration to any Medicare or Medicaid beneficiary that is likely to influence the individual to order or receive its items or services from a particular provider or supplier.

The exclusion statute requires the exclusion of entities and individuals who have been convicted of federal-program related crimes or healthcare felony fraud or controlled substance charges. The statute also permits the exclusion of those that have been convicted of any form of fraud, the AKS, for obstructing an investigation or audit, certain controlled substance offenses, those whose healthcare license has been revoked or suspended and those who have filed claims for excessive charges or unnecessary services. If we were to be excluded, our products and services would be ineligible for reimbursement from any federal programs, including Medicare and Medicaid, and no other entity participating in those programs would be permitted to enter into contracts with us. In order to preserve access to beneficial healthcare items and services, the government may elect to exclude officers and key employees of manufacturers, rather than excluding the organization. Such enforcement actions would prohibit us from engaging those individuals, which could adversely affect operations and result in significant reputational harm.

Congress has also enacted statutes that impose criminal liability for healthcare fraud and abuse. The Health Care Fraud Statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from governmental payor programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefit programs, items or services-public or private. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from governmental payor programs.

The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal governmental payor program. The *qui tam* provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has defrauded the federal government by submitting a false claim to the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. *Qui tam* complaints are filed under seal, and the cases may progress for a number of years before a complaint is unsealed and a healthcare provider or supplier becomes aware of its existence. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from $11,463 to $22,927 for each false claim. The False Claims Act is the federal government's primary civil tool in healthcare fraud cases. False Claims Act liability is not limited to direct providers of health items or services. The government has asserted liability under the False Claims Act against manufacturers and other third parties who caused another party to file a false claim.

In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a governmental payor program.

On October 25, 2018, the Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act of 2018 ("SUPPORT Act") was enacted. The SUPPORT Act included the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), which establishes an all-payor anti-kickback prohibition that extends to arrangements with recovery homes, clinical laboratories and clinical treatment facilities. EKRA includes a number of statutory exceptions, and directs agencies to develop further exceptions. Current exceptions in some cases reference and in others differ from the AKS safe harbors. Significantly, the prohibitions apply with respect to the soliciting or receipt of remuneration for any referrals to recovery homes, clinical treatment facilities, or clinical laboratories, whether or not related to treating substance use disorders. Further, the prohibitions cover the payment or offer of remuneration to induce a referral to, or in exchange for, an individual using the services of, such providers. This new law creates additional risk that relationships with referral sources could be problematic.

For anti-corruption legislation, the U.S. Foreign Corrupt Practices Act ("FCPA") is the most widely enforced law. It is the first to introduce corporate liability, responsibility for third parties and extraterritoriality for corruption offences, meaning companies and persons can be held criminally and civilly responsible for corruption offences committed abroad. It was enacted for the purpose of making it unlawful for certain classes of persons and entities to make payments to foreign government officials to assist in obtaining or retaining business. With the enactment of certain amendments in 1998, the anti-bribery provisions of the FCPA now also apply to foreign firms and persons who cause, directly or through agents, an act in furtherance of such a corrupt payment to take place within the territory of the United States. The FCPA also requires companies whose securities are listed in the United States to meet its accounting provisions, which were designed to operate in tandem with the anti-bribery provisions, require corporations covered by the provisions to (a) make and keep books and records that accurately and fairly reflect the transactions of the corporation and (b) devise and maintain an adequate system of internal accounting controls.

In Europe, various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties or significant fines, for individuals or companies committing a bribery offence. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which came into effect in July 2011, a bribery offense occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under this regime, an individual found in breach of the Bribery Act 2010 faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, if found to have committed an offense, as can commercial organizations that are found to have failed to prevent bribery. Most recently, France has passed an anti-bribery and compliance law ("Sapin II"), and the new French anti-corruption agency ("AFA") has been established. The Sapin II law makes it compulsory for companies within the scope of the law to implement internal procedures to fight corruption. One of the items that must be prepared is a corruption risk map, as well as an anti-corruption code of conduct. These documents are subject to investigation by the AFA and failure to comply with the requirements can lead to a fine of up to €1.0 million for a company and €200,000 for executives.

Currently, we are not subject to the jurisdictional requirements of the UK Bribery Act or Sapin II as we do not have offices in either country and do not employ a requisite amount of employees in these countries. If we were to have future growth in the European market, these laws could potentially apply to us.

U.S. Physician Referral Prohibitions

The Criminal Health Care Fraud Statute and The Ethics in Physician Referrals Act ("Stark Law") prohibits physicians from referring patients to entities with which the physician or an immediate family member has a financial relationship, such as ownership, investment or compensation, for designed health services ("DHS") payable by Medicare and Medicaid, unless the financial arrangement meets an applicable exception. DHS includes clinical laboratory tests. See "*Risk Factors—Risks Relating to Government Regulation—We are subject to various laws and regulations, such as healthcare fraud and abuse laws, false claim laws and health information privacy and security laws, among others, and failure to comply with these laws and regulations may have an adverse effect on our business*."

Corporate Practice of Medicine in the United States

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging physicians to practice medicine, generally referred to as the prohibition against the corporate practice of medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. For example, California's Medical Board has indicated that determining what diagnostic tests are appropriate for a particular condition and taking responsibility for the ultimate overall care of the patient, including providing treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these corporate practice of medicine laws may result in civil or criminal fines, as well as sanctions imposed against us or the professional through licensure proceedings. Typically such laws are only applicable to entities that have a physical presence in the state.

Other Regulatory Requirements

Our laboratory is subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood and bone marrow samples and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste.

Our partners in the development of therapeutic agents are responsible for developing and manufacturing those products. In so doing, they are subject to FDA and Medicare regulatory requirements related to, among other things, manufacture, promotion, price reporting and fraud and abuse laws.

Our laboratories are subject to extensive requirements related to workplace safety established by the U.S. Occupational Safety and Health Administration. These include requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

U.S. Healthcare Reform

In the United States, a number of recent legislative and regulatory changes at the federal and state levels have sought to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Affordable Care Act ("ACA") became law. This law substantially changed the way healthcare is financed by both commercial and government payors, and it has significantly impacted our industry. Since 2016 there have been efforts to repeal all or part of the ACA. For example, the Tax Cuts and Jobs Act ("TCJA"), among other things, removes penalties for not complying with the ACA's individual mandate to carry health insurance. The U.S. Congress may take further action regarding the ACA, including, but not limited to, repeal or replacement. Additionally, all or a portion of the ACA and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, or reduced coverage for insured individuals, and which could adversely affect our business. However, it remains to be seen whether or when new legislation modifying the ACA will be enacted, what any such the new legislation might provide and what impact it might have on the size and coverage of the insured population or on efforts to contain or lower the cost of healthcare. We cannot predict the implications, if any, of such legislation on our and our collaborators' businesses and financial conditions.

We anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and commercial payors to reduce costs while trying to expand individual healthcare benefits. If enacted, some such proposals could expand or contract the insured population, increasing or decreasing demand for our products and services. On the other hand, some proposals could impose additional limitations on the prices we will be able to charge for our tests or on the coverage of or the amounts of reimbursement available for our tests from payors, including commercial payors and government payors.

The federal physician payment transparency requirements ("Physician Payments Sunshine Act") and its implementing regulations, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, with certain exceptions, to annually report to HHS information related to certain payments or other transfers of value made or distributed to physicians, defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The SUPPORT Act, under a provision entitled "Fighting the Opioid Epidemic with Sunshine," extends the Physician Payments Sunshine Act to payments and transfers of value to physician assistants, nurse practitioners and other mid-level healthcare providers, with reporting requirements going into effect in 2022 for payments and transfers of value made to these practitioners in 2021.

Coverage and Reimbursement Generally

Patients who have diagnostic tests ordered or are prescribed treatments and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of our products and services will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products and services will be paid by third-party payors, including health maintenance, managed care and similar healthcare management organizations, or reimbursed by government health administration authorities, such as Medicare and Medicaid, private health insurers.

In the United States, our ability to commercialize and the commercial success of our product and service offerings will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for these offerings. Government authorities, private health insurers and other organizations generally decide which devices they will pay for and establish reimbursement levels for healthcare. Medicare is a federally funded program for the elderly and disabled managed by CMS, through local contractors that administer coverage and reimbursement for certain healthcare items and services. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels that is funded jointly by federal and state governments and managed by each state. Similarly, the federal government manages other healthcare programs, including the Veterans Health Administration, the Indian Health Service, and Tricare, the healthcare program for military personnel, retirees and related beneficiaries. Many states have also created pharmacy assistance programs for individuals who do not qualify for federal programs. In the United States, private health insurers and other third-party payors often provide reimbursement for products and services based in part on the coverage and payment rates set by the Medicare or Medicaid programs.

Certain countries, including a number of member states of the EU, set prices and make reimbursement decisions for diagnostics and pharmaceutical products, or medicinal products, as they are commonly referred to in the EU. In addition, an increasing number of countries are taking initiatives to attempt to control the healthcare budget by focusing cost-cutting efforts on medicinal products, and to a lesser extent, medical devices, provided under their state-run healthcare systems. These international price-control efforts have impacted all regions of the world, but have been most drastic in the EU. Additionally, some countries require approval of the maximum sale price of a product before it can be marketed, and this price may be reviewed during the product lifecycle, or mandatory discounts or profit caps may be applied. In many countries, the pricing review period begins after marketing or product licensing approval is granted or the CE mark is obtained.

Federal programs in the United States also sometimes impose price controls through mandatory ceiling prices on purchases by federal agencies and federally funded hospitals and clinics and mandatory rebates on retail pharmacy prescriptions paid by Medicaid and Tricare. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government programs may result in lower reimbursement for our products and services or exclusion of our products and services from coverage. In addition, government programs like Medicaid include what are in effect substantial penalties for increasing commercial prices of certain products over the rate of inflation which can affect realization and return on investment.

Increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly approved healthcare products. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological program pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

As a result of the above trends, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost effectiveness of our products and services, in addition to the costs required to obtain the FDA and other comparable foreign regulatory authority approvals. Our products and services may not be considered medically necessary or cost effective, or the discount percentages required to secure coverage may not yield an adequate margin over cost.

There is often pressure to renegotiate pricing and reimbursement levels, including, in particular, in connection with changes to Medicare coverage and reimbursement. Third-party payors continue to demand discounted fee structures, and the trend toward consolidation among third-party payors tends to increase their bargaining power over price structures. If third-party payors reduce their rates for our products and services, then our revenue and profitability may decline and our operating margins will be reduced. Because some third-party payors rely on all or portions of Medicare payment systems to determine payment rates, changes to government healthcare programs that reduce payments under these programs may negatively impact payments from third-party payors. Our inability to maintain suitable financial arrangements with third-party payors could have a material adverse impact on our business. Additionally, the reimbursement process is complex and can involve lengthy delays. Third-party payors may disallow, in whole or in part, providers' requests for reimbursement based on determinations that certain amounts are not reimbursable under plan coverage, that the services provided were not medically necessary or that additional supporting documentation is necessary. Retroactive adjustments may change amounts realized from third-party payors. Delays and uncertainties in the reimbursement process may adversely affect market acceptance and utilization of our candidate products, resulting in reduced revenue. The unavailability or inadequacy of third-party coverage and reimbursement could negatively affect the market acceptance of our products and services and the future revenue we may expect to receive from those products and services. In addition, we are unable to predict what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on our business.

Many hospitals implement a controlled and defined process for covering and approving diagnostic tests and medical devices. Any marketing efforts that are determined to have violated such policies could result in the denial or removal of our products from that hospital's list of approved products.

Moreover, a payor's decision to provide coverage for a device does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in device development. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products and services or exclusion of our products and services from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenue from the sale of any approved products and services. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our products and services in whole or in part.

For additional information on coverage and reimbursement, see "*Risk Factors—Risks Relating to Government Regulation—Future Medicare payment rates are uncertain*."

Our Compliance Program

Our compliance program is intended to prevent and detect violations of law or our policies. It was developed in view of both adopting the principles of the AdvaMed Code of Ethics and addressing the HHS OIG's elements of a compliance program. We have designed our compliance program to fit the size, resources, market position and other unique aspects of our company. Our code of conduct is our statement of ethical and compliance principles that guide our daily operations. In addition, we have developed policies and procedures, and corresponding education and training, to effectively communicate our standards to employees as it relates to job functions and legal obligations under applicable state and federal healthcare program requirements, as well as those outside the United States. We regularly perform live and process monitoring activities on a risk-based approach, and audit capabilities are built into our transparency procedures. We maintain a hotline available via multiple channels to report any known or suspected compliance violations, and we have a strict non-retaliation policy for all claims brought forward in good faith.

Corporate Information

We were incorporated in the State of Washington on September 8, 2009 under the name Adaptive TCR Corporation. On December 21, 2011, we changed our name to Adaptive Biotechnologies Corporation. In January 2015, we acquired Sequenta, Inc. ("Sequenta"), a San Francisco, California-based company that was also developing an NGS test for MRD ("Sequenta Acquisition"). Our principal executive offices are located at 1551 Eastlake Avenue East, Suite 200, Seattle, Washington 98102, and our telephone number is (206) 659-0067.

Available Information

We maintain a website at www.adaptivebiotech.com. The contents of our website are not incorporated in, or otherwise to be regarded as part of, this Annual Report on Form 10-K. We make available, free of charge on our website, access to our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as soon as reasonably practicable after we file or furnish them electronically with the Securities and Exchange Commission ("SEC"). Investors and others should note that we announce material financial information to our investors using our investor relations website (http://investors.adaptivebiotech.com), SEC filings, press releases, public conference calls and webcasts. We use these channels as well as social media to communicate with our members and the public about our company, our services and other issues. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on social media channels.

Item 1A. Risk Factors

Investing in our Company involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all other information in this Annual Report on Form 10-K, including our financial statements and related notes and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section before investing in our Company. Any of the risk factors we describe below could adversely affect our business, financial condition, results of operations, prospects or the trading price of our securities. The risks described below are not the only ones we face and additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business, financial condition, operating results, prospects and the trading price of our securities. .

Risks Relating to Our Business

We have incurred significant losses since inception, we expect to incur losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability.

We have incurred significant losses since our inception. For the years ended December 31, 2019, 2018 and 2017, we incurred net losses of $68.6 million, $46.4 million and $42.8 million, respectively. As of December 31, 2019, we had an accumulated deficit of $365.5 million. We have funded our operations to date principally from the sale of convertible preferred stock and common stock, including the sale of common stock in our initial public offering, and, to a lesser extent, sequencing and development revenue. We have devoted most of our financial resources to the research and development of products and services under our immune medicine platform. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we continue to invest in the development of products and services utilizing our immune medicine platform to support the validation of additional clinical diagnostic and therapeutic products and services. We will need to generate significant additional revenue to achieve and sustain profitability.

We expect to make significant investments in our continued research and development of new products and services, which may not be successful.

We are seeking to leverage our immune medicine platform to develop a pipeline of future disease-specific research, diagnostic and therapeutic products and services. For example, we are attempting to extend clonoSEQ into additional indications and sample types, and we are developing our TCR-Antigen Map with a view toward advancing the development of immunoSEQ Dx, a diagnostic test that may enable early detection of multiple diseases, including acute Lyme and celiac disease, from a single blood test. In addition, we are developing certain therapeutic product candidates under our collaboration agreement with Genentech by leveraging our platform to identify TCRs that can be engineered into personalized cellular immunotherapies. We expect to incur significant expenses to advance these development efforts, but they may not be successful.

Developing new products and services is a speculative and risky endeavor. Products or services that initially show promise may fail to achieve the desired results or may not achieve acceptable levels of analytical accuracy or clinical utility. We may need to alter our products in development and repeat clinical studies before we identify a potentially successful product or service. Product development is expensive, may take years to complete and can have uncertain outcomes. Failure can occur at any stage of the development. If, after development, a product or service appears successful, we or our collaborators may, depending on the nature of the product or service, still need to obtain FDA and other regulatory clearances, authorizations or approvals before we can market it. The FDA's clearance, authorization or approval pathways are likely to involve significant time, as well as additional research, development and clinical study expenditures. The FDA may not clear, authorize or approve any future product or service we develop. Even if we develop a product or service that receives regulatory clearance, authorization or approval, we or our collaborators would need to commit substantial resources to commercialize, sell and market it before it could be profitable, and the product or service may never be commercially successful. Additionally, development of any product or service may be disrupted or made less viable by the development of competing products or services.

New potential products and services may fail at any stage of development or commercialization and if we determine that any of our current or future products or services are unlikely to succeed, we may abandon them without any return on our investment. If we are unsuccessful in developing additional products or services, our potential for growth may be impaired.

If we are not successful in leveraging our immune medicine platform to discover, develop and commercialize additional products and services, our ability to expand our business and achieve our strategic objectives would be impaired.

A key element of our strategy is to leverage our immune medicine platform to discover, develop and potentially commercialize additional products and services beyond our current portfolio to diagnose and treat various disease states. In particular, for clonoSEQ we are attempting to generate sufficient clinical evidence to support a new regulatory submission to add additional lymphoid cancers beyond ALL, MM and CLL, while also adding blood as a validated sample type for all lymphoid cancers. If we are unable to extend clonoSEQ into other indications or to use additional sample types, our platform may face a broader obstacle to using our immunosequencing data for commercially viable products and services.

Identifying new products and services requires substantial technical, financial and human resources, whether or not any products or services are ultimately developed or commercialized. We may pursue what we believe is a promising opportunity to leverage our platform only to discover that certain of our risk or resource allocation decisions were incorrect or insufficient, or that individual products, services or our science in general has technology or biology risks that were previously unknown or underappreciated. Our strategy of pursuing the value of our immune medicine platform over a long time horizon and across a broad array of human diseases may not be effective. In the event material decisions in any of these areas turn out to be incorrect or sub-optimal, we may experience a material adverse impact on our business and ability to fund our operations and we may never realize what we believe is the potential of our immune medicine platform.

Our efforts to develop our TCR-Antigen Map may not be successful, and it may not yield the insights we expect at all or on a timetable that allows us to develop or commercialize any new diagnostic products.

We are leveraging our collaboration with Microsoft to develop our TCR-Antigen Map. Together we are using immunosequencing, proprietary computational modeling and machine learning to map TCR sequences to the antigens they bind. However, we may not be successful in developing a comprehensive TCR-Antigen Map for any number of reasons. Our collaboration with Microsoft is in the early stages, and our computations and algorithmic-based methods are largely untested and may not allow us to accurately pair TCR sequences to a meaningful number of antigens. As a result, it may require significantly more time and resources for us to determine how to use machine learning to accelerate our mapping process, which could adversely impact our ability to develop or commercialize new diagnostic products or services. In addition, even with the aid of machine learning, we expect the TCR-Antigen Map to take us several years to develop.

The TCR-Antigen Map we are developing may not yield clinically actionable insights on a timetable that is commercially viable, or at all. Our goal is to leverage the TCR-Antigen Map to develop a diagnostic product, immunoSEQ Dx, that may enable early detection of many diseases from a single blood test. However, we are still validating early detection testing for a set of discrete diseases where antigen specificity is well-known, and while we have established proof of concept for early detection of acute Lyme disease, we do not expect to validate more than two additional indications in 2020. If our computational modeling and machine learning efforts do not accelerate the pace at which we can validate association of TCR sequences to the antigens they bind, the timetable for our business model may not be commercially viable. Even if we can accelerate this timeline, our products and services derived from our novel technologies may have product or service level errors. If we are unable to make meaningful progress in our TCR-Antigen Map and successfully use it to develop and commercialize new diagnostic products or services, our business and results of operations will suffer.

We are exposed to risks associated with our agreement with Genentech, and we may not realize the advantages we expect from it.

In December 2018, we entered into a worldwide collaboration and license agreement with Genentech ("Genentech Agreement"), with the goal of accelerating the development and commercialization of novel cancer-specific antigen and neoantigen directed T cell therapies for the treatment of a broad range of tumor types. Under the terms of the Genentech Agreement, we received $300.0 million in an initial upfront payment in February 2019 and may be eligible to receive approximately $1.8 billion in additional payments over time upon achievement of specified development, regulatory and commercial milestones. In addition, Genentech will pay us royalties on sales of products commercialized under the agreement. We may not be successful in achieving these milestones, and products developed under the Genentech Agreement may not be commercialized in the timeframe we expect, achieve significant sales, or be commercialized at all.

We are exposed to numerous risks associated with the Genentech Agreement, including sharing a measure of control over the operations of our research and development portions of the collaboration with Genentech and Genentech having sole control over the commercialization of any products developed via the collaboration. The Genentech Agreement also prevents us from, among other things, developing or commercializing TCR-based cellular therapies outside the scope of the collaboration in the field of oncology on our own or with any third party. Our collaboration involves risks that are different from the risks involved in independently conducting operations, including that Genentech may:

- have or develop economic or business interests that are inconsistent with ours;
- take actions contrary to our instructions, requests, policies or objectives;
- take actions that reduce our return on investment for this collaboration;
- fail to distinguish itself from biosimilar competition; or
- take actions that harm our reputation or restrict our ability to run our business.

Genentech's degree of control over collaboration development and commercialization efforts may impact the amounts we receive under the Genentech Agreement. For example, Genentech may decide not to pursue commercialization of product candidates at all, or it may agree to pay royalties to third parties or adopt a pricing model that reduces the amount of royalties we might otherwise expect. It is also possible that effective cell therapies will not be developed under the Genentech Agreement or, if developed, approved by the FDA or comparable regulatory authorities outside of the United States. Genentech may also terminate the Genentech Agreement at its convenience, at any time and without cause.

We may not be able to perform our product research, development and commercialization related obligations under the Genentech Agreement, including performing TCR screening activities for product candidates being developed and commercialized under that agreement. For example, in the event a product is commercialized under the Genentech Agreement, as the volume of product sales grows, we will likely need to continue to increase our workflow capacity for sample intake, customer service and general process improvements, and expand our internal quality assurance program to support TCR screening on a larger scale within expected turnaround times. We will likely need additional certified laboratory scientists and other scientific and technical personnel for the Personalized Product to identify and target therapeutically relevant, patient-specific neoantigens. We will likely also need to acquire additional laboratory space and equipment, which can take several months or more to procure, set up and validate. These process enhancements and increases in scale, expansion of personnel, laboratory space and equipment may not be successfully implemented, and we may not have adequate space in our existing laboratory facilities to accommodate the required expansion. If we cannot satisfy our obligations, Genentech is entitled to trigger a technology transfer of our TCR screening process (specific to the Personalized Product) or terminate the Genentech Agreement. In addition, due to our significant obligations under the Genentech Agreement, we may face challenges in keeping existing customers, collaborators and suppliers and obtaining new customers, including any biopharmaceutical customers that are actual or potential competitors with Genentech.

If we support the commercialization of one or more products under the Genentech Agreement, we may need to incorporate new equipment, implement new technology systems and laboratory processes and 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, both under the Genentech Agreement and otherwise. As a result, our relationship with Genentech may not result in the realization of its anticipated benefits.

We have limited experience with the development and commercialization of cellular therapeutics, and future TCR-based cellular therapies may never be successfully developed and commercialized as part of our Genentech collaboration.

We have limited experience with the development of cellular therapeutics, and no experience with the commercialization, marketing and distribution of cellular therapeutics. Our therapeutic product candidates are at an early stage of discovery and development under our Genentech collaboration, and we are continuing to develop our TruTCR process being used under that collaboration to develop TCR-based cellular therapies for the treatment of cancer. Under our Genentech collaboration, Genentech has invested significant financial resources to develop future TCR-based cellular therapies, including conducting preclinical studies and other early research and development activities, and providing general and administrative support for these operations. Our future success is dependent on our and Genentech's ability to successfully develop therapeutic product candidates, and Genentech's ability, where applicable, to obtain regulatory and marketing approval for, and then successfully commercialize, cellular therapeutics. We and Genentech have not yet developed and commercialized any cellular therapeutics, and we may not be able to do so.

We currently use, and in the future expect to increase our use of, collaborators for several aspects of our operations, and if we cannot maintain current and enter new relationships with collaborators, our business will suffer.

We have limited resources to conduct our life sciences research, clinical diagnostics and drug discovery operations and have not yet fully established infrastructure for sales, marketing or distribution in connection with our products and services. Accordingly, we have entered into collaboration agreements under which our collaborators have provided, and may in the future provide, funding and other resources for developing and potentially commercializing our products and services. In particular, we have entered into the Genentech Agreement, with the goal of accelerating the development and commercialization of T cell therapies for the treatment of a broad range of tumor types, and a strategic collaboration agreement with Microsoft ("Microsoft Agreement"), which provides us with access to Microsoft's research and machine learning technologies that we are using to develop our TCR-Antigen Map. These collaborations may result in our incurring significant expenses in pursuit of potential products and services, and we may not be successful in identifying, developing or commercializing any potential products or services.

Our future success depends in part on our ability to maintain these relationships and to establish new relationships. Many factors may impact the success of such collaborations, including our ability to perform our obligations, our collaborators' satisfaction with our products and services, our collaborators' performance of their obligations to us, our collaborators' internal priorities, resource allocation decisions and competitive opportunities, the ability to obtain regulatory approvals, disagreements with collaborators, the costs required of either party to the collaboration and related financing needs, and operating, legal and other risks in any relevant jurisdiction. In addition to reducing our revenue or delaying the development of our future products and services, the loss of one or more of these relationships may reduce our exposure to research, data, clinical trials or computing technologies that facilitate the collection and incorporation of new information into our clinical immunomics database. All of the risks relating to product and service development, regulatory clearance, authorization or approval and commercialization described herein apply to us derivatively through the activities of our collaborators.

We engage in conversations with companies regarding potential collaborations on an ongoing basis. These conversations may not result in a commercial agreement. Even if an agreement is reached, the resulting relationship may not be successful, and any products and services developed as part of the collaboration may not produce successful outcomes. Speculation in the industry about our existing or potential collaborations can be a catalyst for adverse speculation about us, or our products or services, which can adversely affect our reputation and our business.

Significant additional research and development and, in certain instances, clinical trials or validation will be required before we can potentially seek regulatory clearance, authorization or approval for, or commercialize any of our products or services in development.

We are developing a pipeline of immune-driven diagnostics and therapeutics, including immunoSEQ Dx and cellular therapies in oncology, but significant additional research and development activities and clinical trials or validations could be required before we and our collaborators will have a chance to achieve additional commercially viable products. Our research and development efforts remain subject to all of the risks associated with the development of new products and services based on immune-driven diagnostics and immune-mediated therapies. Development of the underlying technology may be affected by unanticipated technical or other problems, among other research and development issues, and the possible insufficiency of funds needed to complete development of these products and services. Safety, regulatory and efficacy issues, clinical hurdles or other challenges may result in delays and cause us to incur additional expenses that would increase our losses. If we and our collaborators cannot complete, or if we experience significant delays in developing, our clinical diagnostics or cellular therapies, particularly after incurring significant expenditures, our business may fail and investors may lose the entirety of their investment.

Prior to obtaining regulatory clearances, authorizations or approvals for the commercial sale of any new products or services, we must demonstrate that our products and services are both safe and effective for use in each target disease indication. Clinical studies may be necessary to demonstrate that a product or service is safe and effective. Clinical testing or validation is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time. For therapeutics, the results of preclinical studies and early clinical trials of products and services in development may not be predictive of the results of later-stage clinical trials, and initial success in clinical trials may not be indicative of results obtained when clinical trials are completed. There is typically an extremely high rate of failure as therapeutic products in development proceed through clinical trials. Products in later stages of clinical trials or validation also may fail to show the desired safety and efficacy profile despite having progressed through non-clinical studies and initial clinical trials or validations. Any delays in the development of our products and services may harm our business, financial condition and prospects significantly.

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

We are creating new products and services, many of which are initially based on largely untested technologies. As all of our products and services progress, we or others may determine that we made product or service level scientific or technological mistakes. The testing processes utilize a number of complex and sophisticated biochemical, informatics, optical and mechanical processes, many of which are highly sensitive to external factors. An operational or technology failure in one of these complex processes or fluctuations in external factors may result in less efficient processing or variation between testing runs. Refinements to our processes may initially result in unanticipated issues that reduce the efficiency or increase variability. In particular, sequencing, which is a key component of these processes, could be inefficient with higher than expected variability thereby increasing total sequencing costs and reducing the number of samples we can process in a given time period. Therefore, inefficient or variable processes can cause variability in our operating results and damage our reputation.

In addition, our laboratory operations could result in any number of errors or defects. Our quality assurance system may fail to prevent us from inadvertent problems with samples, sample quality, lab processes including sequencing, software, data upload or analysis, raw materials, reagent manufacturing, assay quality or design, or other components or processes. In addition, our assays may have quality or design errors, and we may have inadequate procedures or instrumentation to process samples, assemble our proprietary primer mixes and commercial materials, upload and analyze data, or otherwise conduct our laboratory operations. If we provide products or services with undiscovered errors to our customers, our clinical diagnostics may falsely indicate a patient has a disease or fail to detect disease in a patient who requires treatment. We believe our customers are likely to be particularly sensitive to product and service defects, errors and delays, including if our products and services fail to indicate the presence of residual disease with high accuracy from clinical specimens or if we fail to list or inaccurately indicate the presence or absence of disease in our test report. In drug discovery, such errors may interfere with our collaborators' clinical studies or result in adverse safety or efficacy profiles for their products in development. This may harm our customers' businesses and may cause us to incur significant costs, divert the attention of key personnel, encourage regulatory enforcement action against us, create a significant customer relations problem for us and cause our reputation to suffer. We may also be subject to warranty and liability claims for damages related to errors or defects in our products or services. Any of these developments could harm our business and operating results.

Our current and future products and services may never achieve significant commercial market acceptance.

Our success depends on the market's confidence that we can provide immune-driven research, diagnostic and therapeutic products and services that improve clinical outcomes, lower healthcare costs and enable better biopharmaceutical development. Failure of our products and services, or those jointly developed with our collaborators, to perform as expected could significantly impair our operating results and our reputation. We believe patients, clinicians, academic institutions and biopharmaceutical companies are likely to be particularly sensitive to defects, errors, inaccuracies, delays and toxicities in or associated with our products and services. Furthermore, inadequate performance of these products or services may result in lower confidence in our immune medicine platform in general.

We and our collaborators may not succeed in achieving significant commercial market acceptance for our current or future products and services due to a number of factors, including:

- our ability to demonstrate the clinical utility of our immune medicine platform and related products and services and their potential advantages over existing life sciences research, clinical diagnostic and drug discovery technologies to academic institutions, biopharmaceutical companies and the medical community;
- our ability, and that of our collaborators, to secure and maintain FDA and other regulatory clearance, authorization or approval for our products;
- the agreement by third-party payors to reimburse our diagnostics, the scope and extent of which will affect patients' willingness or ability to pay for our diagnostics and will likely heavily influence physicians' decisions to recommend our tests;

- the rate of adoption of our immune medicine platform and related products and services by academic institutions, clinicians, key opinion leaders, advocacy groups and biopharmaceutical companies; and
- the impact of our investments in product innovation and commercial growth.

Additionally, our customers and collaborators may decide to decrease or discontinue their use of our products and services due to changes in their research and development plans, failures in their clinical trials, financial constraints, the regulatory environment, negative publicity about our products and services, competing products or the reimbursement landscape, all of which are circumstances outside of our control. We may not be successful in addressing these or other factors that might affect the market acceptance of our products and services and technologies. Failure to achieve widespread market acceptance of our immune medicine platform and related products and services would materially harm our business, financial condition and results of operations.

We rely on a limited number of suppliers or, in many cases, single suppliers, for laboratory equipment and materials and may not be able to find replacements or immediately transition to alternative suppliers.

We rely on a limited number of suppliers, or in many cases single suppliers, to provide certain sequencers and equipment that we use in our laboratory operations, as well as reagents and other laboratory materials for our products and services. An interruption in our laboratory operations, kit distribution or technology transfer could occur if we encounter delays, quality issues or other difficulties in securing these sequencers, equipment, reagents or other materials, and if we cannot then obtain an acceptable substitute. In addition, we would likely be required to incur significant costs and devote significant efforts to find new suppliers, acquire and qualify new equipment, validate new reagents and revalidate aspects of our existing assays, which may cause delays in our processing of samples or development and commercialization of products and services. Any such interruption could significantly affect our business, financial condition, results of operations and reputation.

In particular, we have purchased and rely on the Illumina NextSeq System. Illumina supplies us with reagents that have been designed for use solely with this sequencer and Illumina is the sole provider of maintenance and repair services for the Illumina NextSeq System. We also license our laboratory information management software from Illumina and receive services from Illumina related to that software. We believe there are only a few other equipment manufacturers that are currently capable of supplying the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of sequencers manufactured by a company other than Illumina would require us to alter our laboratory operations. Transitioning to and qualifying a new sequencer would be time-consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate the reagents of our immunoSEQ kits, immunoSEQ Dx or clonoSEQ diagnostic testing services, and could require us to obtain additional clearance, authorization, approval, accreditation, or licensure for the changes. We may not be able to secure and implement alternative sequencers, associated reagents and other materials without experiencing interruptions in our workflow. In the case of an alternative supplier to Illumina, any replacement sequencers and various associated reagents may not be available or may not meet our quality control and performance requirements for our laboratory operations. If we should encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and reagents we require for our products and services, our business, financial condition, results of operations and reputation could be adversely affected. In addition, Illumina is not obligated to meet all of our requirements for reagent supply. In the event Illumina ceases or slows its production of, or is otherwise unwilling or unable to continue to supply the sequencer reagents necessary for and currently used in our business at or near current pricing, we may be required to purchase different reagents from Illumina or to purchase from a different reagent vendor under terms and conditions which could be less favorable to us. Any disruption in Illumina's operations or the suppliers of our reagents could impact our supply chain and laboratory operations of our immune medicine platform and our ability to conduct our business and generate revenue.

We have limited experience in marketing and selling products and services, and if we are unable to expand our direct sales and marketing force or partner with collaborators in certain product areas and markets to adequately address our customers' needs, our business may be adversely affected.

We have limited experience in marketing and selling our research and diagnostic products and services and no experience marketing and selling therapeutic products and services. Accordingly, we or our collaborators may not be able to market and sell our current or future products and services effectively enough to support our planned growth.

Our research and diagnostic sales and marketing efforts are targeted at a large and diverse market with highly specialized segments, including department heads, laboratory directors, principal investigators, core facility directors, clinicians, payors and research scientists and pathologists at leading academic institutions, biopharmaceutical companies, research institutions and contract research organizations. As a result, we believe it is necessary for our sales representatives to have relevant, specialized market experience. Our internal sales organization is currently small, and competition for experienced sales and marketing personnel is intense. We may not be able to attract and retain personnel or be able to build or adequately train an efficient and effective sales organization, which could negatively impact sales and market acceptance of our clinical diagnostics and limit our revenue growth and potential profitability. We are also seeking distribution partners, particularly for our improved immunoSEQ RUO kit by researchers who want to perform immunosequencing in their local labs. We may not be able to engage a distribution partner on favorable terms, or at all.

We established a collaboration with Genentech for the research, development, marketing, promotion, distribution and sale of TCR-based cellular therapies for the treatment of cancer. Under the Genentech Agreement, Genentech has the sole right and authority to commercialize products developed under that agreement. It will be Genentech's responsibility to locate, qualify and engage distribution partners, clinicians and local hospitals with industry experience and knowledge to effectively market and sell products developed under that agreement. Genentech may not be able to engage distribution partners, clinicians or hospitals on favorable terms, or at all. If Genentech's sales and marketing efforts with respect to products developed under the Genentech Agreement are not successful, we may not achieve significant market acceptance for our drug discovery services and platform, which would materially and adversely impact our business operations.

If we or our collaborators experience any of a number of possible unforeseen events in connection with clinical trials, our or their ability to conduct further clinical trials of, obtain regulatory clearance, authorization or approval of or commercialize future products and services or improvements to current products and services, could be delayed or prevented.

We or our collaborators may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our or their ability to conduct further clinical trials or obtain regulatory clearance, authorization or approval of or commercialize future products and services or improvements to current products and services, including:

Evolving Regulatory Requirements and Policies

- the area of "precision medicine" or "personalized medicine" and its regulation may be subject to ongoing changes in terms of regulatory requirements and governmental policies, in ways we cannot predict;

Trial Design

- regulatory authorities or ethical review boards, including IRBs, may not authorize commencement of a clinical trial or conduct a clinical trial at a prospective trial site;
- there may be delays in reaching or failure to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- the FDA or other regulatory authorities may disagree with a clinical trial design or a sponsor's interpretation of data and may change the requirements for product clearance, authorization or approval even after they have reviewed and commented on the clinical trial design;
- differences in trial design between early stage clinical trials and later-stage clinical trials may make it difficult to extrapolate the results of earlier clinical trials to later clinical trials;
- the FDA or other regulatory authorities may disagree about whether study endpoints are clinically meaningful;
- the number of patients, or amount of data, required for clinical trials, or improvements to current products, may be larger than anticipated, patient enrollment in these clinical trials may be slower than anticipated or patients may drop out of clinical trials at a higher rate than anticipated;

Testing

- changes may be made to product candidates after commencing clinical trials, which may require that previously completed stages of clinical testing be repeated or delay later stages of testing, for example, we, or our collaborators, may pursue one or more different product development pathways for our T cell immunotherapies;
- clinical trials may fail to satisfy the applicable regulatory requirements of the FDA or other regulatory authorities responsible for oversight of the conduct of clinical trials in other countries;
- regulators may elect to impose a clinical hold, or governing IRBs, data safety monitoring board or ethics committees may elect to suspend or terminate our clinical research or trials for various reasons, including non-compliance with regulatory requirements or a finding that the participants are being exposed to unacceptable risks to their health or the privacy of their health information being disclosed;
- the cost of clinical trials of future products and services, or improvements to current products and services, may be greater than we anticipate;

- we may not have sufficient capacity in our laboratories, including the additional capacity we expect to come online as the result of the anticipated expansion of our corporate headquarters, to perform testing as requested or volumes requested or with the requested turnaround times necessary for clinical trials;
- the supply or quality of materials or data necessary to conduct clinical trials of future products and services, or improvements to current products and services, may be insufficient or inadequate;

Trial Outcomes

- the outcome of our collaborators' preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;
- product candidates may be associated with negative or inconclusive results in clinical trials, and we or our collaborators may decide to deprioritize or abandon these product candidates, or regulatory authorities may require us to abandon them or impose onerous changes or requirements, which could lead to deprioritization or abandonment;
- product candidates may have undesirable side effects which could lead to serious adverse events, or other unexpected characteristics. One or more of such effects or events could cause regulators to impose a clinical hold on the applicable trial, or cause us, our collaborators or their investigators, IRBs or ethics committees to suspend or terminate the trial of that product candidate;
- clinical trials may suggest or demonstrate that products or services are not as efficacious or safe as other similar diagnostics or therapies; and
- preclinical and clinical data are often susceptible to varying interpretations and analyses, and our products and services in development may fail to obtain regulatory clearance, authorization or approval, even if they perform satisfactorily in preclinical studies and clinical trials.

Delays of this nature could also allow competitors to bring products to market before we or our collaborators do, potentially impairing our ability to successfully commercialize our products and services in development and harming our business and results of operations. Any delays in the development of our products and services or those jointly developed with our collaborators may significantly harm our business, financial condition and prospects. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory clearance, authorization or approval of products and services in development.

We will need to develop and expand our workforce, commercial infrastructure and laboratory operations to support anticipated growth in demand for our products and services, and we may encounter difficulties in managing this development and expansion and in meeting fluctuations in this demand.

We will need to expand our workforce, commercial infrastructure and laboratory operations to support anticipated growth in demand for our products and services. If we are unable to support fluctuations in the demand for our products and services, including ensuring that we have adequate capacity to meet increased demand, our business could suffer. As of December 31, 2019, we had 453 full-time employees and we expect to increase the number of employees and the scope of our operations as we continue to develop our clinical diagnostic products and services. As we and our collaborators commercialize additional products and services, we may need to incorporate new equipment, implement new technology systems and laboratory processes and hire new personnel with different qualifications. For example, in connection with our Genentech collaboration, we may need to procure additional laboratory space and personnel to allow us to increase TCR screening times with respect to product candidates being developed under the Genentech Agreement. Failure to manage this growth or transition could result in turnaround time delays, higher service costs, declining service 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 services and could damage our reputation and the prospects for our business.

To manage our anticipated expansion, we must continue to implement and improve our managerial, operational and financial systems, continue to expand our facilities (including our corporate headquarters in Seattle, Washington and cellular lab in South San Francisco, California) and continue to recruit and train additional qualified personnel. Also, our management team may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources and early stage of growth, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, operational mistakes, slower development of our products and services, missed or delayed milestone achievement, significant cost overruns, loss of business opportunities, loss of employees, inability to execute on hiring plans and reduced productivity among remaining employees.

If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance, and our ability to develop and commercialize our products and services and compete effectively, will depend, in part, on our ability to effectively manage our future development and expansion.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this Annual Report on Form 10-K:

- the timing of upfront payments from our collaborators;
- our ability and that of our collaborators to develop and successfully commercialize our products and services;
- our ability to achieve collaboration-based milestones on currently contemplated timelines, or at all;
- availability and extent of reimbursement by governmental and private payors for our products and services;
- the ability of our clinical sales teams to convert physicians from using incumbent products in the market to clonoSEQ and new diagnostic products and services we may develop;
- our ability to drive repeat usage of the clonoSEQ diagnostic test by physicians and get reimbursed for that repeat usage by commercial and government payors for monitoring of MRD;
- the outcomes of research initiatives, clinical trials or other product development or approval processes conducted by us or our collaborators;
- the level of demand for our products and services, which may vary significantly;
- our relationships, and any associated exclusivity terms, with collaborators;
- our ability to manage our growth;
- our contractual or other obligations to provide resources to fund our products and services and to provide resources to our collaborations;
- delays or failures in advancement of future products in clinical trials by us or our collaborators;
- risks associated with the future international expansion of our business, including the potential to conduct clinical trials and commercialize our products and services in multiple international locations;
- our ability and that of our collaborators to consistently manufacture our products;
- our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect and enforce our intellectual property rights;
- our ability to prevent the theft or misappropriation of our intellectual property, know-how or technologies;
- our ability to obtain additional capital that may be necessary to expand our business;
- our ability to accurately report our financial results in a timely manner;
- business interruptions such as power outages, strikes, acts of terrorism or natural disasters; and
- our ability to use our net operating loss (“NOL”) carryforwards to offset future taxable income.

The cumulative effects of factors discussed above could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. In any particular period, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

While as a general matter we intend to periodically report on the status of our development initiatives, including anticipated next steps, we may not provide forward-looking guidance on the timing of those next steps. In addition, we do not control the timing of disclosure of any such milestones related to any of our products and services that are managed by our collaborators. Any disclosure by us or our collaborators of data that is perceived as negative may have a material adverse impact on our stock price or overall valuation. Our stock price may decline as a result of unexpected clinical trial results in one or more of our products and services, including adverse safety events reported for any of our products or services.

We have estimated the sizes of the markets for our current and future products and services, and these markets may be smaller than we estimate.

Our estimates of the annual addressable markets for our current products and services and those under development are based on a number of internal and third-party estimates, including, without limitation, the number of patients who have developed one or more of a broad range of cancers, the number of individuals who are at a higher risk for developing one or more of a broad range of cancers, the number of individuals who have developed or are at a higher risk of developing certain autoimmune disorders, the number of individuals with certain infectious diseases we or our collaborators are able to treat through our products and services, the number of potential tests utilized per treatment course per patient and the assumed prices at which we can sell our current and future products and services for markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual addressable market for our current or future products and services may prove to be incorrect. If the actual number of patients who would benefit from our products or services, the price at which we can sell future products and services or the annual addressable market for our products or services is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

If we do not compete effectively with scientific and commercial competitors, we may not be able to successfully commercialize our products and services.

The biotechnology and pharmaceutical industries, including the fields of life sciences research, clinical diagnostics and drug discovery are intense and highly competitive. These fields are characterized by rapidly advancing technologies and a strong emphasis on intellectual property. Given the breadth and promise of immune medicine, we face substantial competition from many different sources, including life sciences tools, diagnostics, pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions across various components of our platform and product and service offerings. Due to the significant interest and growth in immune-driven medicine more broadly, we expect the intensity of the competition to increase.

For instance, in life sciences research, immunoSEQ faces competition from a number of companies, including Thermo Fisher Scientific Inc. and 10X Genomics, Inc., among others. In clinical diagnostics, our clonoSEQ diagnostic test faces competition primarily from institutions performing flow cytometry in-house, particularly outside of the United States. In drug discovery, clinical trials of immune-driven medicines are being undertaken by a number of industry and academic players.

Our competitors may have or obtain the knowledge necessary to generate and characterize similar data to our known data for the purpose of identifying and developing products or services that could compete with any of our products or services. Further, immune medicine is being pursued by several biotechnology companies as well as by large-cap biopharmaceutical companies. Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, regulatory approval and compliance, and sales and distribution than we do.

We could be adversely affected if we do not develop our life sciences research, clinical diagnostic and drug discovery products and services, obtain required regulatory and other clearances, authorizations or approvals, obtain or enforce patents covering our discoveries and launch our products and services before our competitors. Moreover, our competitors may succeed in developing immunosequencing-based life sciences research, clinical diagnostics and drug discoveries that circumvent our technologies, products or services. Our competitors may succeed in developing and commercializing research or diagnostic products or services that are more accurate, more convenient to use or more cost-effective than our products or services or therapeutic products that prove to be safer, more effective, more convenient to administer or more cost-effective than any therapeutic products we may develop with our collaborators or that would render our technologies, products and services less competitive or obsolete. We expect competition to intensify in the fields in which we are involved as technical advances in these fields occur and become more widely known. For additional information regarding our competition, see the "*Business—Competition*" section of this Annual Report on Form 10-K.

The life sciences industry is subject to rapid change, which could make our immune medicine platform and related products and services that we develop obsolete.

Our industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product and service introductions and enhancements and evolving industry standards, all of which could make our current and future products and services obsolete. Our future success will depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. In recent years, there have been numerous advances in technologies relating to life sciences research and the diagnosis and treatment of cancer, other diseases and autoimmune disorders. There have also been advances in technologies used to computationally analyze very large amounts of biologic information. If we do not update our products and services to reflect new scientific knowledge about immunosequencing, immunology, computational biology, software development, new disease diagnostics and therapies or the diseases we seek to treat, our products and services could become obsolete and sales of our current products and services and any future products and services we develop based on our immune medicine platform could decline or fail to grow as expected.

The loss of any member of our senior management team or our inability to attract and retain highly skilled scientists, clinicians and salespeople could adversely affect our business.

Our success depends on the skills, experience and performance of key members of our senior management team, including Chad Robins, our Chief Executive Officer and Co-Founder, Dr. Harlan Robins, our Chief Scientific Officer and Co-Founder, and Julie Rubinstein, our President. The individual and collective efforts of these employees will be important as we continue to develop products and services based on our immune medicine platform. The loss or incapacity of existing members of our executive management team could adversely affect our operations if we experience difficulties in hiring qualified successors. Our executive officers have signed employment agreements with us, but their service is at-will and may end at any point in time.

Our research and development initiatives and laboratory operations depend on our ability to attract and retain highly skilled scientists, technicians and software engineers. We may not be able to attract or retain qualified scientists, technicians or software engineers in the future due to the competition for qualified personnel among life science and technology businesses, particularly near our headquarters located in Seattle, Washington and our laboratory facilities located in South San Francisco, California. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We may have difficulties locating, recruiting or retaining qualified salespeople. Recruiting, training and retention difficulties can limit our ability to support our research and development and commercialization efforts. All of our employees are at-will, which means that either we or the employee may terminate their employment at any time.

In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory and commercialization strategy. Our consultants and advisors may provide services to other organizations and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current consultants or advisors might impede the achievement of our research, development, regulatory and commercialization objectives. In addition, we have flexibly grown our workforce through the use of contractors and part-time workers. We may not be able to retain the services of such personnel which might result in delays in the operation of our business.

If we lose the support of key thought leaders, it may be difficult to establish products and services enabled by our immune medicine platform as industry standards, which may limit our revenue growth and ability to achieve profitability.

We have established relationships with leading oncology, hematology, immunology, autoimmunity or inflammatory disease, transplantation and solid tumor thought leaders at premier academic and research institutions. If these key thought leaders determine that our immune medicine platform or our current or future products or services are not clinically effective, determine that alternative technologies are more effective or elect to use internally developed services, we could encounter significant difficulty validating our products or services, driving adoption or establishing our immune medicine platform as an industry standard, which would limit our revenue growth and our ability to achieve profitability. In addition, negative publications or reviews by clinicians, industry groups or other important stakeholders may negatively impact our revenue growth and ability to achieve profitability.

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, including third-party cloud computing infrastructure, operating systems and artificial intelligence platforms, for significant elements of our operations, including our laboratory information management system, clinical immunomics database, immunoSEQ Analyzer, TCR-Antigen Map, laboratory workflow tools, customer and collaborator reporting and related functions. We also depend on our proprietary workflow software to support new product and service launches and regulatory compliance.

We use complex software processes and pipelines to manage samples and evaluate sequencing result data. These are subject to initial design or ongoing modifications which may result in unanticipated issues that could cause variability in patient results, leading to service disruptions or errors, resulting in liability.

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 systems handling human resources, financial controls and reporting, contract management, regulatory compliance and other infrastructure operations. In addition to these business systems, we have installed, and intend to extend, the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation and general administrative activities. In addition, our third-party billing and collections provider depends upon technology and telecommunications systems provided by outside vendors.

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 these systems or those used by our collaborators or subcontractors could prevent us from conducting our comprehensive immunosequencing analysis, clinical diagnostics and drug discovery, preparing and providing reports to researchers, clinicians and our collaborators, billing payors, handling physician inquiries, conducting research and development activities 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 and our reputation, and we may be unable to regain or repair our reputation in the future.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Because we and our collaborators currently market our products and services outside of the United States and may market future products and services outside of the United States, if cleared, authorized or approved, our business is subject to risks associated with doing business outside of the United States, including an increase in our expenses and diversion of our management's attention from the development of future products and services. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- multiple, conflicting and changing laws and regulations such as privacy, security and data use regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, anticorruption laws, regulatory requirements, reimbursement or payor regimes and other governmental approvals, permits and licenses;
- failure by us, our collaborators or our distributors to obtain regulatory clearance, authorization or approval for the use of our products and services in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining intellectual property protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- difficulties in negotiating favorable reimbursement negotiations with governmental authorities;
- logistics and regulations associated with shipping samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to conduct our immunosequencing or clinical diagnostic services locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and services and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the FCPA, its books and records provisions, or its anti-bribery provisions,

or laws similar to the FCPA in other jurisdictions in which we may now or in the future operate, such as the United Kingdom's Bribery Act of 2010; and

- anti-bribery requirements of several member states in the European Union ("EU") and other countries, such as the United Kingdom's Bribery Act of 2010, that are constantly changing and require disclosure of information to which U.S. legal privilege may not extend.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

We may never obtain approval in the EU or in any other foreign country for any of our products or services and, even if we do, we or our collaborators may never be able to commercialize them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to eventually market any of our current or future products and services in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding quality, safety, performance and efficacy. In addition, clinical trials or clinical investigations conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory clearance, authorization or approval in one country does not guarantee regulatory clearance, authorization or approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking foreign regulatory clearance, authorization or approval could result in difficulties and costs for us and our collaborators and require additional preclinical studies, clinical trials or clinical investigations which could be costly and time-consuming. Regulatory requirements and ethical approval obligations can vary widely from country to country and could delay or prevent the introduction of our products and services in those countries. The foreign regulatory clearance, authorization or approval process involves all of the risks and uncertainties associated with FDA clearance, authorization or approval. We currently sell our RUO kits outside of the United States and have completed a technology transfer process for research use to sites in Toulouse, France, Bologna, Italy, and Heidelberg, Germany, but have no experience in obtaining regulatory clearance, authorization or approval in international markets. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required regulatory clearances, authorizations or approvals in international markets, or if those approvals are delayed, our target market will be reduced and our ability to realize the full market potential of our products and services will be unrealized.

If our laboratory facilities become damaged or inoperable or we are required to vacate our existing facilities, our ability to conduct our laboratory processes and analysis and pursue our research and development efforts may be jeopardized.

We operate laboratory facilities located in Seattle, Washington and South San Francisco, California, and are currently expanding our corporate headquarters in Seattle, Washington to enable us to expand our laboratory capacity and research and development footprint. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure or terrorism, which may render it difficult or impossible for us to operate our immune medicine platform for some period of time. The inability to perform our laboratory processes or to reduce the backlog of sequences that could develop if our facilities are inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future.

Furthermore, our facilities and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace, and we may not be able to execute on our anticipated expansion, which may increase the backlog of sequences if our laboratory space is not expanded to meet our expected increased throughput. It would be difficult, time-consuming and expensive to rebuild our facilities, to locate and qualify new facilities or license or transfer our proprietary technologies to a third party, particularly in light of licensure and accreditation requirements. Even in the unlikely event we are able to find a third party with such qualifications to enable us to conduct our laboratory processes, we may be unable to negotiate commercially reasonable terms.

We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all.

We may need to raise additional capital to fund our existing operations, develop additional products and services, commercialize new products and services or expand our operations.

Based on our current business plan, we believe our current cash, cash equivalents and marketable securities and anticipated cash flow from operations, will be sufficient to meet our anticipated cash requirements over at least the next 12 months. If our available cash and investment balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our products and services as a result of risks described herein, we may seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding or seek other debt financing.

We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts to drive market adoption of our life sciences research, clinical diagnostics and therapeutics;
- fund development efforts for our current and future products and services;
- expand our products and services into other disease indications and clinical applications;
- acquire, license or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures, such as our corporate headquarters expansion, and general and administrative expenses.

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

- our ability to achieve revenue growth;
- our rate of progress in establishing payor coverage and reimbursement arrangements with domestic and international commercial third-party payors and government payors;
- the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our immunoSEQ research services and kits, and reimbursement for our clonoSEQ diagnostic test, our immunoSEQ Dx early detection test and cellular therapies developed under the Genentech Agreement;
- our rate of progress in, and cost of research and development activities associated with, products and services in research and early development;
- the effect of competing technological, product and market developments;
- costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products and services.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our shareholders could result. Any preferred equity securities issued also could provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our platform technologies or products and services or grant licenses on terms that are not favorable to us.

Our ability to use our NOL carryforwards and certain other tax attributes may be limited.

We have incurred net losses since our inception and we may never achieve or sustain profitability. Generally, losses incurred will carry forward until such losses expire (for losses generated prior to January 1, 2018) or are used to offset future taxable income, if any. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ("Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change in its equity ownership by certain shareholders over a three-year period, the corporation's ability to use its pre-ownership change NOL carryforwards and other pre-ownership change tax attributes, such as research tax credits, to offset its post-ownership change income or taxes may be limited. Under the TCJA, which significantly reformed U.S. tax law, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of annual taxable income. It is uncertain if and to what extent various states will conform to the TCJA. If there should be an ownership change, our ability to utilize our NOL carryforwards and credits could be limited. We have completed a study of our ownership changes prior to our initial public offering and related tax losses through December 31, 2018, and believe $225.4 million of losses are not subject to permanent limitation. We may experience ownership changes in the future as a result of shifts in our stock ownership, which may be outside of our control. As a result, if we earn net taxable income, our ability to use our pre-ownership change NOL carryforwards to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. As a result, even if we attain profitability, we may be unable to use a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

In addition, the TCJA reduced the corporate tax rate from a top marginal tax rate of 35% to a flat rate of 21%, limited the tax deduction for net business interest expense to 30% of adjusted taxable income, eliminated NOL carrybacks and modified or repealed many business deductions and credits, including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs." The U.S. Department of the Treasury and the U.S. Internal Revenue Service ("IRS") have already issued and are expected to continue to provide guidance on the implementation of the TCJA. We continue to examine the impact this tax reform legislation may have on our business and the operations of our collaborators. However, the effect of the TCJA on our business and the operations of our collaborators, whether adverse or favorable, is uncertain and may not become evident for some period of time. We urge investors to consult with their legal and tax advisors regarding the implications of the TCJA on an investment in our Company.

We could be adversely affected by violations of the FCPA and other worldwide anti-bribery laws.

As we expand geographically, commercialize our products and services, and attempt to obtain required clearances, authorizations or approvals required to offer products and services for sale, we or our collaborators may be deemed to do business outside the United States, including because international customers may be able to order our products and services. As a result, we or our collaborators would be subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. In addition, our collaborators or any third-party distributors could be deemed to be our agents and we could be held responsible for their actions, including violations of the FCPA. Other U.S. companies in the life sciences industry have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with non-U.S. government officials. We may also become subject to similar anti-bribery laws in the jurisdictions in which we may operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and we may be required in the future to alter one or more of our practices to be in compliance with these laws. Accordingly, our expansion internationally will demand a high degree of vigilance, and any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

We may acquire other businesses or form joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our shareholders' ownership, increase our debt or cause us to incur significant expense.

We may pursue acquisitions of businesses and assets. We also may pursue joint ventures or investments that leverage our immune medicine platform and industry experience to expand our offerings or distribution. We have no experience forming joint ventures and limited experience investing in or acquiring other companies. We may not be able to find suitable joint ventures, investment or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate the acquired company successfully into our existing business, and we could assume unknown or contingent liabilities, including regulatory violations such as the FCPA or similar laws. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations and financial condition. We may not realize the anticipated benefits of any acquisition, technology license, collaboration or joint venture.

To finance any acquisitions or joint ventures, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our shareholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration.

Unfavorable U.S. or global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our products and services and our ability to raise additional capital when needed on favorable terms, if at all. A weak or declining economy could strain our collaborators, possibly resulting in supply disruption, or cause delays in their payments to us. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We use biological and hazardous materials that require considerable expertise and expense for handling, storage and disposal and may result in claims against us.

We work with materials, including chemicals, biological agents and compounds and samples that could be hazardous to human health and safety or the environment. Our operations also produce hazardous and biological waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental laws and regulations may restrict our operations. If we do not comply with applicable regulations, we may be subject to fines and penalties.

In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes, which could cause an interruption of our commercialization efforts, research and development programs, and business operations, as well as environmental damage resulting in costly cleanup and liabilities under applicable laws and regulations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. While our property insurance policy provides limited coverage in the event of contamination from hazardous and biological products and the resulting cleanup costs, we do not currently have any additional insurance coverage for legal liability for claims arising from the handling, storage or disposal of hazardous materials. Accordingly, in the event of contamination or injury, we could be liable for damages or penalized with fines in an amount exceeding our resources and our operations could be suspended or otherwise adversely affected.

If we were to be sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our products and services could lead to the filing of product or professional liability claims were someone to allege that our products or services identified inaccurate, incomplete or untimely information regarding the sequence or antigen specificities of TCRs, BCRs or antigens analyzed or the clonality characterized, or MRD or malignancy detected, or that our products or services otherwise failed to perform as designed or intended. We could also be potentially exposed to claims relating to therapeutic failures of products commercialized under our collaborations, such as a cellular therapy marketed by Genentech that is manufactured based on TCR-related sequences and data we provide. We may also be subject to liability for errors in, a misunderstanding of or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Regardless of merit or eventual outcome, product liability and professional liability claims may result in:

- decreased demand for any products, services or clinical solutions that we have developed or may develop;
- loss of revenue;
- substantial monetary awards to patients or their families;
- significant time and costs to defend related litigation;
- withdrawal of clinical trial participants;
- the inability to commercialize any products, services or clinical solutions that we have developed or may develop; and
- injury to our reputation and significant negative media attention.

We maintain product and professional liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause current collaborators to terminate existing agreements or potential collaborators to seek other companies, any of which could impact our results of operations.

We or our collaborators may be adversely affected by natural or man-made disasters or other business interruptions, such as cybersecurity attacks, and our business continuity and disaster recovery plans, or those of our collaborators, may not adequately protect us from the effects of a serious disaster.

Natural and man-made disasters and other events beyond our control could severely disrupt our operations, or those of our collaborators, and have a material adverse impact on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, cybersecurity attack or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our laboratory facilities or those of our collaborators, limited our or our collaborators' ability to access or use our respective digital information systems or that otherwise disrupted our respective operations, it may be difficult or, in certain cases, impossible for us or our collaborators to continue our respective businesses for a substantial period of time. The disaster recovery and business continuity plans we and our collaborators currently have in place are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. Our cybersecurity liability insurance may not cover any or all damages, depending on the severity and extent, we or our collaborators could sustain based on any breach of our respective computer security protocols or other cybersecurity attack. We may incur substantial expenses as a result of the limited nature of our respective disaster recovery and business continuity plans, which could have a material adverse impact on our business.

Risks Relating to Government Regulation

We conduct our business in a heavily regulated industry, and changes in regulations or violations of regulations may, directly or indirectly, reduce our revenue, adversely affect our results of operations and financial condition and harm our business.

The life sciences industry is highly regulated, and the regulatory environment in which we and our collaborators operate may change significantly and adversely to us in the future. Areas of the regulatory environment that may affect our ability to conduct business include, without limitation, federal and state laws relating to:

- laboratory testing, including CLIA and state laboratory licensing laws;
- the development, testing, use, distribution, promotion and advertising of research services, kits, clinical diagnostics and cellular therapies, including certain LDTs, which are regulated by the FDA under the FDCA;
- test ordering, documentation of tests ordered, billing practices and claims payment under CMS and the HHS OIG enforcing those laws and regulations;
- cellular therapies, medical device and *in vitro* diagnostic clearance, marketing authorization or approval;

- laboratory anti-mark-up laws;
- the handling and disposal of medical and hazardous waste;
- fraud and abuse laws such as the False Claims Act, the AKS, and the Stark Law;
- Occupational Safety and Health Administration rules and regulations;
- HIPAA and other federal and state medical data privacy and security laws;
- the Genetic Information Nondiscrimination Act ("GINA") and similar state laws; and
- coverage and restrictions on coverage and reimbursement for research services, kits, clinical diagnostics and cellular therapies and Medicare, Medicaid, other governmental payors and private insurers reimbursement levels.

In particular, the laws, regulations and policies governing the marketing of RUO products, LDTs and clinical diagnostic tests and services are extremely complex and in many instances there are no significant regulatory or judicial interpretations of these laws and regulations. For example, our immunoSEQ research services and kits offered as RUO could, in the future, be subject to greater regulation by the FDA pursuant to the medical device provisions of the FDCA beyond the current regulations governing RUO labeling. The FDA defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent or other similar or related article, including a component, part or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals. Our clonoSEQ diagnostic tests and related clinical products, including our clinical laboratory tests that are *in vitro* diagnostic products, are diagnostic products that are considered by the FDA to be medical devices, and are subject to the requirement for marketing authorization prior to commercialization. We obtained marketing authorization for clonoSEQ as currently commercially marketed through the FDA's *de novo* review and authorization process. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, design, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance, authorization or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure they are safe and effective. In addition, the FDA regulates the import and export of medical devices. If we do not comply with these requirements, or later become subject to these requirements and fail to adequately comply, our business operations may be harmed. These requirements may additionally cause delays in our or our collaborators' ability to market and sell our products or services, which may, directly or indirectly, reduce our revenue, adversely affect our results of operations and financial condition and harm our business.

The insurance coverage and reimbursement status of newly approved products and services, in a new category of diagnostics and therapeutics, is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for current or future products and services could limit our ability, and that of our collaborators, to fully commercialize our products and services and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford the clinical diagnostic tests and cellular therapeutics that we and our collaborators currently or plan to develop and sell. In addition, because our clinical diagnostics and therapeutic products and services represent new approaches to the research, diagnosis, detection and treatment of diseases, we cannot accurately estimate how our products and services, and those jointly created with our collaborators, would be priced, whether reimbursement could be obtained or any potential revenue generated. Sales of our products and services will depend substantially, both domestically and internationally, on the extent to which the costs of our products and services are paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize some of our products or services. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment in any of our products or services. Changes in the reimbursement landscape may occur, which are outside of our control, and may impact the commercial viability of our products and services.

There is significant uncertainty related to the insurance coverage and reimbursement of newly cleared, authorized or approved products and services. In the United States, many significant decisions about reimbursement for new diagnostics and medicines are typically made by CMS, an agency within the HHS. CMS decides whether and to what extent a new diagnostic or medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel products and services such as ours. Additionally, reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement, or have been approved under restricted conditions, in certain European countries.

Outside the United States, the reimbursement process and timelines vary significantly. Certain countries, including a number of member states of the EU, set prices and make reimbursement decisions for diagnostics and pharmaceutical products, or medicinal products, as they are commonly referred to in the EU, with limited participation from the marketing authorization or Conformité Européene ("CE") mark holders, or may take decisions that are unfavorable to the authorization or CE mark holder where they have participated in the process. We cannot be sure that such prices and reimbursement decisions will be acceptable to us or our collaborators. If the regulatory authorities in these foreign jurisdictions set prices or make reimbursement criteria that are not commercially attractive for us or our collaborators, our revenues and the potential profitability of our products and services in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to control the healthcare budget by focusing cost-cutting efforts on medicinal products, and to a lesser extent, medical devices, provided under their state-run healthcare systems. These international price control efforts have impacted all regions of the world, but have been most prominent in the EU. Additionally, some countries require approval of the sale price of a product before it can be marketed or mandatory discounts or profit caps may be applied. Further, after the sale price is approved, it remains subject to review during the product lifecycle. In many countries, the pricing review period begins after marketing or product licensing approval is granted or the CE mark is obtained. As a result, we or our collaborators might obtain marketing approval for a product or service in a particular country, but then may experience delays in the reimbursement approval or be subject to price regulations that would delay the commercial launch of our product or service, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of that product or service in that particular country.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly cleared, authorized or approved devices and medicines and, as a result, they may not cover or provide adequate payment for our clinical diagnostics or the cellular therapies to be sold by us or our collaborators. For example, the U.S. government recently released a "blueprint," or plan, to reduce the cost of drugs. This blueprint contains certain measures that HHS is already working to implement. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological program pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, which are, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect to experience pricing pressures on our clinical diagnostics and cellular therapies sold by us and our collaborators due to the trend toward value-based pricing and coverage, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Our business could be harmed by the loss, suspension or other restriction on a license, certification or accreditation, or by the imposition of a fine or penalties, under CLIA, its implementing regulations or other state, federal and foreign laws and regulations affecting licensure or certification, or by future changes in these laws or regulations.

Federal law requires virtually all clinical laboratories to comply with CLIA, which generally involves becoming certified by the federal and state government for the testing that will be performed and complying with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that testing services are accurate and reliable. CLIA certification is also a prerequisite to be eligible to bill state and federal healthcare programs, as well as many private third-party payors, for laboratory research and clinical diagnostic testing services. As a condition of our CLIA certification, our Seattle, Washington laboratory is subject to survey and inspection every other year, additional random inspections and surprise inspections based on complaints received by state or federal regulators. The biennial survey and inspection is conducted by CMS, a CMS agent or, if the laboratory holds a CLIA certificate of accreditation, a CMS-approved accreditation organization, such as CAP. Sanctions for failure to comply with CLIA requirements, including proficiency testing violations, may include suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as the imposition of significant civil, administrative or criminal sanctions against the lab, its owners and other individuals. In addition, we are subject to regulation under certain state laws and regulations governing laboratory licensure. Some states, including Washington, have enacted laboratory licensure and compliance laws that are more stringent than CLIA. Changes in state licensure laws that affect our ability to offer and provide research and diagnostic products and services across state or foreign country lines could materially and adversely affect our business. In addition, state and foreign requirements for laboratory certification may be costly or difficult to meet and could affect our ability to receive specimens from certain states or foreign countries.

Any sanction imposed under CLIA, its implementing regulations or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license or accreditation, could have a material adverse effect on our business.

Changes in law relating to health insurance coverage and payment may adversely affect our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. clinical diagnostic and biopharmaceutical industries. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and medical devices, including laboratory kits, and promoted a new Medicare Part D coverage gap discount program. Considerable uncertainty remains regarding the implementation and impact of the ACA.

Some of the provisions of the ACA have yet to be fully implemented and certain provisions have been subject to judicial and Congressional challenges. The TCJA includes a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on October 13, 2017, an Executive Order was signed terminating the cost-sharing reduction ("CSR") subsidies that reimburse insurers under the ACA. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Another Executive Order was signed directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. The U.S. District Court for the Northern District of Texas struck down the ACA, deeming it unconstitutional given that Congress repealed the individual mandate in the TCJA. In December 2019, the U.S. Court of Appeals for the Fifth Circuit agreed that the individual mandate is unconstitutional, but remanded to the district court for an analysis of which ACA provisions should be severed from the individual mandate and upheld. It is unclear how this decision, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA. It is also unclear how regulatory provisions and sub-regulatory guidance, both of which fluctuate continually, may affect interpretation and implementation of the ACA and its practical effects on our business.

The ACA has provided health insurance coverage or expanded Medicaid coverage for many Americans that were previously uninsured. Recent efforts to reduce the scope of the ACA, however, appear to have impeded the growth of the insured population. In addition, given the challenges to the ACA at the federal and state levels, the future outlook for insurance coverage remains uncertain. Changes in the number of patients that can look to third-party payment to help afford our products and services may affect the demand for these products and services.

With the current presidential administration and Congress, there may be additional administrative or legislative changes, including reinstatement, modification, repeal or replacement of all, or certain provisions of, the ACA. However, it remains to be seen whether new legislation modifying the ACA will be enacted and, if so, precisely what the new legislation will provide, when it will be enacted and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. The implications, if any, of a potential repeal or replacement of the ACA on our and our collaborators' business and financial condition are not yet clear.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, as amended, reduced funding under certain conditions to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which remain in effect through 2027. In addition, the CMS has promulgated or amended a number of cost containment and value-based reimbursement measures in the ordinary course of business and is expected to continue revising its regulations and policies in response to changes in law, administration policy and market conditions.

Post approval or authorization, the delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines and devices, is almost exclusively a matter of national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products and services. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines and devices. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products and services, this could prevent or delay marketing approval of our and our collaborators' products in development, restrict or regulate post-approval activities, and affect our ability to commercialize any products or services for which we obtain marketing approval.

We expect that additional foreign, state and federal healthcare reform measures or proposals will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products and services or additional pricing pressures. In the event that the pricing structures for healthcare products change materially and limit payments for our products and services, our business will be adversely impacted because our products or services may no longer be commercially viable based on their expected net present value, we may have invested significant resources in products and services that cannot be commercially developed or marketed, or we may determine that products or services that have reached an early phase of development cannot or will not be taken into further development. In addition, products or services that are part of our collaborations may no longer be deemed commercially viable to pursue based on our collaborators' assessments of the impact of any proposed, announced or legislated pricing reforms.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase downward pressure on drug and device pricing. Such reforms could have an adverse effect on anticipated revenues from our products and services, including those that we jointly develop with our collaborators, and may affect our overall financial condition and ability to develop or obtain regulatory clearance, authorization or approval for our products and services.

Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services 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 may rely, which could negatively impact our business.

The ability of the FDA to review and clear, authorize or 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 statutory, regulatory and policy changes. In addition, government funding of 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 new drugs and devices to be reviewed and cleared, authorized or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We must maintain compliance with FDA requirements for our products and services and failure to maintain compliance with FDA requirements may prevent or delay the marketing of our products and services.

Even after we have obtained marketing authorization, as we have for clonoSEQ, we must comply with the scope of that clearance, authorization or approval. Failure to comply with those limitations or the additional, extensive and ongoing post-marketing obligations imposed by the FDA or other regulatory requirements of other regulatory agencies could result in unanticipated compliance expenditures, a range of administrative enforcement actions, injunctions and criminal prosecution. FDA post-market obligations include, among other things, compliance with the FDA QSR, establishing registration and device listings, labeling requirements, reporting of certain adverse events and malfunctions, and reporting of certain recalls. In addition, circumstances may arise that cause us to recall equipment used in connection with our products and services. Such recalls could have an adverse effect on our ability to provide those products and services, which in turn would adversely affect our financial condition. Our collaborators will also be required to maintain FDA clearance, authorization or approval for the products and services that we jointly develop. Any failure by us or our collaborators to maintain such clearance, authorization or approval could impair or cause a delay in our ability to profit from these collaborations.

Products and services offered RUO may be subject to regulatory scrutiny.

Certain of our products are currently labeled and sold for RUO and not for the diagnosis or treatment of disease. Because such products are not intended for diagnostic use, and the products do not include clinical or diagnostic claims or provide directions for use as diagnostic products, they are not subject to the same level of regulation by the FDA as medical devices. In particular, while the FDA regulations require that RUO products be appropriately labeled, "For Research Use Only," the regulations do not subject such products to the FDA's pre- and post-market controls for medical devices. Pursuant to FDA guidance on RUO products, a company may not make clinical or diagnostic claims about an RUO product or provide clinical directions or clinical support services to customers of RUO products. A product labeled RUO but deemed by the FDA to be intended for clinical diagnostic use may be viewed by the FDA as adulterated and misbranded under the FDCA and subject to FDA enforcement action. The FDA considers the totality of the circumstances surrounding distribution and use of a product labeled as RUO, including how the product is marketed and to whom, when determining its intended use. If the FDA were to disagree with our RUO classification or modify its approach to regulating products labeled for RUO, we could experience reduced revenue or increased compliance and other costs, which could adversely affect our business, prospects, results of operations and financial condition. In the event that the FDA requires marketing authorization of our RUO products in the future, the FDA may not ultimately grant any clearance, authorization or approval requested by us in a timely manner, or at all.

Future changes in FDA enforcement discretion for LDTs could subject our operations to much more significant regulatory requirements.

In addition to offering the FDA *de novo* marketing authorized version of clonoSEQ as a test for MRD in certain blood cancers, we also currently offer an LDT version of this test and other NGS-based LDTs for MRD ("NGS-based MRD"). The FDA has a policy of enforcement discretion with respect to LDTs whereby the FDA does not actively enforce its medical device regulatory requirements for such tests. However, in October 2014, the FDA issued two draft guidance documents stating that the FDA intended to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. Although the FDA halted finalization of the guidance in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give Congressional authorizing committees the opportunity to develop a legislative solution, it is unclear if Congress or the FDA will modify the current approach to the regulation of LDTs in a way that would subject our current or future services marketed as LDTs to the enforcement of FDA regulatory requirements. The FDA Commissioner and the Director of the Center for Devices and Radiological Health ("CDRH") have expressed significant concerns regarding disparities between some LDTs and *in vitro* diagnostics that have been reviewed, cleared, authorized or approved by the FDA. If the FDA were to determine that NGS-based MRD tests offered as LDTs are not within the policy for LDTs for any reason, including new rules, policies or guidance, or due to changes in statute, our tests may become subject to extensive FDA requirements or our business may otherwise be adversely affected. If the FDA were to disagree with our LDT status or modify its approach to regulating LDTs, we could experience reduced revenue or increased costs, which could adversely affect our business, prospects, results of operations and financial condition. If required, the regulatory marketing authorization process required to bring our current or future LDTs into compliance may involve, among other things, successfully completing additional clinical validations and submitting to and obtaining clearance from the FDA for a premarket clearance (510(k)) submission or authorization for a *de novo* or approval of a PMA. Furthermore, pending legislative proposals, if passed, such as the VALID Act, could create new or different regulatory and compliance burdens on us and could have a negative effect on our ability to keep products on the market or develop new products, which could have a material effect on our business. In the event that the FDA requires marketing authorization of our LDTs in the future, the FDA may not ultimately grant any clearance, authorization or approval requested by us in a timely manner, or at all. In addition, if the FDA inspects our laboratory in relation to the marketing of our FDA-authorized clonoSEQ test, any enforcement action the FDA takes might not be limited to the FDA-authorized clonoSEQ test and could encompass our NGS-based MRD testing service.

For each product and service we are developing that requires FDA premarket review prior to marketing, the FDA may not grant clearance, authorization or premarket approval and failure to obtain necessary approvals for our future products and services would adversely affect our ability to grow our business.

Before we begin to manufacture, label and market additional clinical diagnostic products for commercial diagnostic use in the United States, we may be required to obtain either clearance, marketing authorization or approval from the FDA, unless an exemption applies or the FDA exercises its enforcement discretion and refrains from enforcing its requirements. For example, the FDA currently has a policy of refraining from enforcing its medical device requirements with respect to LDTs, which the FDA considers to be a type of *in vitro* diagnostic test that is designed, manufactured and used within a single properly licensed laboratory.

The process of obtaining PMA is much more rigorous, costly, lengthy and uncertain than the 510(k) clearance process. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. Conversely, in the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a legally marketed "predicate" device in order for the product to be cleared for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics or if it has different technological characteristics as the predicate device, the proposed device must be as safe and effective as, and not raise different questions of safety or effectiveness than, the predicate device. Clinical data is sometimes required to support substantial equivalence. For lower-risk devices that would otherwise automatically be placed into Class III, which require a PMA because no predicate device is available and the devices do not fall within an existing 510(k)-exempt classification, an applicant may submit a *de novo* request to down classify the device into Class II or Class I, which would not require a PMA. In the *de novo* process, the FDA must determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness of a device, which is low to moderate risk and has no predicate. In other words, the applicant must justify the "down-classification" to Class I or II for a new product type that would otherwise automatically be placed into Class III, but is lower risk. Clinical data may be required. For laboratory tests for which FDA clearance, authorization or approval is required, the FDA may also require data to support analytical and clinical validity.

The 510(k), *de novo* and PMA processes can be expensive and lengthy and require the payment of significant fees, unless an exemption applies. The FDA's 510(k) clearance pathway usually takes from three to nine months from submission, but it can take longer for a novel type of product. The FDA's *de novo* classification pathway usually takes from six to 12 months, but for many applicants can take up to 18 months or more.

The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory clearances, authorizations or approvals would have a material adverse effect on our business, financial condition and prospects.

The FDA can delay, limit or deny clearance, authorization or approval of a device for many reasons, including:

- the inability to demonstrate to the satisfaction of the FDA that the products are safe or effective for their intended uses;
- the disagreement of the FDA with the design, conduct or implementation of the clinical trials or the analysis or interpretation of data from preclinical studies, analytical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in clinical trials;
- the data from preclinical studies, analytical studies and clinical trials may be insufficient to support clearance, authorization or approval, where required;
- the inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- an advisory committee, if convened by the FDA, may recommend against approval of a PMA or other application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee makes a favorable recommendation, the FDA may still not approve the product;
- the FDA may identify deficiencies in our marketing application;
- the FDA may identify deficiencies in our or our collaborators' manufacturing processes, facilities or analytical methods;
- the potential for policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering clinical data or regulatory filings insufficient for clearance, authorization or approval; and
- the FDA or foreign regulatory authorities may audit clinical trial data and conclude that the data is not sufficiently reliable to support a PMA.

There are numerous FDA personnel assigned to review different aspects of marketing submissions, which can present uncertainties based on their ability to exercise judgment and discretion during the review process. During the course of review, the FDA may request or require additional data and information, and the development and provision of these data and information may be time-consuming and expensive. The process of obtaining regulatory clearances, authorizations or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances, authorizations or approvals on a timely basis, or at all for our products in development. If we are unable to obtain clearance, authorization or approval for any products for which we plan to seek clearance, authorization or approval, our business may be harmed.

Modifications to our products with FDA marketing authorization may require new FDA clearances, authorizations or approvals, or may require us to cease marketing or recall the modified clinical diagnostic products or future clinical products until clearances are obtained.

Any modification to a 510(k)-cleared device that significantly affects its safety or effectiveness, or that constitutes a major change in its intended use, could require a new 510(k) clearance, a new *de novo* authorization or approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances, authorizations or approvals are necessary.

For any product approved pursuant to a PMA, we would be required to seek supplemental approval for many types of modifications to the approved product. The FDA requires manufacturers in the first instance to determine whether a PMA supplement or other regulatory filing is needed or whether the change may be reported via the PMA Annual Report, but may disagree with a company's assessment.

If the FDA disagrees with our determination, which it may not review until we submit an annual report or the FDA conducts an inspection or other inquiry, and requires us to seek new clearances, authorizations or approvals for modifications to our previously cleared, authorized or approved clinical diagnostic products for which we have concluded new clearances, authorizations or approvals are unnecessary, we may be required to cease marketing or distribution of these clinical diagnostic products or to recall the modified products until we obtain clearance, authorization or approval. We may also be subject to enforcement action, including, among other things, significant regulatory fines or penalties.

Our employees, principal investigators, consultants and collaborators may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, consultants and those of our collaborators. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent improper marketing, fraud, misconduct, kickbacks, bribery, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct. In addition, our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such investigations or actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, which could have a significant impact on our business. We currently have a compliance program in accordance with the elements of an effective program outlined by the OIG, which could help mitigate damages, but cannot prevent all misconduct. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, suffer adverse publicity and reputational harm, and have the attention of management diverted in defending ourselves against any of these claims or investigations.

If third-party payors, including private payors and government healthcare programs, do not provide coverage of, or adequate reimbursement for, our clinical diagnostic products, our commercial success will be negatively affected.

Our revenue depends in part on achieving broad coverage and reimbursement for our diagnostic tests from payors, including both private and government payors. Certain large private payors have issued policies that decline to cover testing methods that they regard as experimental or investigational. Other payors may issue similar non-coverage policies. If payors do not provide coverage of, or do not provide adequate reimbursement for, a substantial portion of the price of our diagnostic tests, we may need to seek payment from the patient where this is not precluded by law or contract, which may adversely affect demand for our tests. Coverage determinations by a payor may depend on a number of factors, including, but not limited to, a payor's determination that a certain diagnostic test is appropriate, medically necessary or cost-effective. If we are unable to provide payors with sufficient evidence of the clinical utility and validity of our diagnostic tests, they may not provide coverage, or may provide limited coverage, which will adversely affect our revenues and our ability to succeed. To the extent that more competitors enter our markets, the availability of coverage and the reimbursement rate for our tests and new diagnostic products may decrease as we encounter pricing pressure from our competitors.

Each payor makes its own decision regarding coverage of our tests and the applicable payment rates, and payors may not provide adequate coverage or reimbursement for our current or future products. Although we may contract with certain payors, working with payors through contract or otherwise to assure reimbursement is time-consuming and costly and outcomes are uncertain. In addition, the determinations by a payor whether to cover our clinical diagnostic product and the amount it will reimburse for them are often made on an indication-by-indication basis. In cases where there is no coverage policy or we do not have a contracted rate for reimbursement as a participating provider, the patient is typically responsible for a greater share of the cost of the test, which may result in further delay of our revenue, increase our collection costs or decrease the likelihood of collection. Through our Adaptive Assist patient support program, we provide clonoSEQ diagnostic tests for reduced rates or without charge to qualified low-income patients that may result in payors requiring us to provide evidence of eligibility of such patients to pay reduced out-of-pocket amounts.

Our claims for reimbursement from payors may be denied upon submission, and we may need to take additional steps to receive payment, such as appealing the denials. Such appeals and other processes are time-consuming, expensive and may not result in payment. Payors may perform audits of historically paid claims and attempt to recoup funds years after the funds were initially distributed if the payors believe the funds were paid in error or determine that our clonoSEQ diagnostic tests or other clinical diagnostic products were medically unnecessary. In addition, similar to federal payors, state and federal laws permit commercial payors to seek civil and criminal penalties against a manufacturer if they feel they have been defrauded. If a payor audits our claims and issues a negative audit finding, and we are not able to overturn the audit findings through appeal, the recoupment may result in a material adverse effect on our revenue. Additionally, in some cases commercial payors for whom we are not a participating provider may elect at any time to review claims previously paid and determine the amount they paid was too much. In these situations, the payor will typically notify us of their decision and then offset whatever amount they determine they overpaid against amounts they owe us on current claims. We do not have a mechanism to dispute these retroactive adjustments and we cannot predict when, or how often, a payor might engage in these reviews.

Future Medicare payment rates are uncertain.

In March 2018, CMS issued a National Coverage Determination ("NCD") for molecular diagnostic laboratory testing services utilizing a NGS methodology, which includes our clinical diagnostic products, for Medicare beneficiaries with advanced cancer. In the NCD, CMS states that such tests are covered nationally when: (1) performed in a CLIA-certified laboratory; (2) ordered by a treating physician; (3) the patient meets certain clinical and treatment criteria; (4) the test is approved or cleared by the FDA as a companion *in vitro* diagnostic for an FDA-approved or cleared indication for use in that patient's cancer; and (5) results are provided to the treating physician for management of the patient using a report template to specify treatment options. The NCD also states that each Medicare Administrative Contractor ("MAC") may determine coverage of other NGS tests in its jurisdiction for patients with advanced cancer when the test is performed by a CLIA-certified laboratory, ordered by a treating physician and the patient meets the same clinical and treatment criteria required of nationally covered NGS tests under the NCD.

In January 2019, Noridian Healthcare Solutions ("Noridian"), the MAC that processes our laboratory's Medicare Part B claims, issued written guidance based on the MAC authority to cover NGS tests not explicitly covered under the NCD that provides coverage for our FDA-authorized clonoSEQ test for assessment of MRD in patients with ALL or MM. Because all clonoSEQ tests are performed within Noridian's jurisdiction, this policy applies to all of our testing billed under Medicare Part B. At the same time, three other MACs issued the same guidance.

Noridian's guidance (A56270, clonoSEQ Assay for Assessment of MRD in Patients with Specific Lymphoid Malignancies) provides for payment for a single episode of testing and considers testing for MRD with clonoSEQ to constitute a series of assays to be billed at the start of each episode of testing. Medicare's Part B payment rate for clonoSEQ, because the test is billed with a "miscellaneous" code, is determined by the MAC. Noridian has agreed to pay our claims for clonoSEQ at an adequate rate, which will be reviewed annually. This guidance may not persist in its current form and it may not be followed by other MACs or Medicare Advantage ("MA") plans. And because MA plans are not required to reimburse lab tests at the Medicare Part B rate to in-network labs, if we become in-network for a given MA plan, our reimbursement may be lower than what we previously received from Noridian. It is possible that Noridian will further limit or even withdraw coverage or reduce its reimbursement amount, which will negatively affect our revenue. It is also possible CMS will revise or clarify the NCD in a way that will further limit or withdraw coverage for clonoSEQ. Further, if in the future we were to develop kits for sale to other laboratories, Part B coverage of those tests would be governed by the coverage policies of the MACs where these laboratories are located, which may be different from Noridian's policy or may not cover clonoSEQ at all. Noridian's policy has been adopted by three other MACs participating in the MolDx program, but it may not necessarily be followed by other MACs. Finally, if clinicians increase the frequency of testing for their Medicare-covered patients and our rate for a single episode of testing is not correspondingly increased, our costs would increase without a corresponding increase in revenue, and our financial results would be negatively impacted.

Under Medicare Part B, payment for most diagnostic laboratory tests is made under the Clinical Laboratory Fee Schedule ("CLFS"), which assigns payment amounts to tests based on billing codes. Under the Protecting Access to Medicare Act of 2014 ("PAMA"), certain laboratories that receive the majority of their Medicare revenue from payments made under the CLFS or Medicare's Physician Fee Schedule are required to report to CMS every three years, or annually for "advanced diagnostic laboratory tests," commercial payor payment rates and volumes for tests they perform and that are assigned specific billing codes. PAMA has special provisions relating to "advanced diagnostic laboratory tests," as defined by the statute, and these provisions affect the rate-setting at the time of launch and the periodicity of rate reporting and revision. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. Currently, the only test we offer commercially, our clonoSEQ diagnostic test, is coded with a "miscellaneous" code, and under CMS' guidance laboratories do not report rates and volumes for such tests. If, in the future, clonoSEQ or any of our tests are assigned a specific code we would be required to report commercial payor payment data on those tests. Payments for tests billed under miscellaneous codes are determined by the MACs, which also have discretion to change those payment rates.

CMS uses the data reported by laboratories to calculate a payment rate for each CLFS test, other than those coded with miscellaneous codes and certain others, based on the volume-weighted median of the private payor rates. These rates apply for three years, except that payment rates for advanced diagnostic laboratory tests apply for one year. This rate-setting apparatus is not currently applicable to clonoSEQ because clonoSEQ is coded with a miscellaneous code. If, in the future, clonoSEQ is assigned a specific code or if we offer other tests with specific codes, this apparatus would apply. Under these circumstances, Medicare's payment rates would be determined by the rates we and other laboratories, if any, with tests that share the specific codes we use, obtain from commercial payors. In that case, if we are unable to obtain and maintain adequate reimbursement rates from commercial payors, this may adversely affect our Medicare rates. If Noridian reduces our payment rate or MA plans pay us less than Noridian, this would adversely affect our financial condition, results of operations, cash flow and revenue. In addition, CMS is considering changes to its NCD for molecular diagnostic laboratory testing services using a NGS methodology. Any changes made by CMS to the NCD could affect our Medicare rates and those of other laboratory testing services covered by the NCD.

In some circumstances, our tests may be furnished to hospital inpatients and paid by Medicare under different rules. For example, when a specimen is obtained from a patient who is at the time classified by Medicare as a hospital inpatient, Medicare would not make a separate payment for the test and we would have to look to the hospital for payment. We do not know how often this will occur or whether hospitals will resist paying us for our tests. In this situation, Medicare coverage would be determined by the MAC for the jurisdiction where the hospital is located, which may not cover our tests.

Our RUO, clinical diagnostic and therapeutic products or services, and those jointly developed with our collaborators, may in the future be subject to product or service recalls. A recall of products or services, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our or our collaborators' products or services, could have a significant adverse impact on us.

The FDA has the authority to require the recall of commercialized products or services that are subject to FDA regulation. Manufacturers may, under their own initiative, recall a product or service if any deficiency is found. The FDA requires that certain corrections and removals, including recalls intended to reduce a health risk, be reported to the FDA within ten working days of initiating such correction or removal. For reportable corrections and removals, companies are required to make additional periodic submissions to the FDA after initiating the recall, and often engage with the FDA on their recall strategy prior to initiating the recall. A government-mandated or voluntary recall by us, one of our distributors or our collaborators could occur as a result of an unacceptable health risk, component failures, failures in laboratory processes, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our commercialized products or services or those jointly developed with our collaborators would divert managerial and financial resources and adversely affect our reputation, results of operations and financial condition. We may also be subject to liability claims, be required to bear other costs or take other actions that may negatively impact our future sales and our ability to generate profits. Companies are also required to maintain certain records of corrections and removals, even if these do not require reporting to the FDA. We or our collaborators may initiate voluntary recalls involving our commercialized products or services in the future that we determine do not require FDA notification. If the FDA disagrees with our determinations, they may require us to report those actions as recalls. A future recall announcement by us or our collaborators could harm our reputation with customers and negatively affect our results of operations and financial condition. In addition, the FDA or other agency could take enforcement action for failing to report the recalls when they were conducted.

If we or our collaborators initiate a recall, including a correction or removal, for one of our commercialized products or services, issue a safety alert, or undertake a field action or recall to reduce a health risk, this could lead to increased scrutiny by the FDA, other governmental and regulatory enforcement bodies, and our or our collaborators' customers regarding the quality and safety of our products and services, and to negative publicity, including FDA alerts, press releases, or administrative or judicial actions. Furthermore, the submission of these reports could be used against us by competitors and cause customers to delay purchase decisions or cancel orders, which would harm our reputation.

Any additional commercialized products and services or any future products and services that obtain regulatory clearance, authorization, approval, accreditation or licensure will remain subject to regulatory scrutiny and our failure to maintain our regulatory clearances, authorizations, approvals, accreditations or licensures could adversely affect our reputation, business and results of operations.

Even if we or our collaborators obtain regulatory clearance, authorization, approval, accreditation or licensure in a jurisdiction for our products and services, the applicable regulatory authority may still impose significant restrictions on the indicated uses or marketing of our products and services, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance of our or our collaborators' manufacturing and distribution. Advertising for certain devices and labeling, including promotional labeling, for all devices must comply with FDA requirements. In addition, device advertising and promotion may also be subject to other federal and state laws. For example, the FDA shares jurisdiction over the regulation of device advertising with the FTC. Advertising for devices characterized as restricted by the FDA is subject to specified FDA requirements, while advertising for non-restricted devices is regulated by the FTC.

If we or our collaborators fail to comply with applicable regulatory requirements following clearance, authorization, approval, accreditation or licensure of any of our products and services, a regulatory agency may:

- initiate an inspection of our or our collaborators' facilities;
- issue an untitled or warning letter asserting that we or our collaborators are in violation of law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory clearance, authorization or approval, or revoke a license or accreditation;
- suspend any ongoing clinical studies;
- delay or refuse clearance, authorization or approval of a pending regulatory submission or supplement submitted by us or our collaborators;
- impose restrictions on our or our collaborators' cleared, authorized, approved, accredited or licensed products or services;
- seize or recall the product or service;
- partially suspend or entirely shut down our or our collaborators' manufacturing or laboratory operations;
- issue advisories or other field actions;
- impose operating restrictions;
- refuse to allow us or our collaborators to enter into supply contracts, including government contracts; or
- refer matters to the DOJ or other enforcement or regulatory bodies.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our and our collaborators' ability to commercialize any cleared, authorized or approved products and services and generate revenues.

If any of our diagnostic products or services cause or contribute to a death or serious injury, or malfunction in certain ways, we will be required to report such death, serious injury or malfunction under applicable medical device reporting regulations, and such events can result in voluntary corrective actions or agency enforcement actions.

Under FDA MDR regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or one of our similar devices were to recur. If such a death, serious injury or malfunction were to occur, and we or our collaborators are unable to demonstrate that the adverse events were caused by factors other than our or our collaborator's products and services, regulatory authorities could order us to cease further development of, or deny clearance, authorization or approval of, any of our or our collaborators' products and services for any or all targeted indications. Even if we and our collaborators are able to demonstrate that any serious adverse events are not related to our products and services, such occurrences could affect patient recruitment or the ability of enrolled trial participants to complete the trial. Moreover, if we or our collaborators elect, or are required, to delay, suspend or terminate any clinical trial of any product in development, the commercial prospects of such product in development may be harmed and our ability to generate product revenues may be delayed or eliminated. Any of these occurrences may harm our and our collaborators' ability to identify and develop future products and services, and may significantly harm our business, financial condition, result of operations and prospects.

We are subject to various laws and regulations, such as healthcare fraud and abuse laws, false claim laws and health information privacy and security laws, among others, and failure to comply with these laws and regulations may have an adverse effect on our business.

Healthcare providers, physicians, hospitals and third-party payors often play a primary role in the recommendation and prescription of any currently marketed products and services for which we may obtain clearance, authorization or approval. Our current and future arrangements with healthcare providers, physicians, hospitals and third-party payors, and our sales, marketing and educational activities related to our products and services, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations at the federal and state level that may constrain our business or financial arrangements, and the relationships through which we market, sell and distribute our products and services. In addition, our operations are also subject to various federal and state fraud and abuse, physician payment transparency, and privacy and security laws, including, without limitation:

- The AKS, which prohibits, among other things, persons and entities, including clinical laboratories, from knowingly and willfully soliciting, receiving, offering or paying remuneration, whether directly or indirectly, overtly or covertly, in case or in kind, to induce or reward or in return for either the referral of an individual or the purchase, lease, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program such as Medicare or Medicaid. The AKS has been interpreted broadly to apply to, among other things, arrangements between clinical laboratories and prescribers and purchasers of our tests. The term "remuneration" expressly includes kickbacks, bribes or rebates and has been broadly interpreted to include anything of value, including gifts, discounts, waivers of payment, ownership interests and any goods or services provided at less than their fair market value. We are also subject to the Beneficiary Inducement Statute set forth in the civil monetary penalty provisions of the AKS. There are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, however, these exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. The failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct *per se* illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of the facts and circumstances to determine whether one purpose of the remuneration in the arrangement was to induce referrals or generate business that is payable by a federal healthcare program. A violation of the AKS may be grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the False Claims Act. Moreover, certain AKS safe harbors currently protecting rebates paid by device manufacturers to third parties and other arrangements between device manufacturers and third parties may later be modified or repealed pursuant to a pending regulatory proposal, which could require us to revisit or modify our business practices. Our practices may not meet all of the criteria for safe harbor protection from AKS liability in all cases. A person or entity does not need to have actual knowledge of the AKS or specific intent to violate any AKS provisions to have committed a violation.
- Section 8122 of the SUPPORT Act, EKRA, which establishes an all-payor anti-kickback prohibition that extends to arrangements with recovery homes, clinical laboratories and clinical treatment facilities. EKRA includes a number of statutory exceptions, and directs agencies to develop further exceptions. Current EKRA exceptions in some cases reference, and in others differ from, the AKS safe harbors. Significantly, the EKRA prohibitions apply to the soliciting or receipt of remuneration for any referrals to recovery homes, clinical treatment facilities or clinical laboratories, whether or not related to the treatment of substance use disorders. Further, the EKRA prohibitions cover the payment or offer of remuneration to induce a referral to, or in exchange for, an individual using the services of such providers. EKRA creates additional risk that relationships with referral sources could be problematic.
- Federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to, or approval by, the federal government that are false, fictitious or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery. In addition, AKS violations implicate the False Claims Act. Conduct that results in a False Claims Act violation may also implicate various federal criminal statutes.

- HIPAA, which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the AKS, a person or entity does not need to have actual knowledge of HIPAA or specific intent to violate any HIPAA provisions to have committed a violation.
- The Stark Law, which is directed at "self-referral," prohibits, with certain exceptions, referrals for certain DHS, including laboratory services, that are covered by Medicare and Medicaid by physicians who personally, or through a family member, have an investment or ownership interest in, or a compensation arrangement with, an entity performing the tests. The prohibition also extends to payment for any testing referred in violation of the Stark Law. Because the Stark Law is a strict liability statute, proof of specific intent to violate the law is not a required element of a violation. Any person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to $100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to Medicare or Medicaid in violation of the Stark Law is subject to civil monetary penalties of up to $15,000 per bill submission, an assessment of up to three times the amount claimed and possible exclusion from participation in federal governmental payor programs, and those claims are considered false claims for which the parties to the arrangement may be liable under the False Claims Act. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states have comparable laws that are not limited to Medicare and Medicaid referrals. The Stark Law also places an annual cap, currently at $423 for 2020, on the amount of non-monetary compensation, which consists of meal spend and educational items, that a company can spend on a physician in the aggregate. This annual cap requires careful tracking and coordination and if it is exceeded, as long as the amount exceeded is less than 50% of the total annual cap and is recouped from the physician within 180 calendar days or before the end of the calendar year, it is not a violation. This "return" option may only be used once every three years with respect to the same referring physician. We occasionally enter into financial relationships, usually compensation relationships, such as a consulting arrangement, with physicians who refer patients for testing. If these arrangements do not meet the Stark Law's requirements, any claims submitted to Medicare or Medicaid could violate the law and put both the physician referral source and us at risk.
- The administrative simplification provisions of HIPAA, as amended and supplemented by HITECH, impose, among other things, obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information ("PHI") held by certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, and their respective business associates. Among other things, HITECH made certain aspects of HIPAA's rules, notably the "HIPAA Security Rule," directly applicable to business associates, independent contractors or agents of covered entities that create, receive, maintain or transmit PHI in connection with providing a function on behalf of, or a service to, a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA regulation and seek attorneys' fees and costs associated with pursuing federal civil actions. The HHS Office for Civil Rights ("OCR") has increased its focus on compliance and continues to train state attorneys general for enforcement purposes. The OCR has recently increased both its efforts to audit HIPAA compliance and its level of enforcement, with one recent penalty exceeding $16 million.
- GINA, which restricts employers and health insurance companies from requiring or using the results of genetic tests in specific contexts and does not provide a private right of action. A number of states have also adopted laws regarding genetic tests, some aligned with GINA and some with broader applicability, including granting broader rights to individuals.
- The Physician Payments Sunshine Act created under the ACA, and its implementing regulations, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, with certain exceptions, to annually report to HHS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The Physician Payments Sunshine Act has been extended to payments and transfers of value to physician assistants, nurse practitioners and other mid-level healthcare providers, with reporting requirements going into effect in 2022 for payments and transfers of value made to these practitioners in 2021. In addition, certain state and local laws may impose additional transparency and healthcare compliance requirements on medical device manufacturers, as well as certain restrictions or limits on interactions with healthcare professionals.

- The FTCA, which the FTC interprets to require taking appropriate steps to secure consumers' personal information and considers the failures to do so to constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTCA. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards, and the FTC's guidance for appropriately securing consumers' personal information is consistent with what is required by the HIPAA Security Rule. Some states, most notably Massachusetts and Nevada, also have adopted laws requiring the implementation of security measures to protect personal information, and all 50 states and the District of Columbia, Puerto Rico and Guam, have adopted breach notification laws.
- Analogous state laws and regulations, such as state anti-kickback, self-referral and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and in some cases even in self-pay scenarios. In addition, some state laws require life sciences companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to impose transparency requirements or restrictions on marketing activities.
- Various state, federal and foreign laws and regulations govern our ability to communicate, prospect, advertise and market our products and services through email, phone, text messages, facsimile and online methods.

Because of the breadth of these laws and the narrowness of the exceptions and safe harbors available under them, it is possible that certain of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of the ongoing interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that business arrangements with third parties comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert management's attention from our business.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in government healthcare programs, injunctions, private *qui tam* actions brought by individual whistleblowers in the name of the government and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our results of operations.

Our collection, use and disclosure of personal information, including health and employee information, is subject to state, federal and foreign privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm.

The privacy and security of personal information stored, maintained, received or transmitted, including electronically, is a major issue in the United States and abroad. While we strive to comply with all applicable privacy and security laws and regulations, including, in our case, our own posted privacy policies, legal standards for privacy, including but not limited to ''unfairness'' and ''deception,'' as enforced by the FTC and state attorneys general, these laws and regulations continue to evolve and any failure or perceived failure to comply may result in proceedings or actions against us by government entities or others, or could cause us to lose customers, which could have a material adverse effect on our business. Recently, there has been an increase in public awareness of privacy issues in the wake of revelations about the data-collection activities of various government agencies and in the number of private privacy-related lawsuits filed against companies (including a new private right of action under the CCPA as described below). Concerns about our practices with regard to the collection, use, retention, disclosure or security of personal information or other privacy-related matters, even if unfounded and even if we are in compliance with applicable laws, could damage our reputation and harm our business. Additionally, we receive personal information, including PHI from third parties, and if such third parties breach their representations to us regarding their compliance with applicable privacy and security laws, we could be exposed to proceedings or actions by government agencies or others.

Numerous foreign, federal and state laws and regulations govern the collection, dissemination, use and confidentiality of personal information, including genetic, biometric and health information, including state privacy, data security and breach notification laws, federal and state consumer protection and employment laws, HIPAA, GINA, the GDPR and other foreign data protection laws. These laws and regulations are increasing in complexity and number, may change frequently and sometimes conflict.

The HIPAA privacy, security and breach notification regulations, including the expanded requirements under HITECH, establish comprehensive federal standards with respect to the uses and disclosures of PHI by health plans, healthcare providers, including laboratories, and healthcare clearinghouses, in addition to setting standards to protect the confidentiality, integrity and security of PHI. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient;
- a patient's rights to access, amend and receive an accounting of certain disclosures of PHI;
- requirements to notify individuals if there is a breach of their unsecured PHI;
- the contents of notices that must be provided to patients regarding our privacy practices for PHI;
- administrative, technical and physical safeguards required of entities that use or receive PHI; and
- the safeguarding of PHI.

Penalties for violations of these laws vary. For instance, penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include civil monetary penalties of up to $58,490 per violation, which cap has been increased to account for inflation, not to exceed approximately $1.75 million per calendar year, for each provision of HIPAA that is violated and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and imprisonment. However, a single breach can result in findings of violations of multiple provisions, leading to possible penalties in excess of $1.75 million for violations in a calendar year. Any person who knowingly obtains or discloses PHI in violation of HIPAA may face a criminal penalty of up to $50,000 and up to one year of imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. In addition, responding to government investigations regarding alleged violations of these and other laws and regulations, even if they ultimately result in no findings of violations or no penalties imposed, can consume our resources and impact our business and, if public, harm our reputation.

Computer networks are vulnerable to breach and unauthorized persons may in the future be able to exploit weaknesses in the security systems of our computer networks and gain access to PHI. Additionally, we share PHI with third-party contractors, and while they are contractually obligated under business associate agreements to safeguard and maintain the confidentiality of PHI, their indemnification of us would not insulate us from reputational harm. Unauthorized persons may be able to gain access to PHI stored in such third-party contractors' computer networks. Any wrongful use or disclosure of PHI by us or our third-party contractors, including disclosure due to data theft or unauthorized access to our or our third-party contractors' computer networks, could subject us to fines or penalties that could adversely affect our business and results of operations. Although HIPAA and the regulations promulgated thereunder do not provide for a private right of action, we could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personal information. These laws and regulations are not necessarily preempted by HIPAA, but they afford greater protection to individuals than HIPAA. Where state laws are more protective, we and our collaborators must comply with the stricter provisions where they apply. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. The CCPA, which went into effect on January 1, 2020 and will be enforceable by the California Attorney General six months after the publication of the final regulations or July 1, 2020, created new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to access, delete, obtain and opt in or opt out of certain use, sharing or sale of their personal information and to sue for statutory damages for certain security breaches. Although the CCPA includes limited exceptions from its prescriptions, including exceptions for certain information collected as part of clinical trials, as specified in the law, and for PHI collected by covered entities or business associates subject to HIPAA, as specified in the law, the CCPA may regulate or impact our processing of PHI and other personal information depending on the context. It remains unclear how this legislation will be interpreted in regulations. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and our customers and potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy, security and data use issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our immune medicine platform and related products and services could intensify. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as PHI, along with increased customer demand for enhanced data security infrastructure, could greatly increase the cost of providing our products and services, decrease demand for our products and services, reduce our revenue and subject us to additional liabilities.

In addition, the interpretation and application of consumer, health-related and data protection laws, especially with respect to genetic samples and data, in the United States, the EU and elsewhere, are often uncertain, contradictory and in flux. We may eventually operate in a number of countries outside of the United States whose laws may in some cases be more stringent than the requirements in the United States. For example, the EU has specific requirements relating to cross-border transfers of personal data to certain jurisdictions, including to the United States. In addition, some countries have stricter consumer notice or consent requirements relating to personal data collection, use or sharing, have more stringent requirements relating to organizations' privacy programs and provide stronger individual rights. Moreover, international privacy and data security regulations may become more complex and result in greater penalties. For instance, as of May 25, 2018, the GDPR, has replaced the EU Data Protection Directive with respect to the collection and use of personal data of data subjects in the EU and the EEA. The GDPR applies extra-territorially under certain circumstances and imposes stringent requirements on controllers and processors of personal data, including, for example, requirements to obtain consent or other legal bases from individuals to process their personal data, provide robust disclosures to individuals, accommodate a set of individual data rights, provide data security breach notifications within 72 hours after discovering the breach, limit retention of personal information and apply enhanced protections to health data and other special categories of personal data. The GDPR also applies to pseudonymized data, which is defined as "the processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information," and imposes additional obligations when we contract with third-party processors in connection with the processing of any personal data. The GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data, could cause our costs to increase and could harm our financial condition. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20 million or up to 4% of the total worldwide annual turnover of our preceding fiscal year, whichever is higher, and other administrative penalties. Further, as the GDPR has only recently become enforceable, enforcement priorities and official interpretations of certain provisions are still unclear. To comply with the new data protection rules imposed by the GDPR, we may be required to put in place additional mechanisms ensuring compliance, which may result in other substantial expenditures. This may be onerous and adversely affect our business, financial condition, results of operations and the profitability of our platform of products and services. Failure to comply with the GDPR and other countries' privacy or data security-related laws, rules or regulations could result in material penalties imposed by regulators, affect our compliance with contracts entered into with our collaborators and other third-party payors, and have an adverse effect on our business and financial condition. Currently, the GDPR is only applicable to us as a processor, but as we continue to expand into the European market, the GDPR will have direct applicability to us as a controller.

The GDPR also imposes strict rules on the transfer of personal data out of the EU to the United States. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. In addition, these rules are consistently under scrutiny. For example, following a decision of the Court of Justice of the EU in October 2015, the transfer of personal data to U.S. companies that had certified as members of the U.S. Safe Harbor Scheme ("Safe Harbor Scheme") was declared invalid. In July 2016, the European Commission adopted the EU-U.S. Privacy Shield Framework ("Privacy Shield Framework") which replaced the Safe Harbor Scheme. The Privacy Shield Framework is reviewed by European authorities annually, and there is currently litigation challenging other EU mechanisms for adequate data transfers. It is uncertain whether the Privacy Shield Framework or the standard contractual clauses might similarly be invalidated by European courts.

Organizations operating in Canada and covered by the Personal Information Protection and Electronic Documents Act ("PIPEDA"), or equivalent Canadian provincial laws, must obtain an individual's consent when they collect, use or disclose that individual's personal information. Individuals have the right to access and challenge the accuracy of their personal information held by an organization, and personal information may only be used for the purposes for which it was collected. If an organization intends to use personal information for another purpose, it must again obtain that individual's consent.

Because of the breadth of these data protection laws and the narrowness of their exceptions and safe harbors, it is possible that our business or data protection policies could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of heightened regulatory focus on data privacy and security issues. If our operations are found to be in violation of any of the data protection laws described above or any other laws that apply to us, we may be subject to penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in government healthcare programs, injunctions, private *qui tam* actions brought by individual whistleblowers in the name of the government, class action litigation and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corrective action plan or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our results of operations.

Security breaches, loss of data and other disruptions could compromise confidential, personal and 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 and our collaborators collect and store sensitive data, including PHI, personal information, credit card and other financial information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, third-party payors, our collaborators, government entities, insurance companies and other parties. We manage and maintain our applications and data through a combination of on-site systems and cloud-based data centers. We utilize external security and infrastructure vendors to manage components of our data centers. We also transmit sensitive data, including patient data, telephonically, through our website and pursuant to arrangements with multiple third-party vendors and their subcontractors. These applications and data encompass a wide variety of critical business information, including research and development information, patient data, commercial information and financial information. We face a number of risks related to protecting this critical information, including loss-of-access risk, unauthorized access, use, disclosure or modification, and the risk of our inability to adequately monitor, audit and modify our respective control over our critical information. This risk extends to the data we entrust to the third-party vendors and subcontractors that help us manage this sensitive data or otherwise process it on our behalf.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take reasonable measures to protect sensitive and proprietary data from unauthorized access, use or disclosure, no security measures can be perfect and our respective information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, liability under federal or state laws that protect the privacy of personal information, such as HIPAA or HITECH, and regulatory penalties. Notice of breaches may be required to be provided to affected individuals, the Secretary of HHS or other federal, state and foreign regulators, the media or state attorneys general. Such a notice could harm our reputation and ability to compete. Although we have implemented security measures and formal, dedicated enterprise security programs to prevent unauthorized access to patient and other personal data, such data is currently accessible through multiple channels and we may experience one or more data breaches. Unauthorized access, loss or dissemination could also disrupt our operations and damage our reputation, which could adversely affect our results of operations and financial condition.

No TCR-based cellular therapies have been approved in this new potential category of medicines and may never be approved as a result of efforts by others or us. TCR-based cellular therapy drug discovery has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new category of immune-driven medicines.

As a potential new category of medicines, no TCR-based cellular therapies have been approved to date by the FDA or other regulatory agency. Successful discovery and development of TCR-based cellular therapies by us and our collaborators is highly uncertain and depends on numerous factors, many of which are beyond our and their control. We and our collaborators have made and will continue to make a series of business decisions and take calculated risks to advance our development efforts and pipeline of immune-driven therapeutic product candidates, including those related to TCR-based cellular therapies, delivery technology and manufacturing processes, which may be shown to be incorrect based on further work by us, our collaborators or others. Our cellular therapeutics product candidates that appear promising in the early phases of development may fail to advance, experience delays in the clinic, experience clinical holds or fail to reach the market for many reasons, including:

- discovery efforts identifying potential TCR-based cellular therapies may not be successful;
- nonclinical or preclinical study results may show potential TCR-based cellular therapies to be less effective than desired or to have harmful or problematic side effects;
- clinical trials may fail to meet one or more endpoints, or results may show the TCR-based cellular therapies to be less effective than expected or to have unacceptable side effects or toxicities;
- adverse effects relating to any one of our therapeutic product candidates or adverse effects relating to our TruTCR process may lead to delays in or termination of one or more of our products or services;
- the inability of our translational models to reduce risk or predict outcomes in humans, given that each component of our therapeutic product candidates may have a dependent or independent effect on safety, tolerability and efficacy, and that such effects may, among other things, be species-dependent;
- manufacturing failures or insufficient supply of current good manufacturing practices (“cGMP”) materials for future clinical trials, or higher than expected cost, could delay or set back clinical trials or make TCR-based cellular therapies commercially unattractive;
- our collaborators’ improvements in the manufacturing processes for this new class of potential immune-driven medicines may not be sufficient to satisfy the clinical or commercial demand of our jointly developed TCR-based cellular therapies or regulatory requirements for clinical trials;

- changes that we or our collaborators make to optimize manufacturing, testing or formulating of cGMP materials could impact the safety, tolerability and efficacy of our therapeutic products in development;
- pricing or reimbursement issues or other factors that delay clinical trials or make any TCR-based cellular therapies uneconomical or noncompetitive with other immunotherapies;
- failure to timely advance our or our collaborators' therapeutic products or receive the necessary regulatory clearances, authorizations or approvals or a delay in receiving such clearances, authorizations or approvals due to, among other reasons, slow or failure to complete enrollment in clinical trials, withdrawal by trial participants from trials, failure to achieve trial endpoints, additional time requirements for data analysis, data integrity issues, Biologics License Application or the equivalent application, discussions with the FDA or the European Medicines Agency, a regulatory request for additional nonclinical or clinical data, or safety formulation or manufacturing issues may lead to our inability to obtain sufficient funding; and
- the proprietary rights of others and their competing products and services that may prevent our TCR-based cellular therapies from being commercialized or threaten future commercialization activities.

Risks Relating to our Intellectual Property

We may not be successful in obtaining or maintaining sufficient intellectual property protection for our products, services and technologies and uses thereof, and the scope of the intellectual property protection obtained may not be sufficiently broad.

As is the case with other companies engaged in the life sciences industry, our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others, or license from third parties, particularly patents, in the United States and other countries with respect to our products, services and technologies. We rely on patent protection in addition to 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 enable us to gain or maintain any competitive advantage. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us. In addition, we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

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 barriers to competition, our competitive position could be adversely affected, as could our business.

We apply for or in-license patents covering our products and technologies and uses thereof, as we deem appropriate. However, obtaining and enforcing patents is costly, time-consuming and complex, and we may fail to apply for patents on important products, services and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. We may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications or to maintain the rights to patents licensed from third parties. Consequently, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

As of December 31, 2019, we own or have rights to 336 active patents and patent applications filed in the United States, Europe and elsewhere. Of these, there are 104 pending patent applications and 283 granted patents. Our pending patent applications may not result in issued patents in a timely fashion or at all. Even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products or services, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is also possible that others will design around our current or future patented technologies.

Some of our patents, licensed patents or patent applications may be challenged in the future, and we may not be successful in defending any such challenges. For example, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office ("USPTO"), or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights. Any successful third-party challenge to our patents could result in patent claims being narrowed, or patents being invalidated or held unenforceable, in whole or in part, which could lead to increased competition to our business. Conversely, we may have to challenge the patents or patent applications of third parties. The outcome of patent litigation or other proceeding can be uncertain, and any attempt by us to enforce our patent rights against others or to challenge the patent rights of others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products or services. The patent positions of biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Inconsistent policies regarding the eligibility for patent protection and the breadth of patentable claims in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods and compositions of matter useful in relation to immunosequencing.

The patent position of companies engaged in the development and commercialization of clinical diagnostic tests, like our clonoSEQ diagnostic test, are particularly uncertain. Various courts, including the U.S. Supreme Court, have rendered decisions that affect the eligibility and scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related technology. These decisions state, among other things, that a patent claim that recites an abstract idea, natural phenomenon or law of nature (for example, the relationship between particular immune receptors and cancer) may not be patentable. Precisely what constitutes a law of nature is uncertain, and it is possible that certain aspects of our clinical diagnostics would be considered natural laws. The evolving case law in the United States may adversely affect our ability to obtain patents or defend patents we have obtained or have licensed and may facilitate third-party challenges to any owned or licensed patents. The laws of some foreign countries do not protect intellectual property rights to the same extent or for the same subject matter as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. The legal systems of many other 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 in such countries. 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.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products and services in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, 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 obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that 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.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many other 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 in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost 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.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products and services.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries or regions may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In the United States, prior to March 16, 2013, assuming that other requirements for patentability were satisfied, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On or after March 16, 2013, under the Leahy-Smith America Invents Act ("America Invents Act"), enacted in September 16, 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are satisfied, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, a third party that files a patent application in the USPTO before us could be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either file any patent application related to our products or services or invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. 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. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business.

Recent U.S. Supreme Court rulings have also narrowed the scope of patent protection available in certain circumstances and weakened 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 would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Issued patents covering our products and services could be found invalid or unenforceable if challenged.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and some of our patents or patent applications, including licensed patents, may be challenged, in courts or patent offices in the United States and abroad, in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference. Additionally, if we and our licensing partners initiate or become involved in legal proceedings against a third party to enforce a patent covering one of our products or technologies, the defendant could counterclaim that the patent covering our product is invalid or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent eligible subject matter, lack of novelty, obviousness or non-enablement. 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. In addition, the United States now awards patent priority to the first party to file a patent application, and others may submit patent claims covering our inventions prior to us. 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. A successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents, which could have a material adverse impact on our business. Furthermore, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products and services.

We may not be aware of all third-party intellectual property rights potentially relating to our immune medicine platform, products and services. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until approximately 18 months after filing or, in some cases, not until such patent applications issue as patents. We might not have been the first to make the inventions covered by each of our pending patent applications and we 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, derivation proceedings or other post-grant proceedings declared by the USPTO. The outcome of such proceedings is uncertain, and other patent applications may have priority over our patent applications. Such proceedings could also result in substantial costs to us and divert our management's attention and resources.

We rely on licenses from third parties in relation to certain products and services and if we lose these licenses then we may be subjected to future litigation.

We are a party to license agreements that grant us rights to use certain intellectual property, including patents and patent applications, typically in certain specified fields of use. Some of those licensed rights could provide us with freedom to operate for aspects of our products and services. We may need to obtain additional licenses from others to advance our research, development and commercialization activities.

Our success may depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property. Our licensors may not successfully prosecute the patent applications we license. Even if patents issue in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, disputes may also 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 products, services, 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 under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If we do not prevail in such disputes, we may lose any or all of our rights under such license agreements.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize any affected products or services, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Absent the license agreements, we may infringe patents subject to those agreements, and if the license agreements are terminated, we may be subject to litigation by the licensor. Litigation could result in substantial costs to us and distract our management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees, costs and expenses and royalties or be enjoined from selling our products or services, which could adversely affect our ability to offer products or services, our ability to continue operations and our financial condition.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, collaborators, academic institutions, life sciences research partners and, when needed, our advisers as well as other third parties. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. 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. If we are required to assert our rights against such party, it could result in significant cost and distraction. 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, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems. Besides the possibility that these security measures could be breached, such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may also not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

Certain former employees have obtained employment with companies or academic institutions that could be considered competitive with us. This competition may be limited by contractual provisions which may or may not be enforceable by us in certain jurisdictions. In addition, we may not be aware of such competitive employment arrangements until after our trade secrets have been disclosed to potentially competitive companies.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ, and expect to employ in the future, individuals who were previously employed at universities or other companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or other third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. A loss of key research personnel work product could hamper or prevent our ability to commercialize potential products and services, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may not be able to protect and enforce our trademarks.

We have not yet registered certain of our trademarks in all of our potential markets, although we have registered Adaptive Biotechnologies, clonoSEQ, immunoSEQ, pairSEQ and TruTCR in the United States, the EU and a number of other countries and are seeking to register additional trademarks, including ADAPTIVE and immunoSEQ Dx. As we apply to register our unregistered trademarks in the United States and other countries, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. In certain countries outside of the United States, trademark registration is required to enforce trademark rights. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

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

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. Ownership disputes may arise, for example, from conflicting obligations of employees, consultants or others who are involved in developing our future products and services. Our Co-Founder, Dr. Harlan Robins, had dual employment with Fred Hutch and us until June of 2019, and accordingly has had obligations to assign his rights to inventions to either Fred Hutch or us depending on how and where the inventions were conceived, reduced to practice, developed or created. Disputes may arise in the future between Fred Hutch and us regarding ownership of intellectual property generated by Dr. Robins' work. Fred Hutch may claim to have ownership rights to our intellectual property.

Litigation may be necessary to defend against these and other claims by a third party challenging inventorship of our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product or services. Alternatively, we may need to obtain one or more additional licenses from the third party which will be time-consuming and expensive and could result in substantial costs and diversion of resources and could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our development and commercialization efforts of our products and services.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the life sciences, clinical diagnostics and drug discovery industries, including patent infringement lawsuits, declaratory judgment litigation and adversarial proceedings before the USPTO, including interferences, derivation proceedings, *ex parte* reexaminations, post-grant review and *inter partes* review, as well as corresponding proceedings in foreign courts and foreign patent offices.

We are currently involved in appeals from Opposition Proceedings at the European Patent Office related to two of our patents: EP2364368 and EP2387627. We may, in the future, become involved with litigation or actions at the USPTO or foreign patent offices with various third parties. We expect that the number of such claims may increase as our industry expands, more patents are issued, the number of products or services increases and the level of competition in our industry increases. Any infringement claim, regardless of its validity, could harm our business by, among other things, resulting in time-consuming and costly litigation, diverting management's time and attention from the development of our business, requiring the payment of monetary damages (including treble damages, attorneys' fees, costs and expenses) or royalty payments.

It may be necessary for us to pursue litigation or adversarial proceedings before the patent office in order to enforce our patent and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any such litigation might not be favorable to us, and even if we were to prevail, such litigation could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition.

As we move into new markets and expand our products or services offerings, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product or service revenue and against whom our own patents may provide little or no deterrence or protection.

Third parties may assert that we are employing their proprietary technology without authorization. Given that clinical diagnostics and drug discovery fields are intense and highly competitive areas, there may be third-party intellectual property rights that others believe could relate to our immune medicine platform, products and services. We have been approached on four occasions with an offer from a third-party patent owner or licensee to license rights to us under patents relating to immune medicine. We have been contacted by Invivoscribe, Inc. regarding U.S. Pat. No. 7,785,783 on March 24, 2012; by Keygene NV regarding U.S. Pat. No. 9,453,256 on October 10, 2016; by MorphoSys AG regarding EP Patent 2243030 and U.S. Pat. No. 9,404,929 on October 10, 2018; and by DName-iT NV regarding EP Patent 2201143 and U.S. Pat. No. 8,318,434 in December 2018. In each instance, we have declined to pursue licenses to the patents. One or more of these or other third-party patent owners or licensees may pursue or threaten to pursue litigation against us to enforce one or more patents. It would be costly and time-consuming to defend such claims.

Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our current or future products, technologies and services may infringe. We cannot be certain that we have identified or addressed all potentially significant third-party patents in advance of an infringement claim being made against us. In addition, similar to what other companies in our industry have experienced, we expect our competitors and others may have patents or may in the future obtain patents and claim that making, having made, using, selling, offering to sell or importing our products or services infringes these patents. Defense of infringement and other claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products or services and could result in the award of substantial damages against us, including treble damages, attorneys' fees, costs and expenses if we are found to have willfully infringed. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties and obtain one or more licenses from third parties, or be prohibited from selling certain products or services. We may not be able to obtain these licenses on acceptable or commercially reasonable terms, if at all, or these licenses may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we could encounter delays in product or service introductions while we attempt to develop alternative products or services to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing products or services, and the prohibition of sale of any of our products or services could materially affect our business and our ability to gain market acceptance for our products or services.

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. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, our agreements with some of our customers, suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results or financial condition.

Patent terms may be inadequate to protect our competitive position on our products and services for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products and services are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new products and services, patents protecting such products and services might expire before or shortly after such products and services are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Risks Relating to our Common Stock

The market price of our common stock is volatile and is likely to continue to fluctuate substantially.

We are a new public company and the market price of our common stock has been and is likely to continue to be highly volatile and may fluctuate substantially due to many factors, many of which are beyond our control. These factors include:

- the commencement or termination of our collaborations;
- the timing of achievement of specified milestones in the development of our products and services;
- introductions of new or expanded products or services or new pricing policies by us or by our competitors;
- changes in the status of our regulatory clearances, authorizations, approvals or applications, or those jointly developed with our collaborators;
- where required, the results of clinical trials of our future products and services, those jointly developed with our collaborators or those of our competitors;
- the success of competitive products or technologies;
- announcements by us or our competitors of significant acquisitions, collaborators or divestitures;

- changes in governmental regulations and regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the life sciences, clinical diagnostics or drug discovery industry;
- general economic, industry and market conditions;
- sales of our securities, including sales by our directors, officers or significant shareholders;
- speculation about our business in the media or the investment community; and
- other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. If the market for stock in our industry or the stock market in general experiences uneven investor confidence, the market price of our common stock could decline for reasons unrelated to our business, operating results or financial condition. The market price of our common stock might also decline in reaction to events that affect other companies within, or outside, our industry even if these events do not directly affect us.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in their stock price. This type of litigation, if instituted against us, could result in substantial costs to us and divert our management's attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

If securities analysts do not publish research or reports about our business, or we are the subject of negative publicity, the price of our stock could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not control these analysts. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable evaluations of our company or our stock, the price of our stock could decline. If one or more of these analysts cease coverage of our company or fail to publish reports covering our company regularly, our stock may lose visibility in the market, which in turn could cause our stock price to decline. In addition, if we are the subject of negative publicity, whether from an analyst, academic, industry group or the general or financial press, our stock price may decline.

We are an emerging growth company, and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act"), (2) having the option of delaying the adoption of certain new or revised financial accounting standards, (3) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (4) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We have taken, and in the future may take, advantage of these exemptions until such time that we are no longer an emerging growth company. Accordingly, the information contained herein and in other reports we file with the SEC may be different than the information you receive from other public companies in which you hold stock. Further, we have elected to take advantage of the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. As a result, our operating results and financial statements may not be comparable to the operating results and financial statements of other companies who have adopted the new or revised accounting standards. It is possible that some investors will find our common stock less attractive as a result, which may result in a less active trading market for our common stock and higher volatility in our stock price.

We will remain an emerging growth company until the earliest of (1) December 31, 2024, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. As we work toward adopting and implementing the new revenue accounting standard, management will make judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve as we work toward implementing the new standard. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

Substantial future sales or perceived potential sales of our common stock or other equity securities in the public market could cause the price of our common stock to decline significantly.

Sales of substantial amounts of our common stock or other equity securities in the public market, particularly by our directors, executive officers and significant shareholders, including upon the expiration of any lock-up periods entered into in connection with offerings of our common stock or other equity securities, or the perception that these sales could occur, could materially and adversely affect the price of our common stock and impair our ability to raise capital through the sale of equity securities.

Our management and principal shareholders own a significant percentage of our stock and will be able to exert significant control over matters subject to shareholder approval.

Based on shares outstanding as of December 31, 2019, after giving effect to the completion of our secondary offering of common stock in January 2020, our executive officers, directors and five percent or greater shareholders and their respective affiliates, beneficially owned, in the aggregate, approximately 47.6% of our outstanding common stock. As a result, these shareholders, if they act together, will be able to limit or preclude the ability of our other shareholders to control the management and affairs of our company and most matters requiring shareholder approval, including the election of directors, amendments of our organizational documents and approval of any merger, sale of substantially all our assets or other significant corporate transactions. This concentration of ownership may also prevent or discourage unsolicited acquisition proposals or offers for our common stock that other shareholders may feel are in their best interest as one of our shareholders.

We have and expect to continue to incur increased costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives. We are subject to financial reporting and other requirements for which our accounting and other management systems and resources may not be adequately prepared.

As a public company, and particularly after we are no longer an emerging growth company, we incur and will continue to incur significant legal, accounting and other expenses. In addition, the federal securities laws, including the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and rules and regulations subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including requirements to file annual, quarterly and event-driven reports with respect to their business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. These rules and regulations will increase our legal and financial compliance costs, make certain activities more time-consuming and costly, and require our management and other personnel to devote a substantial amount of time to compliance initiatives. Despite our best efforts, we may not be able to produce reliable financial statements or file such financial statements as part of a periodic report in a timely manner with the SEC or comply with Nasdaq listing requirements. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm, beginning with the first full year after July 1, 2019. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 of the Sarbanes-Oxley Act, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. We will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. We could also become subject to investigations by the SEC or other regulatory authorities, which could require additional financial and management resources.

As a public company, we are also required to maintain disclosure controls and procedures. Disclosure controls and procedures means our controls and other procedures that are designed 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 rules and forms of the SEC. We do not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. We believe a control system, no matter how well-designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and any design may not succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Provisions in our charter documents and Washington law could make an acquisition of our company more difficult and limit attempts by our shareholders to replace or remove our current management.

Our amended and restated articles of incorporation ("Articles of Incorporation") and our amended and restated bylaws ("Bylaws"), as well as Washington law, contain provisions that may have the effect of deterring takeovers or delaying or preventing a change in control of us or changes in our management that a shareholder might deem to be in his or her best interest. Our Articles of Incorporation and Bylaws contain provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without shareholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms, with one class being elected each year by our shareholders;
- specify that special meetings of our shareholders can be called only by our board of directors, the Chairperson of our board of directors, our chief executive officer or our president;
- provide that a director may only be removed from the board of directors for cause and then only by the affirmative vote of our shareholders;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even if less than a quorum;
- specify that only our board of directors may change the size of our board of directors;
- establish an advance notice procedure for shareholder proposals to be brought before an annual meeting of our shareholders, including proposed nominations of persons for election to our board of directors;
- specify that no shareholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our Bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our Articles of Incorporation and Bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management or our board of directors.

In addition, because we are incorporated in the State of Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act ("WBCA"), which prohibits certain business combinations between us and certain significant shareholders unless specified conditions are met. These provisions may also have the effect of delaying or preventing a change in control of our company.

Any provision of our Articles of Incorporation or Bylaws or Washington law that has the effect of delaying or deterring a change in control could limit the opportunity for our shareholders 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.

Our Articles of Incorporation provide that the state courts located in King County, Washington and, to the extent enforceable, the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our Articles of Incorporation provide that, unless we consent in writing to the selection of an alternative forum, the state courts located in King County, Washington (or, if the state courts located within King County, Washington do not have jurisdiction, the federal district court for the Western District of Washington) shall be the sole and exclusive forum for commencing and maintaining any proceeding (1) asserting a claim based on a violation of a duty under the laws of the State of Washington by any of our current or former directors, officers or shareholders in such capacity, (2) commenced or maintained in the right of our corporation, (3) asserting a claim arising pursuant to any provision of the WBCA, our Articles of Incorporation or our Bylaws (as either may be amended from time to time) or (4) asserting a claim concerning our internal affairs that is not included in clauses (1) through (3) above, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction.

Our Articles of Incorporation provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended ("Securities Act"), subject to applicable law.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. Our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our shareholders will not be deemed to have waived our compliance with these laws, rules and regulations. These exclusive-forum provisions may limit a shareholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees.

If a court were to find these exclusive-forum provisions in our Articles of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our results of operations. For example, the Court of Chancery of the State of Delaware recently determined that a provision stating that U.S. federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable under Delaware law. It is unclear whether the Delaware Supreme Court will review and ultimately overturn this decision, and whether Washington courts would reach a similar conclusion under Washington law. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our Articles of Incorporation provide that we will indemnify our directors and officers to the fullest extent permitted by Washington law.

In addition, as permitted by Section 23B.08.510 through Section 23B.08.570 of the WBCA, our Articles of Incorporation and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Washington law. Washington law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;

- The rights conferred in our Articles of Incorporation are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- We may not retroactively amend our Articles of Incorporation provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business, and do not anticipate paying any cash dividends on our common stock for the foreseeable future. In addition, the terms of any future debt agreements may preclude 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.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate headquarters is located in Seattle, Washington, where we currently lease approximately 65,502 square feet of laboratory and office space. This lease expires 142 months following landlord delivery of the to-be-constructed building as set forth below or in March 2024 if the lease described below does not commence, subject in each case to two options to extend the lease for five years. We also lease approximately 14,750 square feet in a separate Seattle location, pursuant to a lease expiring in October 2029, which is subject to our ability to exercise an early termination right after the third year. Additionally, we lease approximately 13,431 square feet of laboratory and office space in South San Francisco, California, pursuant to a lease expiring in March 2026.

In August 2019, we entered into an operating lease to rent 100,000 square feet in a to-be-constructed building in Seattle, Washington. Shell construction is expected to be completed in 2020. The lease term commences on the date that the landlord delivers the premises to us for construction of certain tenant improvements. Rent obligations commence 10 months thereafter, and the lease term ends 142 months from the date rent commences, subject to our option to twice extend the lease for five years. The lease is cancellable under certain circumstances if the landlord fails to deliver the premises to us by May 2021. We plan to occupy the new building in 2021, once interior construction is finished.

We may add new facilities or expand existing facilities as we add employees and scale our operations, and we believe suitable additional or substitute space will be available as needed.

Item 3. Legal Proceedings

From time to time, we may be subject to legal proceedings. We are not currently a party to or aware of any proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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 for common stock

Our common stock began trading on The Nasdaq Global Select Market under the symbol "ADPT" on June 27, 2019. Prior to that date, there was no public trading market for our common stock.

Holders of record

As of February 21, 2020, there were approximately 216 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of shareholders, we are unable to estimate the total number of shareholders represented by these record holders.

Dividend policy

We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We do not intend to pay cash dividends to our shareholders in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Our future ability to pay cash dividends on our common stock may also be limited by the terms of any future debt securities, preferred stock or credit facility.

Recent sales of unregistered equity securities

During the fiscal year ended December 31, 2019, we had the following unregistered securities transactions:

1. We granted stock options to purchase an aggregate of 3,890,331 shares of our common stock, with exercise prices ranging from $7.27 to $9.62 per share, to certain of our employees and directors in connection with services provided to us by such persons.
2. We issued an aggregate of 883,845 shares of our common stock to our employees and consultants upon their exercise of stock options, for aggregate cash consideration of approximately $1.9 million.
3. We issued an aggregate of 249,643 shares of our Series E-1 preferred stock, which automatically converted into the same number of shares of our common stock upon the closing of our initial public offering, to our employees and consultants upon their exercise of stock options, for aggregate cash consideration of approximately $0.1 million.
4. We issued an aggregate of 54,792 shares of our common stock upon the exercise of common stock warrants, for aggregate consideration of $9,000 in cash and, through a cashless exercise, surrender of the right to acquire 240 shares of our common stock.

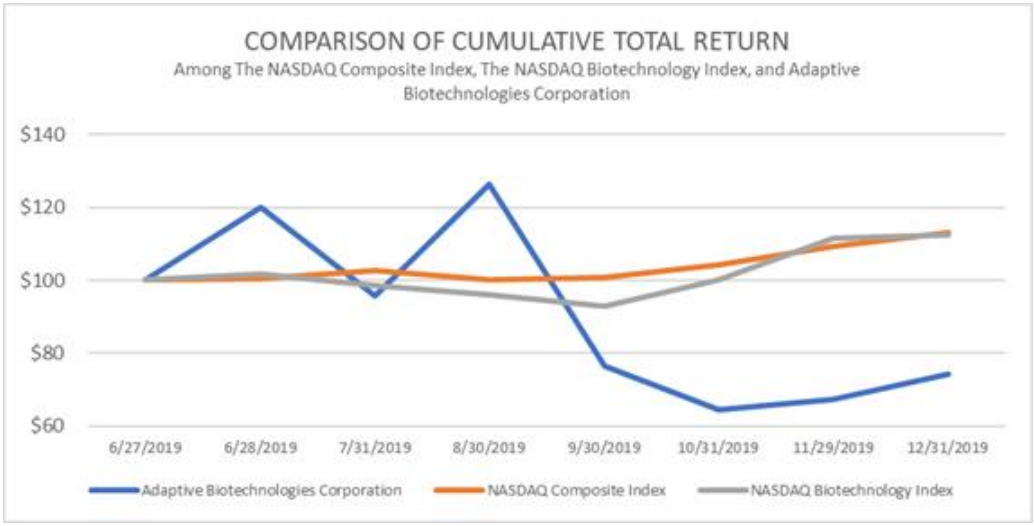
The issuances of the securities described above occurred from January 1, 2019 to July 1, 2019 and were exempt from registration pursuant to Section 4(a)(2) of the Securities Act as transactions by an issuer not involving a public offering or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options and warrants are deemed to be restricted securities for purposes of the Securities Act.

Use of proceeds from our initial public offering of common stock

On July 1, 2019, we closed our initial public offering, in which we issued and sold 17,250,000 shares of our common stock, including the full exercise of the underwriters' over-allotment option, at a public offering price of $20.00 per share for an aggregate offering price of $345.0 million. All of the shares of common stock issued and sold in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-231838), which was declared effective by the SEC on June 26, 2019. Cash used since the initial public offering is as described in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of our periodic reports filed with the SEC. There has been no material change in the planned use of proceeds from our initial public offering as described in our prospectus dated June 26, 2019 filed with the SEC on June 27, 2019 in connection with our initial public offering.

Stock performance graph

The graph below compares the cumulative total shareholder return on our common stock with the cumulative total return on the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes $100 was invested at the market close on June 27, 2019, which was our initial trading day, in our common stock. Data for the NASDAQ Composite Index and the NASDAQ Biotechnology Index assume reinvestment of dividends. Our offering price of our common stock in our initial public offering, which had a closing stock price of $40.30 on June 27, 2019, was $20.00 per share. The stock price performance below is based upon historical data and is not necessarily indicative of, nor intended to forecast, future performance of our common stock.



This graph shall not be deemed to be “soliciting material” or to be “filed” with the SEC for purposes of Section 18 of the Exchange Act or incorporated by reference into any filing of Adaptive Biotechnologies Corporation under the Securities Act or the Exchange Act.

Item 6. Selected Financial Data

The selected financial data set forth below should be read together with our financial statements and the related notes to those statements, as well as the "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" section included elsewhere in this Annual Report on Form 10-K. The statements of operations data for the years ended December 31, 2019, 2018 and 2017 and the balance sheet data as of December 31, 2019 and 2018 have been derived from our financial statements included elsewhere in this Annual Report on Form 10-K. The balance sheet data as of December 31, 2017 is derived from our audited financial statements appearing at the end of our prospectus dated June 26, 2019 filed with the SEC on June 27, 2019 in connection with our initial public offering. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Year Ended December 31,		
	2019	2018	2017
	(in thousands, except share and per share amounts)		
Statements of Operations Data:			
Revenue			
Sequencing revenue	$ 43,519	$ 32,978	$ 22,759
Development revenue	41,552	22,685	15,689
Total revenue	85,071	55,663	38,448
Operating expenses			
Cost of revenue	22,274	19,668	15,680
Research and development	70,705	39,157	31,995
Sales and marketing	38,453	24,486	16,765
General and administrative	30,332	20,409	15,949
Amortization of intangible assets	1,698	1,699	1,694
Restructuring	—	—	840
Total operating expenses	163,462	105,419	82,923
Loss from operations	(78,391)	(49,756)	(44,475)
Interest and other income, net	9,785	3,309	1,644
Net loss	(68,606)	(46,447)	(42,831)
Fair value adjustment to Series E-1 convertible preferred stock options	(964)	102	135
Net loss attributable to common shareholders	$ (69,570)	$ (46,345)	$ (42,696)
Net loss per share attributable to common shareholders, basic and diluted (1)	$ (1.01)	$ (3.67)	$ (3.50)
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	69,165,315	12,629,778	12,196,998
Other Financial and Operating Data:			
Adjusted EBITDA (2)	$ (57,476)	$ (32,607)	$ (30,830)

(1) See Note 15 to our financial statements appearing elsewhere in this Annual Report on Form 10-K for details on the calculation of basic and diluted net loss per share.

(2) Adjusted EBITDA is a non-GAAP financial measure that we define as net loss adjusted for interest and other income, net, income tax benefit (expense), depreciation and amortization, restructuring charges and share-based compensation expenses.

Management uses Adjusted EBITDA to evaluate the financial performance of our business and the effectiveness of our business strategies. We present Adjusted EBITDA because we believe it is frequently used by analysts, investors and other interested parties to evaluate companies in our industry and it facilitates comparisons on a consistent basis across reporting periods. Further, we believe it is helpful in highlighting trends in our operating results because it excludes items that are not indicative of our core operating performance.

Adjusted EBITDA has limitations as an analytical tool and you should not consider it in isolation, or as a substitute for analysis of our results as reported under GAAP. We may in the future incur expenses similar to the adjustments in the presentation of Adjusted EBITDA. In particular, we expect to incur meaningful share-based compensation expense in the future. Other limitations include that Adjusted EBITDA does not reflect:

- all expenditures or future requirements for capital expenditures or contractual commitments;
- changes in our working capital needs;
- income tax expense (benefit), which may be a necessary element of our costs and ability to operate;

- the costs of replacing the assets being depreciated and amortized, which will often have to be replaced in the future;
- the non-cash component of employee compensation expense; and
- the impact of earnings or charges resulting from matters we consider not to be reflective, on a recurring basis, of our ongoing operations.

In addition, Adjusted EBITDA may not be comparable to similarly titled measures used by other companies in our industry or across different industries.

The following is a reconciliation of our net loss to Adjusted EBITDA for the years ended December 31, 2019, 2018 and 2017, respectively (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Net loss	$ (68,606)	$ (46,447)	$ (42,831)
Interest and other income, net	(9,785)	(3,309)	(1,644)
Income tax (benefit) expense	—	—	—
Depreciation and amortization expense	7,791	6,000	5,796
Restructuring (a)	—	—	840
Share-based compensation expense (b)	13,124	11,149	7,009
Adjusted EBITDA	$ (57,476)	$ (32,607)	$ (30,830)

(a) Represents gains and losses recognized in conjunction with restructuring activities.

(b) Represents share-based compensation expense related to option and restricted stock unit awards. See Note 12 to our financial statements appearing elsewhere in this Annual Report on Form 10-K for details on our share-based compensation expense.

	December 31,		
	2019	2018	2017
	(in thousands)		
Balance Sheet Data:			
Cash, cash equivalents and marketable securities	$ 682,301	$ 165,018	$ 201,055
Working capital (1)	534,377	157,918	184,244
Total assets	912,302	332,688	362,489
Total liabilities	341,263	29,942	25,772
Convertible preferred stock	—	560,858	561,333
Total shareholders' equity (deficit)	571,039	(258,112)	(224,616)

(1) We define working capital as current assets less current liabilities.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes and the other financial information appearing elsewhere in this Annual Report on Form 10-K, as well as the other financial information we file with the SEC from time to time. Some of the information contained in this discussion and analysis includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

This section generally discusses 2019 and 2018 items and year-to-year comparisons between 2019 and 2018. Discussions of 2017 items and year-to-year comparisons between 2018 and 2017 may be found in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of our prospectus for our initial public offering, dated June 26, 2019 filed with the SEC on June 27, 2019.

Overview

We are advancing the field of immune-driven medicine by harnessing the inherent biology of the adaptive immune system to transform the diagnosis and treatment of disease. Our immune medicine platform applies our proprietary technologies to read the diverse genetic code of a patient's immune system and understand precisely how it detects and treats disease in that patient. We capture these insights in our dynamic clinical immunomics database, which is underpinned by computational biology and machine learning, and use them to develop and commercialize clinical products and services that we are tailoring to each individual patient. We have two commercial products and services and a robust pipeline of clinical products and services that we are designing to diagnose, monitor and enable the treatment of diseases such as cancer, autoimmune conditions and infectious diseases.

Our immune medicine platform is the foundation for our expanding suite of products and services. The cornerstone of our platform and core immunosequencing product, immunoSEQ, serves as our underlying research and development engine and generates revenue from academic and biopharmaceutical customers. Our first clinical diagnostic product, clonoSEQ, is the first test authorized by the FDA for the detection and monitoring of MRD in patients with MM and ALL and is being validated for patients with other blood cancers. Leveraging our collaboration with Microsoft to create the TCR-Antigen Map, we are also developing a diagnostic product, immunoSEQ Dx, that may enable early detection of many diseases from a single blood test. We have established proof of concept for immunoSEQ Dx in acute Lyme disease, such that we can proceed to clinical validation, and continue to pursue signals for other disease states. Our therapeutic product candidates, being developed under the Genentech Agreement, leverage our platform to identify specific immune cells to develop into cellular therapies in oncology.

Since our inception, we have devoted a majority of our resources to research and development activities to develop our immune medicine platform, which enables the delivery of our products and services for life sciences research, clinical diagnostics and drug discovery customers.

For our life science research customers, we provide two categories of products and services using immunoSEQ, our core sequencing and immunomics tracking technology. First, we provide immunosequencing services, the revenue from which we record as sequencing revenue. Second, we provide certain research customers professional support, for which we may receive payments upon those customers achieving specified milestones. We record these support activities as development revenue.

For our clinical diagnostics customers, we sell our clonoSEQ diagnostic tests, which include our immunosequencing services and are thus recorded as sequencing revenue. In the future, we intend to sell other diagnostics products and services, which we also expect to record as sequencing revenue.

For our current drug discovery collaborator, Genentech, we screen, identify and characterize TCRs in support of our collaboration. We record revenue from this collaboration as development revenue.

Historically, we have sold immunoSEQ as a fee-for-service offering to academic centers and biopharmaceutical customers and further deepened those relationships over time by supporting their development initiatives. These research offerings have comprised the majority of our revenue to date, although our business is pursuing broader opportunities. As we continue to expand the use of our clonoSEQ diagnostic tests, develop and commercialize immunoSEQ Dx and develop and commercialize therapeutic product candidates with our drug discovery collaborator, we expect our mix of revenue to shift to clinical products and services, which we believe will become our largest sources of revenue.

We are actively pursuing opportunities to deepen our relationships with current customers and initiate relationships with new customers. We have an experienced, specialty salesforce that is targeting department heads, laboratory directors, principal investigators, core facility directors, clinicians, payors and research scientists and pathologists at leading academic institutions, biopharmaceutical companies, research institutions and contract research organizations. As MRD assessment becomes standard practice for patient management across a range of blood cancers, we believe it will be essential for clinicians and patients to have access to a highly accurate, sensitive and standardized MRD assessment tool. We are focused on establishing and maintaining collaborative relationships with payors, developing health economic evidence and building billing and patient access infrastructure to expand reimbursement coverage for our clinical diagnostics. We continue to seek expanded coverage of our clonoSEQ diagnostic test and, in 2019, we successfully expanded coverage through contractual agreements or positive medical policies with Medicare and several of the largest national private health insurers in the United States.

We generated revenue of $85.1 million and $55.7 million for the years ended December 31, 2019 and 2018, respectively. Our net losses were $68.6 million and $46.4 million for the years ended December 31, 2019 and 2018, respectively. We have funded our operations to date principally from the sale of convertible preferred stock and common stock, including the sale of common stock in our initial public offering, and, to a lesser extent, sequencing and development revenue. As of December 31, 2019 and 2018, we had cash, cash equivalents and marketable securities of $682.3 million and $165.0 million, respectively. In December 2018, we entered into the Genentech Agreement pursuant to which we received a $300.0 million initial upfront payment in February 2019, may be eligible to receive approximately $1.8 billion over time, including payments upon achievement of specified development, regulatory and commercial milestones, and may receive additional royalties on sales of products commercialized under this agreement.

Initial Public Offering

On July 1, 2019, we completed our initial public offering in which we issued and sold 17,250,000 shares of common stock, including shares issued upon the exercise in full of the underwriters' over-allotment option, at a public offering price of $20.00 per share. We received $315.9 million in net proceeds, after deducting underwriting discounts and commissions of $24.1 million and offering expenses of $5.0 million. Immediately prior to the completion of our initial public offering, 93,039,737 shares of convertible preferred stock then outstanding converted into an equivalent number of shares of common stock.

Components of Results of Operations

Revenue

We derive our revenue from two sources: (1) sequencing revenue and (2) development revenue.

Sequencing revenue. Sequencing revenue reflects the amounts generated from providing sequencing services through immunoSEQ to research customers and from providing testing services through clonoSEQ to clinical and research customers.

For our research customers, which include biopharmaceutical customers and academic institutions, delivery of the sequencing results may include some level of professional support and analysis. Terms with biopharmaceutical customers generally include non-refundable upfront payments, which we record as deferred revenue. For all customers, we recognize revenue as we deliver sequencing results. From time to time, we offer discounts in order to gain rights and access to certain datasets. Revenue is recognized net of these discounts and costs associated with these services are reflected in cost of revenue.

For our clinical customers, we derive revenue from providing our clonoSEQ test report to ordering physicians. We bill commercial payors and medical institutions based on tests delivered to ordering physicians. Amounts paid for clonoSEQ diagnostic tests by commercial payors and medical institutions vary based on respective reimbursement rates and patient responsibilities, which may vary from our targeted list price. To date, the majority of our clonoSEQ diagnostic test revenue has been received from medical institutions. We recognize clinical revenue by evaluating customer payment history, contracted reimbursement rates, if applicable, and other adjustments to estimate the amount of revenue that is collectible. Until 2019, we did not have reimbursement available to us through any government payors for clonoSEQ.

In January 2019, clonoSEQ received Medicare coverage aligned with the FDA label and NCCN guidelines for longitudinal monitoring in MM and ALL. We bill Medicare for an episode of treatment when we deliver the first eligible test results. This billing contemplates all necessary tests required during a patient's treatment cycle, which is currently estimated at approximately four tests per patient, including the initial sequence identification test. Revenue is recognized at the time the initial billable test result is delivered and is based upon cumulative tests delivered to date. Any unrecognized revenue from the initial billable test is recorded as deferred revenue and recognized as we deliver the remaining tests in a patient's treatment cycle.

Development revenue. Development revenue primarily represents regulatory or development support services, other than sequencing revenue, that we provide to biopharmaceutical customers who seek access to our platform to support their therapeutic development activities. Additionally, we generate development revenue from the achievement of regulatory milestones. We enter into collaboration and similar agreements with these customers. When these agreements include sequencing activities, we separately classify those activities as sequencing revenue. These agreements may also include substantial non-refundable upfront payments, which we recognize as development revenue over time as we perform the respective services.

We expect revenue to increase over the long term, particularly as the mix of revenue migrates to clinical diagnostics and drug discovery. The pace by which this mix migrates will be determined by the level of customer adoption and frequency of use of our products and services. Our revenue may fluctuate from period to period due to the uncertain nature of delivery of our products and services, the achievement of milestones by us or our customers, timing of expenses incurred, changes in estimates of total anticipated costs related to our Genentech Agreement and other events not within our control, such as the delivery of customer samples or customer decisions to no longer pursue their development initiatives.

Cost of Revenue

Cost of revenue includes the cost of materials, personnel-related expenses (comprised of salaries, benefits and share-based compensation), shipping and handling, equipment and allocated facility costs associated with processing samples and professional support for our sequencing revenue. Allocated facility costs include depreciation of laboratory equipment, allocated facility occupancy and information technology costs. Costs associated with processing samples are recorded as expense, regardless of the timing of revenue recognition. As such, cost of revenue and related volume does not always trend in the same direction as revenue recognition and related volume. Additionally, costs to support our Genentech Agreement are a component of our research and development activities.

We expect cost of revenue to increase in absolute dollars as we grow our sequencing volume but the cost per sample to decrease over the long term due to the efficiencies we may gain as sequencing volume increases from improved utilization of our laboratory capacity, automation and other value engineering initiatives.

Research and Development Expenses

Research and development expenses consist of laboratory materials costs, personnel-related expenses, allocated facility costs, information technology and contract service expenses. Research and development activities support further development and refinement of existing assays and products, discovery of new technologies and investments into our immune medicine platform. We also include in research and development expenses the costs associated with software development activities to support laboratory scaling and workflow, as well as development of applications to support future commercial opportunities. We are currently conducting research and development activities for several products and services, and we typically use our laboratory materials, personnel, facilities, information technology and other development resources across multiple development programs. Additionally, certain of these research and development activities benefit more than one of our product opportunities. We do not track research and development expenses by specific product candidates.

A component of our research and development activities is supporting clinical and analytical validations to obtain regulatory approval for future clinical products and services. Additionally, the costs to support our Genentech Agreement are a component of our research and development activities. Some of these activities have generated and may in the future generate development revenue.

We expect our research and development expenses to continue to increase in absolute dollars as we innovate and expand the application of our platform. However, we expect research and development expenses to decrease as a percentage of revenue in the long term, although the percentage may fluctuate from period to period due to the timing and extent of our development and commercialization efforts.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of personnel-related expenses for commercial sales, account management, marketing, reimbursement, medical education and business development personnel that support commercialization of our platform products. In addition, these expenses include external costs such as advertising expenses, customer education and promotional expenses, market analysis expenses, conference fees, travel expenses and allocated facility costs.

We expect our sales and marketing expenses to increase in absolute dollars as we expand our commercial sales, marketing and business development teams and increase marketing activities to drive awareness and adoption of our products and services. However, we expect sales and marketing expenses to decrease as a percentage of revenue in the long term, subject to fluctuations from period to period due to the timing and magnitude of these expenses.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses, including share-based compensation, salaries and benefits for our personnel in executive, legal, finance and accounting, human resources and other administrative functions, including third-party billing services. In addition, these expenses include insurance costs, external legal costs, accounting and tax service expenses, consulting fees and allocated facilities costs.

We expect our general and administrative expenses to continue to increase in absolute dollars as we increase headcount and incur costs associated with operating as a public company, including expenses related to legal, accounting, regulatory matters, maintaining compliance with exchange listing and requirements of the SEC, director and officer insurance premiums and investor relations. Though expected to increase in absolute dollars, we expect these expenses to decrease as a percentage of revenue in the long term as revenue increases.

Results of Operations

The following table sets forth our results of operations for the periods presented:

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Revenue			
Sequencing revenue	$ 43,519	$ 32,978	$ 22,759
Development revenue	41,552	22,685	15,689
Total revenue	85,071	55,663	38,448
Operating expenses			
Cost of revenue	22,274	19,668	15,680
Research and development	70,705	39,157	31,995
Sales and marketing	38,453	24,486	16,765
General and administrative	30,332	20,409	15,949
Amortization of intangible assets	1,698	1,699	1,694
Restructuring	—	—	840
Total operating expenses	163,462	105,419	82,923
Loss from operations	(78,391)	(49,756)	(44,475)
Interest and other income, net	9,785	3,309	1,644
Net loss	(68,606)	(46,447)	(42,831)
Fair value adjustment to Series E-1 convertible preferred stock options	(964)	102	135
Net loss attributable to common shareholders	$ (69,570)	$ (46,345)	$ (42,696)

Comparison of the Years Ended December 31, 2019 and 2018

Revenue

(in thousands, except percentages)	Year Ended December 31,		Change		Percent of Revenue	
	2019	2018	$	%	2019	2018
Revenue						
Sequencing revenue	$ 43,519	$ 32,978	$ 10,541	32%	51%	59%
Development revenue	41,552	22,685	18,867	83	49	41
Total revenue	$ 85,071	$ 55,663	$ 29,408	53%	100%	100%

Total revenue was $85.1 million for the year ended December 31, 2019 compared to $55.7 million for the year ended December 31, 2018, representing an increase of $29.4 million, or 53%.

Sequencing revenue increased to $43.5 million for the year ended December 31, 2019, representing an increase of $10.5 million, or 32%. The increase in sequencing revenue was attributable to an increase of approximately $6.3 million in revenue generated from biopharmaceutical and academic customers, inclusive of a decrease in revenue recognized from cancelled customer projects of $1.5 million, and a $4.2 million increase in revenue generated from clinical customers.

Research sequencing volume increased by 18% to 35,491 sequences delivered in the year ended December 31, 2019 from 30,200 sequences delivered in the year ended December 31, 2018. Clinical sequencing volume increased by 48% to 10,168 clinical tests delivered in the year ended December 31, 2019 from 6,867 clinical tests delivered in the year ended December 31, 2018.

Development revenue increased to $41.6 million for the year ended December 31, 2019, representing an increase of $18.9 million, or 83%. The increase was primarily attributable to $35.1 million of revenue generated from the Genentech Agreement, which generated no revenue in 2018, partially offset by a $7.1 million decrease in development revenue generated from translational agreements and a $9.1 million decrease in development revenue generated from MRD agreements, which includes an $8.0 million decrease in regulatory milestones.

Cost of Revenue

(in thousands, except percentages)	Year Ended December 31,		Change		Percent of Revenue	
	2019	2018	$	%	2019	2018
Cost of revenue	$ 22,274	$ 19,668	$ 2,606	13%	26%	35%

Cost of revenue was $22.3 million for the year ended December 31, 2019, compared to $19.7 million for the year ended December 31, 2018, representing an increase of $2.6 million, or 13%. The increase in cost of revenue was primarily attributable to an increase of $1.5 million in the cost of overhead due to the production laboratory expansion and a $1.0 million increase in the cost of materials due to increased sample volumes.

Research and Development

(in thousands, except percentages)	Year Ended December 31,		Change		Percent of Revenue	
	2019	2018	$	%	2019	2018
Research and development	$ 70,705	$ 39,157	$ 31,548	81%	83%	70%

The following table presents disaggregated research and development expenses by cost classification for the periods presented:

(in thousands)	Year Ended December 31,		Change
	2019	2018	
Research and development materials and allocated production laboratory expenses	$ 32,114	$ 14,741	$ 17,373
Personnel expenses	27,570	18,166	9,404
Allocable facilities and information technology expenses	3,510	2,849	661
Software and cloud services expenses	2,443	1,280	1,163
Depreciation and other expenses	5,068	2,121	2,947
Total	$ 70,705	$ 39,157	$ 31,548

Research and development expenses were $70.7 million for the year ended December 31, 2019, compared to $39.2 million for the year ended December 31, 2018, representing an increase of $31.5 million, or approximately 81%. The increase was primarily attributable to $17.4 million in additional cost of materials and allocated production laboratory expenses, which primarily related to supporting our TCR drug discovery efforts, TCR-Antigen Map development and clonoSEQ development.

Sales and Marketing

(in thousands, except percentages)	Year Ended December 31,		Change		Percent of Revenue	
	2019	2018	$	%	2019	2018
Sales and marketing	$ 38,453	$ 24,486	$ 13,967	57%	45%	44%

Sales and marketing expenses were $38.5 million for the year ended December 31, 2019, compared to $24.5 million for the year ended December 31, 2018, representing an increase of $14.0 million, or 57%. The increase was primarily attributable to $8.2 million in additional personnel costs, $2.9 million in additional travel, entertainment and customer event related expenses and $2.4 million in additional consulting and marketing fees.

General and Administrative

(in thousands, except percentages)	Year Ended December 31,		Change		Percent of Revenue	
	2019	2018	$	%	2019	2018
General and administrative	$ 30,332	$ 20,409	$ 9,923	49%	36%	37%

General and administrative expenses were $30.3 million for the year ended December 31, 2019, compared to $20.4 million for the year ended December 31, 2018, representing an increase of $9.9 million, or 49%. The increase was primarily attributable to $4.3 million in additional personnel costs, $1.2 million in additional business taxes, largely due to the Genentech upfront payment received in February 2019, and a $2.0 million increase in insurance expense primarily related to public company director and officer coverage.

Interest and Other Income, Net

(in thousands, except percentages)	Year Ended December 31, 2019	Year Ended December 31, 2018	Change $	Change %
Interest and other income, net	$ 9,785	$ 3,309	$ 6,476	196%

Interest and other income, net was $9.8 million for the year ended December 31, 2019, compared to $3.3 million for the year ended December 31, 2018, representing an increase of $6.5 million, or approximately 196%. The increase was primarily attributable to an $8.8 million increase in interest earned on and investment amortization of a larger portfolio, partially offset by the $2.3 million impact of revaluing a convertible preferred stock warrant liability in 2019.

Quarterly Results of Operations

The following tables set forth our unaudited condensed quarterly statements of operations data for each of the eight quarters in the 24-month period ended December 31, 2019. The information for each of these quarters has been prepared in accordance with GAAP and on the same basis as our audited financial statements included elsewhere in this Annual Report on Form 10-K. In the opinion of management, the financial information reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of results of operations data for these periods. This data should be read in conjunction with our audited financial statements and related notes included elsewhere in this Annual Report on Form 10-K. Our historical quarterly operating results are not necessarily indicative of our operating results for the full year or any future period.

	Three Months Ended December 31, 2019	Three Months Ended September 30, 2019	Three Months Ended June 30, 2019	Three Months Ended March 31, 2019
	(unaudited)			
	(in thousands, except per share amounts)			
Revenue				
Sequencing revenue	$ 13,888	$ 11,683	$ 11,865	$ 6,083
Development revenue	10,321	14,375	10,273	6,583
Total revenue	24,209	26,058	22,138	12,666
Operating expenses				
Cost of revenue	5,951	5,601	5,734	4,988
Research and development	21,189	20,506	16,527	12,483
Sales and marketing	12,640	9,099	8,897	7,817
General and administrative	8,189	8,477	6,662	7,004
Amortization of intangible assets	428	428	423	419
Total operating expenses	48,397	44,111	38,243	32,711
Loss from operations	(24,188)	(18,053)	(16,105)	(20,045)
Interest and other income, net	3,577	4,103	446	1,659
Net loss	(20,611)	(13,950)	(15,659)	(18,386)
Fair value adjustment to Series E-1 convertible preferred stock options	—	—	(710)	(254)
Net loss attributable to common shareholders	$ (20,611)	$ (13,950)	$ (16,369)	$ (18,640)
Net loss per share attributable to common shareholders, basic and diluted	$ (0.17)	$ (0.11)	$ (1.23)	$ (1.45)

	Three Months Ended			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
	(unaudited)			
	(in thousands, except per share amounts)			
Revenue				
Sequencing revenue	$ 10,454	$ 8,463	$ 8,281	$ 5,780
Development revenue	6,738	8,725	3,287	3,935
Total revenue	17,192	17,188	11,568	9,715
Operating expenses				
Cost of revenue	5,275	5,360	5,044	3,989
Research and development	11,067	9,783	9,452	8,855
Sales and marketing	8,071	6,039	5,329	5,047
General and administrative	6,495	4,739	4,632	4,543
Amortization of intangible assets	428	428	424	419
Total operating expenses	31,336	26,349	24,881	22,853
Loss from operations	(14,144)	(9,161)	(13,313)	(13,138)
Interest and other income, net	873	869	820	747
Net loss	(13,271)	(8,292)	(12,493)	(12,391)
Fair value adjustment to Series E-1 convertible preferred stock options	104	(4)	(2)	4
Net loss attributable to common shareholders	$ (13,167)	$ (8,296)	$ (12,495)	$ (12,387)
Net loss per share attributable to common shareholders, basic and diluted	$ (1.03)	$ (0.66)	$ (1.01)	$ (1.01)

Liquidity and Capital Resources

We have incurred losses since inception and have incurred negative cash flows from operations from inception through December 31, 2018. As of December 31, 2019, we had an accumulated deficit of $365.5 million.

We have funded our operations to date principally from the sale of convertible preferred stock and common stock, including the sale of common stock in our initial public offering, and, to a lesser extent, sequencing and development revenue. In December 2018, we entered into the Genentech Agreement pursuant to which we received a $300.0 million initial upfront payment in February 2019, may receive approximately $1.8 billion over time, including payments upon achievement of specified development, regulatory and commercial milestones, and may receive additional royalties on sales of products commercialized under this agreement. As of December 31, 2019, we had cash, cash equivalents and marketable securities of $682.3 million.

We believe our cash flows from operations and our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months. We may consider raising additional capital to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons.

We plan to utilize the existing cash, cash equivalents and marketable securities on hand primarily to fund our commercial and marketing activities associated with our clinical products and services, continued research and development initiatives for our pipeline candidates and drug discovery initiatives, ongoing investments into our immune medicine platform and scaling of our laboratory operations with our anticipated growth. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our funds are held in money market funds and marketable securities consisting of U.S. government debt securities, commercial paper and corporate bonds.

As revenue from sales of immunoSEQ and clonoSEQ is expected to grow, we expect our accounts receivable and inventory balances to increase. Any increase in accounts receivable and inventory may not be completely offset by increases in accounts payable and accrued expenses, which could result in greater working capital requirements. Moreover, we expect to incur additional costs associated with operating as a public company, including expenses related to legal, accounting, regulatory matters and exchange listing and SEC compliance matters, as well as director and officer insurance premiums and investor relations.

If our available cash, cash equivalents and marketable securities balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or convertible debt securities, enter into a credit facility or another form of third-party funding or seek other debt financing. The sale of equity and convertible debt securities may result in dilution to our shareholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. Additional capital may not be available on reasonable terms, or at all.

Cash Flows

The following table summarizes our uses and sources of cash for the years ended December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,	
	2019	2018
Net cash provided by (used in) operating activities	$ 205,404	$ (32,259)
Net cash (used in) provided by investing activities	(481,697)	736
Net cash provided by financing activities	319,916	1,248

Operating Activities

Cash provided by operating activities during the year ended December 31, 2019 was $205.4 million, which was primarily attributable to a net change in our operating assets and liabilities of $254.9 million, non-cash share-based compensation of $13.1 million, non-cash depreciation and amortization of $3.3 million and a $2.3 million fair value adjustment of our convertible preferred stock warrant liability due to an increase in valuation of our common stock, partially offset by a net loss of $68.6 million. The net change in our operating assets and liabilities reflects an increase in deferred revenue of $266.9 million, primarily due to the $300.0 million upfront payment by Genentech, and an increase in accounts payable and accrued liabilities of $6.1 million, primarily due to increased headcount and the growth in operating expenditures and timing of vendor payments. These increases were partially offset by an increase in accounts receivable of $7.8 million, primarily due to an increase in clinical billings, as well as an increase in revenue paid in arrears rather than upfront by biopharmaceutical customers, an increase in prepaid expenses and other current assets of $8.6 million, primarily due to prepaid software, prepaid insurance and interest receivables, an increase in inventory of $1.2 million to support growth in lab operations and $0.6 million in security deposits.

Cash used in operating activities during the year ended December 31, 2018 was $32.3 million, which was primarily attributable to a net loss of $46.4 million, partially offset by non-cash share-based compensation of $11.1 million and non-cash depreciation and amortization of $4.8 million, and a net change in our operating assets and liabilities of $1.7 million. The net change in our operating assets and liabilities reflects an increase in inventory of $3.0 million to support growth in our laboratory, an increase in accounts payable and accrued liabilities of $2.2 million due to increased headcount, a decrease of $0.6 million in deferred revenue due to increased development revenue and a decrease of $0.5 million in deferred rent due to increases in cash rental payments.

Investing Activities

Cash used in investing activities during the year ended December 31, 2019 was $481.7 million, which was primarily attributable to purchases of marketable securities of $884.2 million and purchases of property and equipment of $11.2 million, partially offset by proceeds from maturities of marketable securities of $413.7 million.

Cash provided by investing activities during the year ended December 31, 2018 was $0.7 million, which was primarily attributable to proceeds from maturities of marketable securities of $153.5 million, partially offset by purchases of marketable securities of $146.5 million and purchases of property and equipment of $6.3 million.

Financing Activities

Cash provided by financing activities during the year ended December 31, 2019 was $319.9 million, which was primarily attributable to proceeds from the initial public offering, net of underwriting discounts and commissions, of $320.9 million and proceeds from the exercise of stock options of $4.1 million, partially offset by payment of deferred initial public offering costs of $5.0 million.

Cash provided by financing activities during the year ended December 31, 2018 was $1.2 million, which was primarily attributable to proceeds from the exercise of stock options.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2019, which represents contractually committed future obligations (in thousands):

	Expected Payments by Period				
	Total	2020	2021-2022	2023-2024	More Than 5 Years
Operating lease obligations[1]	$ 143,903	$ 4,352	$ 19,443	$ 22,961	$ 97,147
Purchase commitments[2]	10,173	5,043	4,870	40	220
Total	$ 154,076	$ 9,395	$ 24,313	$ 23,001	$ 97,367

(1) Operating lease obligations reflect remaining minimum commitments for our office and laboratory spaces in Seattle, Washington and South San Francisco, California and a commitment to an office lease in New York City, New York. Please see Note 10 of our financial statements for additional information pertaining to operating lease commitments.

(2) Purchase commitments include commitments for cloud data storage through our collaboration with Microsoft, commitments to support clinical trials utilizing clonoSEQ, software and service license commitments, and minimum commitments for laboratory material suppliers.

Furthermore, in connection with one of our lease agreements, we entered into a letter of credit of $2.1 million with one of our existing financial institutions.

Net Operating Loss Carryforwards

Utilization of our NOL carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986 (“Section 382”) and similar state provisions. The annual limitation may result in the expiration of NOL carryforwards and credits before utilization. If there should be an ownership change, our ability to utilize our NOL carryforwards and credits could be limited. We have completed a Section 382 analysis and have determined there are no permanent limitations on the utilization of approximately $225.4 million of our federal NOLs as of December 31, 2018. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and future years may be carried forward indefinitely, but the deductibility of such federal NOL is subject to an annual limitation. Net operating losses generated prior to 2018 are eligible to be carried forward up to 20 years. Based on the available objective evidence, management determined that it was more likely than not that the net deferred tax assets would not be realizable as of December 31, 2019. Accordingly, management applied a full valuation allowance against net deferred tax assets as of December 31, 2019.

Off-Balance Sheet Arrangements

As of December 31, 2019, we have not had any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Estimates

We have prepared our financial statements in accordance with GAAP. Our preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities and related disclosures at the date of the financial statements, as well as revenue and expense recorded during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and or other relevant assumptions that we believe to be reasonable under the circumstances. Estimates are used in several areas, including, but not limited to, estimates of progress to date for certain performance obligations and transaction price for certain contracts with customers, share-based compensation, including the fair value of stock, the provision for income taxes, including related reserves, and goodwill, among others. These estimates generally involve complex issues and require judgments, involve the analysis of historical results and prediction of future trends, can require extended periods of time to resolve and are subject to change from period to period. Actual results may differ materially from management’s estimates.

While our significant accounting policies are described in more detail in Note 2 to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Our development and sequencing revenue arrangements may include upfront payments for the performance of services in the future, which have both fixed and variable consideration. Non-refundable upfront fees and funding for related development services are generally considered fixed consideration, while milestone payments are identified as variable consideration.

In determining the appropriate amount of revenue to recognize as we fulfill our obligations under these agreements, we perform the following steps to determine the amount of revenue to be recognized: (1) identification of contract or contracts; (2) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (3) measurement of the transaction price, including the constraint on variable consideration; (4) allocation of the transaction price to the performance obligations based on estimated selling prices; and (5) recognition of revenue when (or as) we satisfy each performance obligation.

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in Accounting Standard Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*. Our performance obligations include sequencing services and services associated with regulatory submission and approval processes. Significant management judgment is applied to determine (1) the measurement of the transaction price, including the constraint on variable consideration, (2) the allocation of the transaction price to the performance obligations and (3) the appropriate input or output based method to recognize revenue and the extent of progress to date.

We include the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, we re-evaluate the estimated variable consideration included in the transaction price and any related constraint and, if necessary, adjust our estimate of the overall transaction price.

To determine the allocation of the transaction price to the performance obligations, we apply the adjusted market assessment approach. Using this approach, we evaluate the market in which we sell the services and estimate the price that a customer in that market would be willing to pay for those services.

To select the measure of progress, we consider the expectations of the performance period which may be based on customer-dependent estimates of samples or internal estimates of the performance period based on both the customer and our expected development timeframes. We regularly review our expectations of the extent of progress, including whether any variable consideration is no longer constrained, and, if any changes in estimates are made, we recognize revenue using the cumulative catch-up method.

Share-Based Compensation

We measure share-based compensation expense for stock options granted to our employees and non-employee directors on the date of grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award.

We estimate the fair value of stock options granted to our employees and non-employee directors on the grant date, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of assumptions regarding a number of variables that are complex, subjective and generally require significant judgment to determine. The assumptions used to calculate the fair value of our stock options were:

Fair value of common stock

Prior to the closing of our initial public offering, the fair value of our common stock issuable upon exercise of stock options was determined by our board of directors, with input from management and independent third-party valuations, as discussed in "*—Common Stock Valuations*" below. For valuations of option grants made after the closing of our initial public offering, our board of directors determines the fair value of each share of common stock based on the closing price of our common stock on the date of grant or other relevant determination date, as reported on The Nasdaq Global Select Market.

Expected term

Our expected term represents the period that our stock options are expected to be outstanding. The expected term of options granted to employees and non-employee directors is determined using the "simplified" method, as illustrated in ASC Topic 718, *Compensation—Stock Compensation*, as we do not have sufficient exercise history to determine a better estimate of expected term. Under this approach, the expected term is based on the midpoint between the vesting date and the end of the contractual term of the option.

Expected volatility

As we do not have sufficient trading history for our common stock, the expected volatility is based on the historical volatility of our publicly traded industry peers utilizing a period of time consistent with our estimate of the expected term. The comparable companies are chosen based on their similar size, stage in the life cycle or area of specialty.

Risk-free interest rate

We utilize a risk-free interest rate in the option valuation model based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term of the options.

Expected dividend yield

We do not anticipate paying any cash dividends in the foreseeable future and, therefore, use an expected dividend yield of zero in the option valuation model.

Black-Scholes assumptions

The estimated fair value of options granted during the periods presented was estimated using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,	
	2019	2018
Grant date fair value	$7.80 - $47.81	$6.55
Expected term (in years)	5.27 - 6.08	6.08 - 10.00
Risk-free interest rate	1.4% - 2.5%	2.6% - 3.0%
Expected volatility	64.3% - 72.9%	65.0% - 69.2%
Expected dividend yield	—	—

As of January 1, 2018, we adopted Accounting Standards Update 2016-09, *Compensation—Stock Compensation* (Topic 718) and elected to account for forfeitures as they occur rather than estimate expected forfeitures over the vesting period of the respective grant.

We use judgment in evaluating the assumptions related to our share-based compensation on a prospective basis. As we continue to accumulate additional data related to our common stock, we may have refinements to our estimates, which could materially impact our future share-based compensation expense. At December 31, 2019, unrecognized share-based compensation expense related to unvested stock options was $33.3 million, which was expected to be recognized over a remaining weighted-average period of 2.9 years.

Common Stock Valuations

For periods prior to the closing of our initial public offering, the estimated fair value of the common stock issuable upon exercise of our stock options was determined by our board of directors, with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant, and factors that may have changed from the date of the most recent valuation through the date of the grant, which intended all options granted to be exercisable at a price per share not less than the fair value per share of our common stock issuable upon exercise of those options on the date of grant. We believe our board of directors had the relevant experience and expertise to determine the fair value of our common stock. Prior to our initial public offering, given the absence of a public trading market for our common stock, the valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The assumptions we used in the valuation model were based on future expectations combined with management's judgment. In the absence of a public trading market, our board of directors, with input from management, exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our common stock as of the date of each option grant, including the following factors:

- independent valuations performed at periodic intervals by an independent third-party valuation firm;
- the prices, rights, preferences and privileges of our convertible preferred stock relative to our common stock;
- our operating and financial performance, forecasts and capital resources;
- current business conditions;
- the hiring of key personnel;
- our stage of commercialization;
- the status of research and development efforts;

- the likelihood of achieving a liquidity event for the shares of common stock issuable upon exercise of these stock options, such as an initial public offering or sale of our company, given prevailing market conditions;
- any adjustment necessary to recognize a lack of marketability for our common stock;
- trends and developments in our industry;
- the market performance of comparable publicly traded technology companies; and
- the U.S. and global economic and capital market conditions.

In valuing our common stock prior to the closing of our initial public offering, we utilized a hybrid methodology that includes a probability-weighted expected return method ("PWERM") and an option pricing method ("OPM"), which is a highly complex and subjective valuation methodology. Under a PWERM, the fair market value of the common stock is estimated based upon an analysis of future values for the enterprise assuming various future outcomes. Within one of those potential outcomes, we utilized the OPM. The OPM treats the rights of the holders of convertible preferred stock and common stock as equivalent to that of call options on any value of the enterprise above certain break points of value based upon the liquidation preferences of the holders of preferred stock, as well as their rights to participation and conversion. Based on the timing and nature of an assumed liquidity event in each scenario, a discount for lack of marketability either was or was not applied to each scenario, as appropriate. We then probability-weighted the value of each expected outcome to arrive at an estimate of fair value per share of common stock.

For valuations after the closing of our initial public offering, our board of directors determines the fair value of each share of common stock based on the closing price of our common stock on the date of grant or other relevant determination date, as reported on The Nasdaq Global Select Market.

Goodwill

Goodwill represents the excess of the purchase price over the net amount of identifiable assets acquired and liabilities assumed in a business combination measured at fair value. We assess goodwill for impairment annually on October 1 and upon any occurrence of triggering events or substantive changes in circumstances that could indicate a potential impairment.

We evaluate goodwill for impairment by first assessing qualitative factors to determine whether it is more likely than not that the fair value of our reporting unit is less than its carrying amount. We evaluate certain qualitative factors such as macroeconomic conditions, the market and industry in which we operate, cost factors, overall financial performance and other relevant entity-specific events to determine if there are any negative trends or events that could indicate impairment. Key assumptions in this analysis include anticipated demand for our products and services, including industry and regulatory changes, future revenue growth and cash, cash equivalents and marketable securities on hand. These assumptions are determined based on our historical performance and management's forecasted results. Management's estimates of forecasted results are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. If we determine that it is more likely than not that the fair value of our reporting unit is less than its carrying amount, or if we choose to bypass the qualitative assessment, we perform a quantitative goodwill impairment test. Goodwill impairment exists when the estimated fair value of our one reporting unit is less than its carrying value. If impairment exists, the carrying value of the goodwill is reduced to fair value through an impairment charge recorded in our statements of operations. To date, we have not recognized any impairment of goodwill.

JOBS Act Accounting Election

We are an "emerging growth company" within the meaning of the JOBS Act. The JOBS Act allows an emerging growth company to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. We have elected to use this extended transition period and, as a result, our financial statements may not be comparable to companies that comply with public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

We will remain an emerging growth company until the earliest of (1) December 31, 2024 (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Recent Accounting Pronouncements

See Note 2 to the financial statements included elsewhere in this Annual Report on Form 10-K for more information.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We are exposed to market risk for changes in interest rates related primarily to our cash and cash equivalents and marketable securities. As of December 31, 2019, we had cash and cash equivalents of $96.6 million, held primarily in cash deposits and money market funds. Our marketable securities are held in U.S. government debt securities, commercial paper and corporate bonds. As of December 31, 2019, we had short-term and long-term marketable securities of $585.7 million. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates in the United States. As of December 31, 2019, a hypothetical 100 basis point increase in interest rates would have resulted in an approximate $3.0 million decline of the fair value of our available-for-sale securities. This estimate is based on a sensitivity model that measures market value changes when changes in interest rates occur. Such losses would only be realized if we sold the investments prior to maturity. We do not enter into investments for trading purposes and have not used any derivative financial instruments to manage our interest rate risk exposure.

Item 8. Financial Statements and Supplementary Data

Adaptive Biotechnologies Corporation

Index to Financial Statements

As of December 31, 2019 and 2018 and

For the Years Ended December 31, 2019, 2018 and 2017

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of
Adaptive Biotechnologies Corporation

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Adaptive Biotechnologies Corporation (the Company) as of December 31, 2019 and 2018, the related statements of operations, comprehensive loss, convertible preferred stock and shareholders' (deficit) equity, and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with U.S. 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 2015.

Seattle, Washington
February 26, 2020

Adaptive Biotechnologies Corporation

Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 96,576	$ 55,030
Short-term marketable securities	480,290	109,988
Accounts receivable, net	12,676	4,807
Inventory	9,069	7,838
Prepaid expenses and other current assets	14,079	3,055
Total current assets	612,690	180,718
Long-term assets		
Property and equipment, net	60,355	19,125
Long-term marketable securities	105,435	—
Restricted cash	2,138	61
Intangible assets, net	11,928	13,626
Goodwill	118,972	118,972
Other assets	784	186
Total assets	$ 912,302	$ 332,688
Liabilities, convertible preferred stock and shareholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 4,453	$ 1,793
Accrued liabilities	4,371	2,562
Accrued compensation and benefits	8,124	4,641
Current portion of deferred rent	371	1,109
Current deferred revenue	60,994	12,695
Total current liabilities	78,313	22,800
Long-term liabilities		
Convertible preferred stock warrant liability	—	336
Deferred rent liability, less current portion	6,918	6,102
Financing obligation	36,607	—
Deferred revenue, less current portion	219,332	704
Other long-term liabilities	93	—
Total liabilities	341,263	29,942
Commitments and contingencies (Note 10)		
Convertible preferred stock: $0.0001 par value, no and 93,762,517 shares authorized at December 31, 2019 and 2018, respectively; no and 92,790,094 shares issued and outstanding at December 31, 2019 and 2018, respectively; aggregate liquidation preference of $0 and $572,866 at December 31, 2019 and 2018, respectively	—	560,858
Shareholders' equity (deficit)		
Preferred stock: $0.0001 par value, 10,000,000 and no shares authorized at December 31, 2019 and 2018, respectively; no shares issued and outstanding at December 31, 2019 and 2018	—	—
Common stock: $0.0001 par value, 340,000,000 and 131,000,000 shares authorized at December 31, 2019 and 2018, respectively; 125,238,142 and 12,841,536 shares issued and outstanding at December 31, 2019 and 2018, respectively	12	1
Additional paid-in capital	935,834	37,902
Accumulated other comprehensive gain (loss)	671	(107)
Accumulated deficit	(365,478)	(295,908)
Total shareholders' equity (deficit)	571,039	(258,112)
Total liabilities, convertible preferred stock and shareholders' equity (deficit)	$ 912,302	$ 332,688

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

Adaptive Biotechnologies Corporation

Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2019	2018	2017
Revenue			
Sequencing revenue	$ 43,519	$ 32,978	$ 22,759
Development revenue	41,552	22,685	15,689
Total revenue	85,071	55,663	38,448
Operating expenses			
Cost of revenue	22,274	19,668	15,680
Research and development	70,705	39,157	31,995
Sales and marketing	38,453	24,486	16,765
General and administrative	30,332	20,409	15,949
Amortization of intangible assets	1,698	1,699	1,694
Restructuring	—	—	840
Total operating expenses	163,462	105,419	82,923
Loss from operations	(78,391)	(49,756)	(44,475)
Interest and other income, net	9,785	3,309	1,644
Net loss	(68,606)	(46,447)	(42,831)
Fair value adjustment to Series E-1 convertible preferred stock options	(964)	102	135
Net loss attributable to common shareholders	$ (69,570)	$ (46,345)	$ (42,696)
Net loss per share attributable to common shareholders, basic and diluted	$ (1.01)	$ (3.67)	$ (3.50)
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	69,165,315	12,629,778	12,196,998

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

Adaptive Biotechnologies Corporation

Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,		
	2019	2018	2017
Net loss	$ (68,606)	$ (46,447)	$ (42,831)
Change in unrealized gain (loss) on investments	778	59	(84)
Comprehensive loss	$ (67,828)	$ (46,388)	$ (42,915)

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

Adaptive Biotechnologies Corporation

Statements of Convertible Preferred Stock and Shareholders' (Deficit) Equity
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Gain	Accumulated Deficit	Total Shareholders' (Deficit) Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2016	87,797,854	$ 511,823	12,154,046	$ 1	$ 17,559	$ (82)	$ (207,212)	$ (189,734)
Adjustments to accumulated deficit for adoption of guidance on accounting for revenue recognition	—	—	—	—	—	—	485	485
Issuance of common stock for cash upon exercise of stock options	—	—	54,685	—	95	—	—	95
Issuance of Series F-1 convertible preferred stock for cash, net of issuance costs	4,686,649	49,827	—	—	—	—	—	—
Issuance of Series E-1 convertible preferred stock for cash upon exercise of Series E-1 convertible preferred stock options at fair value	171,526	127	—	—	—	—	—	—
Vested Series E-1 convertible preferred stock option forfeitures	—	(644)	—	—	398	—	246	644
Series E-1 convertible preferred stock option share-based compensation	—	—	—	—	89	—	—	89
Adjustment to redemption value for vested Series E-1 convertible preferred stock options	—	89	—	—	(89)	—	—	(89)
Change in redemption value for vested Series E-1 convertible preferred stock options	—	111	—	—	—	—	(111)	(111)
Common stock option share-based compensation	—	—	—	—	6,920	—	—	6,920
Other comprehensive loss	—	—	—	—	—	(84)	—	(84)
Net loss	—	—	—	—	—	—	(42,831)	(42,831)
Balance as of December 31, 2017	92,656,029	$ 561,333	12,208,731	$ 1	$ 24,972	$ (166)	$ (249,423)	$ (224,616)
Adjustments to accumulated deficit for adoption of guidance on accounting for share-based payment transactions	—	—	—	—	140	—	(140)	—
Issuance of common stock for cash upon exercise of stock options	—	—	632,805	—	1,168	—	—	1,168
Issuance of Series E-1 convertible preferred stock for cash upon exercise of Series E-1 convertible preferred stock options at fair value	134,065	100	—	—	—	—	—	—
Vested Series E-1 convertible preferred stock option forfeitures	—	(767)	—	—	476	—	291	767
Series E-1 convertible preferred stock option share-based compensation	—	—	—	—	3	—	—	3
Adjustment to redemption value for vested Series E-1 convertible preferred stock options	—	3	—	—	(3)	—	—	(3)
Change in redemption value for vested Series E-1 convertible preferred stock options	—	189	—	—	—	—	(189)	(189)
Common stock option share-based compensation	—	—	—	—	11,146	—	—	11,146
Other comprehensive income	—	—	—	—	—	59	—	59
Net loss	—	—	—	—	—	—	(46,447)	(46,447)
Balance as of December 31, 2018	92,790,094	$ 560,858	12,841,536	$ 1	$ 37,902	$ (107)	$ (295,908)	$ (258,112)
Proceeds from initial public offering, net of underwriters' discounts and commissions	—	—	17,250,000	2	320,848	—	—	320,850
Initial public offering costs	—	—	—	—	(4,986)	—	—	(4,986)
Conversion of convertible preferred stock to common stock	(93,039,737)	(561,931)	93,039,737	9	561,922	—	—	561,931
Conversion of convertible preferred stock warrant to common stock warrant	—	—	—	—	2,602	—	—	2,602
Issuance of common stock upon exercise of common stock warrants	—	—	54,792	—	9	—	—	9
Issuance of common stock for cash upon exercise of stock options	—	—	2,043,767	—	4,413	—	—	4,413
Issuance of Series E-1 convertible preferred stock for cash upon exercise of Series E-1 convertible preferred stock options at fair value	249,643	109	—	—	—	—	—	—
Vesting of restricted stock units	—	—	8,310	—	—	—	—	—
Change in redemption value for vested Series E-1 convertible preferred stock options	—	964	—	—	—	—	(964)	(964)
Common stock option and restricted stock unit share-based compensation	—	—	—	—	13,124	—	—	13,124
Other comprehensive income	—	—	—	—	—	778	—	778
Net loss	—	—	—	—	—	—	(68,606)	(68,606)
Balance as of December 31, 2019	—	$ —	125,238,142	$ 12	$ 935,834	$ 671	$ (365,478)	$ 571,039

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

Adaptive Biotechnologies Corporation

Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2019	**2018**	**2017**
Operating activities			
Net loss	$ (68,606)	$ (46,447)	$ (42,831)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation expense	6,093	4,301	4,102
Share-based compensation expense	13,124	11,149	7,009
Intangible assets amortization	1,698	1,699	1,694
Investment amortization	(4,463)	(1,214)	342
Asset impairment	—	17	193
Loss (gain) on equipment disposals	316	(40)	125
Fair value adjustment of convertible preferred stock warrant	2,266	(6)	(23)
Other	43	5	6
Changes in operating assets and liabilities:			
Accounts receivable, net	(7,817)	775	(2,427)
Inventory	(1,231)	(3,046)	(2,697)
Prepaid expenses and other current assets	(8,576)	(318)	(327)
Accounts payable and accrued liabilities	6,149	2,185	(1,517)
Deferred rent	78	(488)	(1,058)
Deferred revenue	266,927	(649)	2,527
Other	(597)	(182)	24
Net cash provided by (used in) operating activities	205,404	(32,259)	(34,858)
Investing activities			
Purchases of property and equipment	(11,200)	(6,318)	(2,421)
Proceeds from sales of equipment	—	19	207
Purchases of intangible assets	—	—	(85)
Purchases of marketable securities	(884,217)	(146,503)	(125,182)
Proceeds from sales and maturities of marketable securities	413,720	153,538	163,913
Net cash (used in) provided by investing activities	(481,697)	736	36,432
Financing activities			
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	—	49,827
Proceeds from exercise of stock options	4,055	1,268	222
Proceeds from initial public offering, net of underwriting discounts and commissions	320,850	—	—
Payment of deferred initial public offering costs	(4,986)	—	—
Proceeds from issuance of common stock upon the exercise of a common stock warrant	9	—	—
Other	(12)	(20)	(15)
Net cash provided by financing activities	319,916	1,248	50,034
Net increase (decrease) in cash, cash equivalents and restricted cash	43,623	(30,275)	51,608
Cash, cash equivalents and restricted cash at beginning of year	55,091	85,366	33,758
Cash, cash equivalents and restricted cash at end of year	$ 98,714	$ 55,091	$ 85,366
Noncash investing and financing activities			
Purchases of equipment included in accounts payable and accrued liabilities	$ 773	$ 832	$ 41
Landlord-funded leasehold improvements	$ —	$ 2,419	$ —
Noncash additions to property through lease financing arrangements	$ 36,607	$ —	$ —
Conversion of convertible preferred stock to common stock upon closing of initial public offering	$ 561,931	$ —	$ —
Conversion of convertible preferred stock warrant to common stock warrant upon closing of initial public offering	$ 2,602	$ —	$ —

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

1. Organization and Description of Business

Adaptive Biotechnologies Corporation ("we," "us" or "our") is a commercial-stage company advancing the field of immune-driven medicine by harnessing the inherent biology of the adaptive immune system to transform the diagnosis and treatment of disease. We believe the adaptive immune system is nature's most finely tuned diagnostic and therapeutic for most diseases, but the inability to decode it has prevented the medical community from fully leveraging its capabilities. Our immune medicine platform is the foundation for our expanding suite of products and services. The cornerstone of our immune medicine platform and core immunosequencing product, immunoSEQ, serves as our underlying research and development engine and generates revenue from academic and biopharmaceutical customers. Our first clinical diagnostic product, clonoSEQ, is the first test authorized by the Food and Drug Administration ("FDA") for the detection and monitoring of minimal residual disease ("MRD") in patients with select blood cancers.

We were incorporated in the State of Washington on September 8, 2009 under the name Adaptive TCR Corporation. On December 21, 2011, we changed our name to Adaptive Biotechnologies Corporation. We are headquartered in Seattle, Washington.

Initial Public Offering

Our registration statement on Form S-1 related to our initial public offering was declared effective on June 26, 2019, and our common stock began trading on the Nasdaq Global Select Market on June 27, 2019. On July 1, 2019, we completed our initial public offering in which we issued and sold 17,250,000 shares of common stock, including shares issued upon the exercise in full of the underwriters' over-allotment option, at a public offering price of $20.00 per share. We received $315.9 million in net proceeds, after deducting underwriting discounts and commissions of $24.1 million and offering expenses of $5.0 million.

Immediately prior to the completion of our initial public offering on July 1, 2019, 93,039,737 shares of convertible preferred stock then outstanding converted into an equivalent number of shares of common stock. On July 1, 2019, in connection with the closing of our initial public offering, our amended and restated articles of incorporation, as filed with the Secretary of State of the State of Washington, and our amended and restated bylaws became effective. Also on July 1, 2019, an initial reserve of 15,519,170 shares under our new 2019 Equity Incentive Plan ("2019 Plan") became effective.

2. Significant Accounting Policies

Basis of Presentation and Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") requires management to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and the related disclosures at the date of the financial statements, as well as the reported amounts of revenues and expenses during the periods presented. We base our estimates on historical experience and other relevant assumptions that we believe to be reasonable under the circumstances. Estimates are used in several areas including, but not limited to, estimates of progress to date for certain performance obligations and the transaction price for certain contracts with customers, share-based compensation, including the fair value of stock, the provision for income taxes, including related reserves, and goodwill, among others. These estimates generally involve complex issues and require judgments, involve the analysis of historical results and prediction of future trends, can require extended periods of time to resolve and are subject to change from period to period. Actual results may differ materially from management's estimates.

Reclassifications

In the accompanying balance sheets, certain prior year amounts have been reclassified to conform to the current period presentation. Specifically, "restricted cash" and "other assets" were included together in the restricted cash and other assets line item and are now separately stated. There was no change to total assets as a result of the reclassification.

Cash and Cash Equivalents

Cash and cash equivalents are stated at fair value. Cash equivalents include only securities having an original maturity of three months or less at the time of purchase. We limit our credit risk associated with cash and cash equivalents by placing our investments with banks that we believe are highly creditworthy and with highly rated money market funds. Cash and cash equivalents primarily consist of bank deposits and investments in money market funds.

Restricted Cash

We are required to maintain certain balances under lease arrangements for our property and facility leases. We had restricted cash of $2.1 million and $0.1 million as of December 31, 2019 and 2018, respectively.

Investments in Marketable Securities

Marketable securities are classified as available-for-sale and primarily consist of U.S. government debt securities, U.S. government agency securities, commercial paper and corporate bonds, and are reported at fair value. Unrealized holding gains and losses are reflected as a separate component of shareholders' equity (deficit) in accumulated other comprehensive gain (loss) until realized. Realized gains and losses on the sale of these securities are recognized in net income or loss. The cost of marketable securities sold is based on the specific identification method.

Concentrations of Risk

We are subject to a concentration of risk from a limited number of suppliers, or in some cases, single suppliers for some of our laboratory instruments and materials. This risk is managed by targeting a quantity of surplus stock.

Cash, cash equivalents and marketable securities are financial instruments that potentially subject us to concentrations of credit risk. We invest in money market funds, U.S. government debt securities, U.S. government agency securities, commercial paper and corporate bonds with high-quality accredited financial institutions.

Significant customers are those which represent more than 10% of our total revenue or accounts receivable, net balances for the periods and as of each balance sheet date presented, respectively. Revenue from these customers reflects their purchase of our products and services and our collaboration efforts with Genentech.

For each significant customer, revenue as a percentage of total revenue for the periods presented and accounts receivable, net as a percentage of total accounts receivable, net as of the periods presented were as follows:

	Revenue			Accounts Receivable, Net	
	Year Ended December 31,			December 31,	
	2019	2018	2017	2019	2018
Customer A	13.9%	18.4%	31.4%	41.8%	*%
Customer B	*	13.5	*	*	15.1
Customer C	*	15.4	*	*	13.2
Genentech, Inc.	42.1	*	*	*	*

* less than 10%

Accounts Receivable

Accounts receivable consists of amounts due from customers for services performed. We review our accounts receivable regularly by analyzing the status of significant past due receivables to determine if any receivable will potentially be uncollectible and to estimate the amount of allowance for doubtful accounts necessary to reduce accounts receivable to its estimated net realizable value.

Additionally, we had $2.4 million and $0.4 million of unbilled receivables as of December 31, 2019 and 2018, respectively. The unbilled receivables are amounts that will become due for which we have an unconditional right to consideration.

Inventory

Inventory consists of laboratory materials and supplies used in lab analysis. We capitalize inventory when purchased and record expense upon order fulfillment for servicing revenue or utilization in our research and development laboratories. Inventory is valued at the lower of cost or market on a first-in, first-out basis. We periodically perform obsolescence assessments and write off any inventory that is no longer usable.

Property and Equipment

Property and equipment consists of computer equipment, computer software, laboratory equipment, leasehold improvements and furniture and office equipment. Property and equipment are recorded at cost and depreciation is recognized using the straight-line method based on estimated useful life. Maintenance and repairs are charged to expense as incurred, and costs of improvements are capitalized.

Useful lives assigned to property and equipment are as follows:

Laboratory equipment	3 to 7 years
Leasehold improvements	Shorter of estimated useful life or remaining lease term
Computer equipment and software	3 years
Furniture and office equipment	5 to 10 years

We review long-lived assets for impairment whenever events or circumstances indicate the carrying amount of an asset group may not be recoverable. Gains and losses from asset disposals and impairment losses are classified within the statements of operations in accordance with the use of the asset.

Goodwill

Goodwill represents the excess of the purchase price over the net amount of identifiable assets acquired and liabilities assumed in a business combination measured at fair value. We assess goodwill for impairment annually on October 1, or more frequently if events or changes in circumstances would more likely than not reduce the fair value of our single reporting unit below its carrying value. We evaluate goodwill for impairment by first assessing qualitative factors to determine whether it is more likely than not that the fair value of our reporting unit is less than its carrying amount. If we so determine, or if we choose to bypass the qualitative assessment, we perform a quantitative goodwill impairment test. Goodwill impairment exists when the estimated fair value of our one reporting unit is less than its carrying value. If impairment exists, the carrying value of the goodwill is reduced to fair value through an impairment charge recorded in our statements of operations. To date, we have not recognized any impairment of goodwill.

Intangible Assets

Intangible assets acquired in a business combination are recognized separately from goodwill and are initially recognized at their fair value at the acquisition date, which is regarded as their cost.

Intangible assets may also result from the purchase of assets and intellectual property in a transaction that does not qualify as a business combination. Intangible assets are amortized over their estimated useful lives on a straight-line basis which approximates their usage pattern. Intangible assets are reviewed for impairment at least annually or if indicators of potential impairment exist. We have not recognized any impairment losses on intangible assets.

Restructuring

We recognize a liability for costs associated with an exit or disposal activity under a restructuring project when the plan has been finalized. Employee termination benefits considered as post-employment benefits are accrued when the obligation is probable and estimable, such as benefits stipulated by human resource policies and practices or statutory requirements. One-time termination benefits are recognized at the date the employee is notified. If the employee must provide future service greater than 60 days, such benefits are recognized ratably over the future service period.

Asset impairments associated with a restructuring project are determined at the asset group level. An impairment may be recognized for assets that are to be abandoned or are to be sold for less than net book value. We may also recognize impairment on an asset group, which is held and used, when the carrying value is not recoverable and exceeds the asset group’s fair value. If the sale of an asset group under a restructuring project results in proceeds that exceed the net book value of the asset group, the resulting gain is recognized within restructuring expense in the statements of operations.

On June 17, 2016, we announced that we were consolidating our South San Francisco, California laboratory operations into our Seattle, Washington location to recognize cost savings. The transition of activities was completed in April 2017.

Leases

Operating Lease Arrangements

We have operating lease agreements for the laboratory and office facilities that we occupy. Rent expense is recognized on a straight-line basis over the terms of the leases. Incentives granted under our facilities leases, including rent holidays, are capitalized and are recognized as adjustments to rent expense on a straight-line basis over the terms of the leases.

Lease Financing Arrangements

Due to our significant involvement during the construction process of a leased building, we qualify as the deemed owner of the building under build-to-suit lease accounting guidance. The cost of the related building is recorded in property and equipment, net and the offsetting lease financing obligation is recorded as a long-term financing obligation on our balance sheet. As of December 31, 2019, $36.6 million of building costs have been recorded in property and equipment, net.

Fair Value of Financial Instruments

The Financial Accounting Standards Board ("FASB") has defined fair value as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date. The FASB established a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The hierarchy defines three levels of inputs that may be used to measure fair value:

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities

A financial instrument categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Our financial instruments consist of Level 1 and Level 2 assets, and has included Level 3 liabilities in the past. In certain cases, where there is limited activity or less transparency around inputs to valuation, financial instruments are classified as Level 3 within the valuation hierarchy. The carrying amounts of certain financial instruments approximate fair value due to their short maturities.

We did not have any nonfinancial assets or liabilities that were measured or disclosed at fair value on a recurring basis as of December 31, 2019 or 2018.

Convertible Preferred Stock Warrant Liability

We had issued a freestanding warrant to a venture capital firm to purchase 56,875 shares of Series C convertible preferred stock with an exercise price of $2.64 in connection with a $5.0 million credit facility entered into in 2014. Immediately prior to and in connection with the completion of our initial public offering, the convertible preferred stock warrant converted to a common stock warrant.

Prior to the conversion, the fair value of this warrant was classified as a non-current liability in the balance sheets, since the underlying convertible preferred stock had been classified as temporary equity instead of shareholders' deficit in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities. Upon certain change in control events that were outside of our control, including liquidation, sale or transfer of control, holders of the convertible preferred stock may have caused its redemption. Prior to conversion, the warrant was subject to remeasurement at each balance sheet date, with changes in estimated fair value recognized as a component of interest and other income, net on the statements of operations. During the year ended December 31, 2019, we recognized $2.3 million of expense related to the revaluation of the convertible preferred stock warrant liability in the interest and other income, net line item on our statements of operations.

When the convertible preferred stock warrant converted to a common stock warrant immediately prior to and in connection with the completion of the initial public offering, the $2.6 million financial liability was reclassified to the additional paid-in capital line item on our December 31, 2019 balance sheet, thereby concluding the need for revaluation.

Revenue Recognition

We recognize revenue in accordance with Accounting Standards Codification ("ASC") Topic 606 ("ASC 606"), *Revenue from Contracts with Customers*. Under ASC 606, for all revenue-generating contracts, we perform the following steps to determine the amount of revenue to be recognized: (1) identify the contract or contracts; (2) determine whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (3) measure the transaction price, including the constraint on variable consideration; (4) allocate the transaction price to the performance obligations based on estimated selling prices; and (5) recognize revenue when (or as) we satisfy each performance obligation. The following is a summary of the application of the respective model to each of our revenue classifications.

Overview

Our revenue is generated from immunosequencing ("sequencing") products and services ("sequencing revenue") and from regulatory or development support services leveraging our immune medicine platform ("development revenue"). When revenue generating contracts have elements of both sequencing revenue and development revenue, we allocate revenue based on the nature of the performance obligation and the allocated transaction price.

Sequencing Revenue

Sequencing revenue reflects the amounts generated from providing sequencing services and testing through our immunoSEQ and clonoSEQ products and services to our research and clinical customers, respectively.

For research customers, contracts typically include an amount billed in advance of services ("upfront"), and subsequent billings as sample results are delivered to the customer. Upfront amounts received are recorded as deferred revenue, which we recognize as revenue upon satisfaction of performance obligations. We have identified two typical performance obligations under the terms of our research service contracts: sequencing services and related data analysis. We recognize revenue for both identified performance obligations as sample results are delivered to the customer.

For other research customers who choose to purchase a research use only kit, the kits are sold on a price per kit basis with amounts payable upon delivery of the kit. Payments received are recorded as deferred revenue. For these customers, we have identified one performance obligation: the delivery of sample results. We recognize revenue as the results are delivered to the customer based on a proportion of the estimated samples that can be reported on for each kit.

For clinical customers, we derive revenues from providing our clonoSEQ test report to ordering physicians, and we bill and receive payments from commercial third-party payors and medical institutions. In these transactions, we have identified one performance obligation: the delivery of a clonoSEQ report. As payment from the respective payors may vary based on the various reimbursement rates and patient responsibilities, we consider the transaction price to be variable and record an estimate of the transaction price, subject to the constraint for variable consideration, as revenue at the time of delivery. The estimate of transaction price is based on historical and expected reimbursement rates with the various payors, which are monitored in subsequent periods and adjusted as necessary based on actual collection experience.

In January 2019, clonoSEQ received Medicare coverage aligned with the FDA label and National Comprehensive Cancer Network ("NCCN") guidelines for longitudinal monitoring in multiple myeloma ("MM") and B cell acute lymphoblastic leukemia ("ALL"). We bill Medicare for an episode of treatment when we deliver the first eligible test results. This billing contemplates all necessary tests required during a patient's treatment cycle, which is currently estimated at approximately four tests per patient, including the initial sequence identification test. Revenue is recognized at the time the initial billable test result is delivered and is based upon cumulative tests delivered to date. We estimate the number of tests we expect to deliver over a patient's treatment cycle based on historical testing frequencies for patients by indication. These estimates are subject to change as we develop more information about utilization over time. During the year ended December 31, 2019, we recognized $1.6 million relating to the coverage policy; $0.4 million of this revenue was related to tests delivered in periods prior to the year ended December 31, 2019. Any unrecognized revenue from the initial billable test is recorded as deferred revenue and is recognized as we deliver the remaining tests in a patient's treatment cycle.

Development Revenue

We derive revenue by providing services through development agreements to biopharmaceutical customers who seek access to our immune medicine platform technologies. We generate revenues from the delivery of professional support activities pertaining to the use of our proprietary immunoSEQ and clonoSEQ services in the development of the respective customers' initiatives. The transaction price for these contracts may consist of a combination of non-refundable upfront fees, separately priced sequencing fees, progress based milestones and regulatory milestones. The development agreements may include single or multiple performance obligations depending on the contract. For certain contracts, we may perform services to support the biopharmaceutical customers' regulatory submission as part of their registrational trials. These services include regulatory support pertaining to our technology intended to be utilized as part of the submission, development of analytical plans for our sequencing data, participation on joint research committees and assistance in completing a regulatory submission. Generally, these services are not distinct within the context of the contract, and they are accounted for as a single performance obligation.

When sequencing services are separately priced customer options, we assess if a material right exists and, if not, the customer option to purchase additional sequencing services is not considered part of the contract. Except for any non-refundable upfront fees, the other forms of compensation represent variable consideration. Variable consideration related to progress based and regulatory milestones is estimated using the most likely amount method where variable consideration is constrained until it is probable that a significant reversal of cumulative revenue recognized will not occur. Progress milestones such as the first sample result delivered or final patient enrollment in a customer trial are customer dependent and are included in the transaction price when the respective milestone is probable of occurring. Milestone payments that are not within our customers' control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. Determining whether regulatory milestone payments are probable is an area that requires significant judgment. In making this assessment, we evaluate scientific, clinical, regulatory and other risks that must be managed, as well as the level of effort and investment required to achieve the respective milestone.

The primary method used to estimate standalone selling price for performance obligations is the adjusted market assessment approach. Using this approach, we evaluate the market in which we sell our services and estimate the price that a customer in that market would be willing to pay for our services. We recognize revenue using either an input or output measure of progress that faithfully depicts performance on a contract, depending on the contract. The measure used is dependent on the nature of the service to be provided in each contract. Selecting the measure of progress and estimating progress to date requires significant judgment.

Deferred Offering Costs

Deferred offering costs consist of fees and expenses incurred in connection with the sale of our common stock in the initial public offering, including legal, accounting, printing and other initial public offering-related costs. Prior to the completion of our initial public offering, deferred offering costs were presented in the restricted cash and other assets line item on our balance sheets. In connection with and as of the closing of our initial public offering, these costs were reclassified to additional paid-in capital, representing a reduction to the initial public offering proceeds. As of December 31, 2019, $5.0 million of these initial public offering-related costs are included in the additional paid-in capital line item on our balance sheet.

Contract Balances

In certain circumstances, billing may occur prior to services being performed. Upfront payments are recorded as deferred revenue, contract liabilities. We classify deferred revenue as current for sequencing revenue, as we expect our performance obligations will be completed within the next twelve months; however, we do not control the timing of customer provided samples. For development services, we assess the performance obligations and recognize deferred revenue as current or non-current based upon forecasted delivery times, which are customer coordinated. In certain circumstances, the customer project may be cancelled or terminated prior to the delivery of all related services covered by a customer's upfront payment. In these circumstances, we recognize revenue when sufficient evidence is obtained that a reversal of revenue is not probable.

Share-Based Compensation

Share-based compensation includes compensation expense for stock option and restricted stock unit ("RSU") grants to employees and non-employees. It represents the grant date fair value of the grants and is recognized over the requisite service period of the awards, usually the vesting period, on a straight-line basis, net of actual forfeitures. We estimate the fair value of stock option grants using the Black-Scholes option-pricing model.

Advertising

Advertising costs are expensed as incurred. Advertising expenses were $6.6 million, $3.5 million and $1.8 million for the year ended December 31, 2019, 2018 and 2017, respectively.

Cost of Revenue

Cost of revenue includes the cost of materials, personnel-related expenses (comprised of salaries, benefits and share-based compensation), shipping and handling, equipment and allocated facility costs associated with processing samples and professional support for our sequencing revenue. Allocated facility costs include depreciation of laboratory equipment, allocated facility occupancy and information technology costs. Costs associated with processing samples are recorded as expense, regardless of the timing of revenue recognition.

Research and Development Expenses

Research and development expenses are comprised of laboratory materials costs, personnel-related expenses, allocated facility costs, information technology and contract service expenses. Research and development costs are expensed as incurred. Upfront payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized, then are recognized as an expense as the goods are consumed or the related services are performed.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of personnel-related expenses for commercial sales, account management, marketing, reimbursement, medical education and business development personnel that support commercialization of our platform products. In addition, these expenses include external costs such as advertising expenses, customer education and promotional expenses, market analysis expenses, conference fees, travel expenses and allocated facility costs.

Income Taxes

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and the operating loss and tax credit carryforwards. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

Deferred tax assets and liabilities are measured at the balance sheet date using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities due to a change in tax rates is recognized in the period such tax rate changes are enacted. Our net deferred tax assets are fully offset by a valuation allowance, because of our history of losses.

We recognize interest and penalties related to income tax matters as a component of tax expense.

Net Loss Per Share Attributable to Common Shareholders

We calculate our basic and diluted net loss per share attributable to common shareholders in conformity with the two-class method required for companies with participating securities. Prior to the conversion of our convertible preferred stock into common stock in connection with our initial public offering, we considered our convertible preferred stock to be participating securities. In the event a dividend is declared or paid on common stock, holders of convertible preferred stock were entitled to a share of such dividend in proportion to the holders of common stock on an as-if converted basis. Under the two-class method, basic net loss per share attributable to common shareholders is calculated by dividing the net loss attributable to common shareholders by the weighted-average number of shares of common stock outstanding for the period. Net loss attributable to common shareholders is determined by allocating undistributed earnings between common and preferred shareholders. The net loss attributable to common shareholders was not allocated to the convertible preferred stock under the two-class method, as the convertible preferred stock did not have a contractual obligation to share in our losses. The diluted net loss per share attributable to common shareholders is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, convertible preferred stock, common stock warrants and stock options are considered common stock equivalents but have been excluded from the calculation of diluted net loss per share attributable to common shareholders, as their effect is anti-dilutive.

Segment Information

We have determined that our chief executive officer is the chief operating decision maker ("CODM"). The CODM reviews financial information presented on a regular basis at the entity level. Resource allocation decisions are made by the CODM based on the results at the entity level, which is determined to be a single reporting unit. There are no segment managers who are held accountable by the CODM for operations, operating results or planning for levels or components below the entity. As such, we have concluded that we operate as one segment. We present disaggregated revenue from contracts with customers by type of service. See Note 3, Revenue.

Recently Adopted Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, *Compensation—Stock Compensation* (Topic 718), intended to simplify the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statements of cash flows. This guidance also allowed for an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. We adopted this guidance as of January 1, 2018 and elected to account for forfeitures as they occur. We utilized a modified retrospective transition method, recorded the cumulative impact of applying this guidance and recognized a cumulative increase to additional paid-in capital and an increase to accumulated deficit of $0.1 million.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles—Goodwill and Other* (Topic 350): *Simplifying the Test for Goodwill Impairment*, intended to simplify the goodwill impairment test. Under the new guidance, goodwill impairment is measured by the amount by which the carrying value of a reporting unit exceeds its fair value, without exceeding the carrying amount of goodwill allocated to that reporting unit. This guidance is effective January 1, 2022 and is required to be adopted on a prospective basis, with early adoption permitted. We adopted this guidance as of January 1, 2018 and the adoption did not have any impact on our financial statements.

In June 2018, the FASB issued ASU 2018-07, C*ompensation—Stock Compensation* (Topic 718): *Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance is effective for us beginning in 2019, with early adoption permitted. We adopted the guidance effective January 1, 2019 and the adoption did not have any impact on our financial statements.

New Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842), intended to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheets and disclosing key information about leasing arrangements. This guidance is effective for us in fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. We have the transition option of retrospectively adjusting prior periods presented or adopting with a cumulative adjustment to retained earnings on the date of adoption. Although we are currently determining the incremental borrowing rate to use and evaluating the impact that adopting this guidance will have on our financial statements, we expect to recognize the right-of-use assets and related lease liabilities related to our operating leases on the balance sheets, which will be based largely on the present value of future minimum lease payments of approximately $54.1 million, excluding our to-be-constructed building lease. Additionally, assuming we do not control the leased building currently being constructed at the date of adoption, we will derecognize the existing asset and liability created in accordance with build-to-suit lease accounting guidance under ASC 840, *Leases*. We will then classify the lease as of the lease commencement date in accordance with the adopted guidance.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses* (Topic 326): *Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. The guidance is effective for us beginning in 2020, with early adoption permitted. Although we are currently evaluating the impact that adopting this guidance prospectively will have on our financial statements, we do not expect the adoption to have a material impact on our financial statements.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles—Goodwill and Other: Internal-Use Software* (Subtopic 350-40), to provide additional guidance on the accounting for costs of implementation activities performed in a cloud computing arrangement. This guidance is effective for fiscal years beginning after December 15, 2019 and early adoption of the amendments in this update are permitted. Furthermore, it can be applied either retrospectively or prospectively. We do not expect the adoption of this guidance to have a material impact on our financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes* (Topic 740): *Simplifying the Accounting for Income Taxes*, which eliminates certain exceptions to the guidance in Accounting Standards Codification 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. Among other things, this guidance also clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. This guidance is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. Early adoption is permitted, and the guidance is to be applied prospectively, except for certain amendments. We do not expect the adoption of this guidance to have a material impact on our financial statements.

3. Revenue

We disaggregate our revenue from contracts with customers by type of service, as we believe this best depicts how the nature, amount, timing and uncertainty of our revenue and cash flows are affected by economic factors. The following table presents our revenue disaggregated by type of products and services for the periods presented (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Sequencing revenue	$ 43,519	$ 32,978	$ 22,759
Development revenue			
Development support	39,552	12,685	15,689
Regulatory milestones	2,000	10,000	—
Total development revenue	41,552	22,685	15,689
Total revenue	$ 85,071	$ 55,663	$ 38,448

Translational Development Agreements

On December 18, 2015, we entered into a translational development agreement with a biopharmaceutical customer for access to certain of our oncology immunosequencing research datasets, including full-time employee support, to accelerate the customer's preclinical, nonclinical and clinical trial testing. Under the initial terms of the agreement, we could be entitled to up to $40.0 million over a period of four years, which does not include any separately negotiated research sequencing contracts. If the biopharmaceutical customer terminates the agreement prior to the end of the initial four-year research term for any reason other than a material uncured breach by us, then the biopharmaceutical partner has agreed to pay us $0.8 million. In May 2019, the agreement was subsequently amended to reduce the services provided, which in turn reduced the fourth year of eligible payments to $2.3 million.

We identified one performance obligation under this agreement, as the services were determined to be highly interrelated. We determined that any separately negotiated sequencing contracts are not performance obligations under the contract, as the contract did not contain any material rights related to such sequencing contracts. For the identified performance obligation, we assessed the work to be performed over the duration of the contract and determined that it is a consistent level of support throughout the period, and therefore, revenue has been recognized on a straight-line basis over the contract term.

Revenue recognized from this translational development agreement, excluding separately negotiated research sequencing contracts, was $2.3 million, $9.3 million and $10.0 million during the year ended December 31, 2019, 2018 and 2017, respectively.

MRD Development Agreements

We have entered into agreements with biopharmaceutical customers to further develop and commercialize clonoSEQ and the biopharmaceutical customers' therapeutics. Under each of the agreements, we received or will receive non-refundable upfront payments and could receive substantial additional payments upon reaching certain progress milestones or achievement of certain regulatory milestones pertaining to the customers' therapeutic and our clonoSEQ test.

Under the contracts, we identify performance obligations, which may include: (1) obligations to provide services supporting the customer's regulatory submission activities as they relate to our clonoSEQ test; and (2) sequencing services for customer-provided samples for their regulatory submissions. The transaction price allocated to the respective performance obligations is estimated using an adjusted market assessment approach for the regulatory support services and a standalone selling price for the estimated immunosequencing services. At contract inception, we fully constrained any consideration related to the regulatory milestones, as the achievement of such milestones is subject to third-party regulatory approval and the customers' own submission decision-making. We recognize revenue relating to the sequencing services as sequencing revenue over time using an output method based on the proportion of sample results delivered relative to the total amount of sample results expected to be delivered and when expected to be a faithful depiction of progress. We use the same method to recognize the regulatory support services. When an output method based on the proportion of sample results delivered is not expected to be a faithful depiction of progress, we utilize an input method based on estimates of effort completed using a cost-based model.

We earned $2.0 million and $10.0 million during the year ended December 31, 2019 and 2018, respectively, in regulatory milestones upon the achievement of regulatory milestones by us and our respective customers' therapeutics. We recognized $3.7 million, $12.8 million and $5.1 million in development revenue related to these contracts, inclusive of the milestones, during the year ended December 31, 2019, 2018 and 2017, respectively.

As of December 31, 2019, in future periods we could receive up to an additional $220.0 million in milestone payments if certain regulatory approvals are obtained by our customers' therapeutics in connection with MRD data generated from our clonoSEQ test.

Genentech Collaboration Agreement

In December 2018, we entered into a worldwide collaboration and license agreement ("Genentech Agreement") with Genentech, Inc. ("Genentech") to leverage our capability to develop cellular therapies in oncology. Subsequent to receipt of regulatory approval in January 2019, we received a non-refundable upfront payment of $300.0 million in February 2019 and may be eligible to receive more than $1.8 billion over time, including payments of up to $75.0 million upon the achievement of specified regulatory milestones, up to $300.0 million upon the achievement of specified development milestones and up to $1,430.0 million upon the achievement of specified commercial milestones. In addition, we are separately able to receive tiered royalties at a rate ranging from the mid-single digits to the mid-teens on aggregate worldwide net sales of products arising from the strategic collaboration, subject to certain reductions, with aggregate minimum floors. Under the agreement, we are pursuing two product development pathways for novel T cell immunotherapies in which Genentech intends to use T cell receptors ("TCRs") screened by our immune medicine platform to engineer and manufacture cellular medicines:

- Shared Products. The shared products will use "off-the-shelf" TCRs identified against cancer antigens shared among patients ("Shared Products").
- Personalized Product. The personalized product will use patient-specific TCRs identified by real-time screening of TCRs against cancer antigens in each patient ("Personalized Product").

Under the terms of the agreement, we granted Genentech exclusive worldwide licenses to develop and commercialize TCR-based cellular therapies in the field of oncology, including licenses to existing shared antigen data packages. Additionally, Genentech has the right to determine which product candidates to further develop for commercialization purposes. We determined that this arrangement meets the criteria set forth in ASC Topic 808, *Collaborative Arrangements* ("ASC 808"), because both parties are active participants in the activity and are exposed to significant risks and rewards depending on the activity's commercial failure or success. Because ASC 808 does not provide guidance on how to account for the activities under a collaborative arrangement, we applied the guidance in ASC 606 to account for the activities related to the Genentech collaboration.

In applying ASC 606, we identified the following performance obligations at the inception of the agreement:

1. License to utilize on an exclusive basis all TCR-specific platform intellectual property to develop and commercialize any licensed products in the field of oncology.
2. License to utilize all data and information within each shared antigen data package and any other know-how disclosed by us to Genentech in oncology.
3. License to utilize all private antigen TCR product data in connection with research and development activities in the field of use.
4. License to existing shared antigen data packages.
5. Research and development services for shared product development including expansion of shared antigen data packages.
6. Research and development services for private product development.
7. Obligations to participate on various joint research, development and project committees.

We determined that none of the licenses, research and development services or obligations to participate on various committees were distinct within the context of the contract given such rights and activities were highly interrelated and there was substantial additional research and development to further develop the licenses. We considered factors such as the stage of development of the respective existing antigen data packages, the subsequent development that would be required to both identify and submit a potential target for investigational new drug acceptance under both product pathways and the variability in research and development pathways given Genentech's control of product commercialization. Specifically, under the agreement, Genentech is not required to pursue development or commercialization activities pertaining to both product pathways and may choose to proceed with one or the other as opposed to both. Accordingly, we determined that all of the identified performance obligations were attributable to one general performance obligation, which is to further the development of our TCR-specific platform, including data packages, and continue to make our TCR identification process available to Genentech to pursue either product pathway.

Separately, we have a responsibility to Genentech to enter into a supply and manufacturing agreement for patient specific TCRs as it pertains to any Personalized Product therapeutic. We determined this was an option right of Genentech should they pursue commercialization of a Personalized Product therapy. Because of the uncertainty as a result of the early stage of development, the novel approach of our collaboration with Genentech and our rights to future commercial milestones and royalty payments, we determined that this option right was not a material right that should be accounted for at inception. As such, we will account for the supply and manufacturing agreement when entered into between the parties.

We determined the initial transaction price shall be made up of only the $300.0 million upfront, non-refundable payment, as all potential regulatory and development milestone payments were probable of significant revenue reversal since their achievement was highly dependent on factors outside our control. As a result, these payments were fully constrained and were not included in the transaction price as of December 31, 2019. We excluded the commercial milestones and potential royalties from the transaction price, as those items relate predominantly to the license rights granted to Genentech and will be assessed when and if such events occur.

As there are potential substantive developments necessary, which Genentech may be able to direct, we determined that we would apply a proportional performance model to recognize revenue for our performance obligation. We measure proportional performance using an input method based on costs incurred relative to the total estimated costs of research and development efforts to pursue both the Shared Product and Personalized Product pathways. We currently expect to recognize the revenue over a period of approximately seven to eight years from the effective date. This estimate of the research and development period considers pursuit options of development activities supporting both the Shared Product and the Personalized Product, but may be reduced or increased based on the various activities as directed by the joint committees, decisions made by Genentech, regulatory feedback or other factors not currently known.

We recognized revenue of $35.1 million during the year ended December 31, 2019 related to the Genentech collaboration. Costs related to the Genentech collaboration are included in research and development expenses.

4. Fair Value Measurements

The following tables set forth the fair value of financial assets and liabilities as of December 31, 2019 and 2018 that were measured at fair value on a recurring basis (in thousands):

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Financial assets				
Money market funds	$ 88,683	$ —	$ —	$ 88,683
Commercial paper	—	121,867	—	121,867
U.S. government debt and agency securities	—	377,243	—	377,243
Corporate bonds	—	86,615	—	86,615
Total financial assets	$ 88,683	$ 585,725	$ —	$ 674,408

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Financial assets				
Money market funds	$ 45,998	$ —	$ —	$ 45,998
Commercial paper	—	16,887	—	16,887
U.S. government debt and agency securities	—	85,623	—	85,623
Corporate bonds	—	7,478	—	7,478
Total financial assets	$ 45,998	$ 109,988	$ —	$ 155,986
Financial liabilities				
Convertible preferred stock warrant liability	$ —	$ —	$ 336	$ 336
Total financial liabilities	$ —	$ —	$ 336	$ 336

Level 1 securities include highly liquid money market funds, which we measure the fair value based on quoted prices in active markets for identical assets or liabilities. Level 2 securities consist of U.S. government debt securities, U.S. government agency securities, commercial paper and corporate bonds, and are valued based on recent trades of securities in inactive markets or based on quoted market prices of similar instruments and other significant inputs derived from or corroborated by observable market data. Level 3 liabilities that were measured at fair value on a recurring basis consisted of a convertible preferred stock warrant liability.

The fair value of the convertible preferred stock warrant liability was last calculated as of June 30, 2019, prior to reclassification to shareholders' equity in connection with the completion of our initial public offering on July 1, 2019. The fair value was estimated using the Black-Scholes option-pricing model with the following inputs: (1) a fair value estimate of $48.30, (2) an expected term of 1.8 years, (3) a risk-free interest rate of 1.8%, (4) an expected volatility of 61.1% and (5) an expected dividend yield of zero. As of December 31, 2018, the fair value of the convertible preferred stock warrant liability was estimated using the Black-Scholes option-pricing model with the following inputs:

	December 31, 2018
Fair value estimate	$ 8.27
Expected term (in years)	2.31
Risk-free interest rate	2.5%
Expected volatility	55.3%
Expected dividend yield	—

5. Investments

Available-for-sale investments consisted of the following as of December 31, 2019 and 2018 (in thousands):

	December 31, 2019			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Short-term marketable securities				
Commercial paper	$ 121,866	$ —	$ —	$ 121,866
U.S. government debt and agency securities	285,963	394	(1)	286,356
Corporate bonds	71,962	109	(3)	72,068
Total short-term marketable securities	$ 479,791	$ 503	$ (4)	$ 480,290
Long-term marketable securities				
U.S. government debt and agency securities	$ 90,750	$ 146	$ (9)	$ 90,887
Corporate bonds	14,513	35	—	14,548
Total long-term marketable securities	$ 105,263	$ 181	$ (9)	$ 105,435

	December 31, 2018			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Short-term marketable securities				
Commercial paper	$ 16,887	$ —	$ —	$ 16,887
U.S. government debt and agency securities	85,722	—	(99)	85,623
Corporate bonds	7,486	—	(8)	7,478
Total short-term marketable securities	$ 110,095	$ —	$ (107)	$ 109,988

All the commercial paper, U.S. government debt and agency securities and corporate bonds designated as short-term marketable securities have an effective maturity date that is less than one year from the respective balance sheet date. Those that are designated as long-term marketable securities have an effective maturity date that is more than one year from the respective balance sheet date.

The following table presents the gross unrealized holding losses and fair value for investments in an unrealized loss position, and the length of time that individual securities have been in a continuous loss position, as of December 31, 2019 (in thousands):

	Less Than 12 Months		12 Months Or Greater	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
U.S. government debt and agency securities	$ 30,196	$ (10)	$ —	$ —
Corporate bonds	5,010	(3)	—	—
Total available-for-sale securities	$ 35,206	$ (13)	$ —	$ —

We evaluated our securities for other-than-temporary impairment and considered the decline in market value for the securities to be primarily attributable to current economic and market conditions. It is not more likely than not that we will be required to sell the securities, and we do not intend to do so prior to the recovery of the amortized cost basis. Based on this analysis, these marketable securities were not considered to be other-than-temporarily impaired as of December 31, 2019.

6. Property and Equipment, Net

Property and equipment as of December 31, 2019 and 2018 consisted of the following (in thousands):

	December 31,	
	2019	2018
Laboratory equipment	$ 20,773	$ 14,009
Computer equipment	2,450	1,819
Furniture and office equipment	1,568	1,300
Computer software	505	429
Construction in progress	1,852	3,942
Leasehold improvements	14,716	10,078
Build-to-suit asset cost	36,607	—
Property and equipment, at cost	78,471	31,577
Less: accumulated depreciation	(18,116)	(12,452)
Property and equipment, net	$ 60,355	$ 19,125

Depreciation expense was $6.1 million, $4.3 million and $4.1 million for the years ended December 31, 2019, 2018 and 2017, respectively.

7. Goodwill and Intangible Assets

There have been no changes in the carrying amount of goodwill since its recognition in 2015.

Intangible assets subject to amortization as of December 31, 2019 and 2018 consisted of the following (in thousands):

	December 31, 2019		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquired developed technology	$ 20,000	$ (8,301)	$ 11,699
Purchased intellectual property	325	(96)	229
Balance at December 31, 2019	$ 20,325	$ (8,397)	$ 11,928

	December 31, 2018		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquired developed technology	$ 20,000	$ (6,636)	$ 13,364
Purchased intellectual property	325	(63)	262
Balance at December 31, 2018	$ 20,325	$ (6,699)	$ 13,626

The developed technology was acquired in connection with our acquisition of Sequenta, Inc. (“Sequenta”) in 2015. The remaining balance of the acquired technology and the purchased intellectual property is expected to be amortized over the next 7.0 years.

As of December 31, 2019, expected future amortization expense for intangible assets was as follows (in thousands):

2020	$ 1,703
2021	1,699
2022	1,699
2023	1,699
2024	1,703
Thereafter	3,425
Total future amortization expense	$ 11,928

8. Accrued Liabilities

Accrued liabilities as of December 31, 2019 and 2018 consisted of the following (in thousands):

	December 31, 2019	December 31, 2018
Accrued legal and professional fees	$ 1,041	$ 1,634
Accrued royalties	78	31
Accrued travel and entertainment	157	73
Accrued tax liabilities	2,062	111
Purchases of property and equipment	555	165
Other	478	548
Total accrued liabilities	$ 4,371	$ 2,562

The accrued tax liabilities balance as of December 31, 2019 includes a $1.9 million tax withholding liability related to unsettled option exercises as of December 31, 2019.

9. Deferred Revenue

Deferred revenue by revenue classification as of December 31, 2019 and 2018 was as follows (in thousands):

	December 31, 2019	December 31, 2018
Current deferred revenue		
Sequencing	$ 12,482	$ 11,238
Development	48,512	1,457
Total current deferred revenue	60,994	12,695
Non-current deferred revenue		
Sequencing	1,459	516
Development	217,873	188
Total non-current deferred revenue	219,332	704
Total current and non-current deferred revenue	$ 280,326	$ 13,399

Genentech deferred revenue represents $48.1 million and $216.8 million of the current and non-current development deferred revenue balances, respectively, at December 31, 2019. In general, the current amounts will be recognized as revenue within 12 months and the non-current amounts will be recognized as revenue over a period of approximately seven to eight years. This period of time represents an estimate of the research and development period to develop cellular therapies in oncology, which may be reduced or increased based on the various development activities.

Changes in deferred revenue during the year ended December 31, 2019 were as follows (in thousands):

Deferred revenue balance at December 31, 2018	$ 13,399
Additions to deferred revenue during the period	317,551
Revenue recognized during the period	(50,624)
Deferred revenue balance at December 31, 2019	$ 280,326

As of December 31, 2019, $8.5 million was recognized that was included in the deferred revenue balance at December 31, 2018. As a result of cancelled customer sequencing contracts, we recognized $1.9 million of sequencing revenue during the year ended December 31, 2019.

10. Commitments and Contingencies

Operating Leases

We have entered into various non-cancelable lease agreements for our office and laboratory spaces.

In July 2011, we entered into a non-cancelable lease agreement with an, at the time, minority shareholder for our current headquarters in Seattle, Washington. The lease terms were subsequently amended multiple times, most recently in August 2019, when we expanded the existing premises. Rent obligations of the expanded premises commence four months after the landlord delivers the expanded premises to us for construction of certain tenant improvements, and the lease term for both the existing premises and the expanded premises ends 142 months after the commencement date of the new lease mentioned below, subject to our option to twice extend the lease for five years. If the new lease mentioned below does not commence, the lease term for the existing premises and the expanded premises ends March 31, 2024. The amended lease also requires us to pay additional amounts for operating and maintenance expenses.

In August 2019, we entered into an operating lease to rent 100,000 square feet in a to-be-constructed building in Seattle, Washington. Shell construction is expected to be completed in 2020. The lease term commences on the date that the landlord delivers the premises to us for construction of certain tenant improvements. Rent obligations commence 10 months thereafter, and the lease term ends 142 months from the date rent commences, subject to our option to twice extend the lease for five years. The lease is cancellable under certain circumstances if the landlord fails to deliver the premises to us by May 1, 2021. We plan to occupy the new building in 2021, once interior construction is finished. In connection with the lease, the landlord agreed to fund $20.0 million in improvements. The lease also requires us to pay additional amounts for operating and maintenance expenses. Furthermore, in connection with the lease, we entered into a letter of credit of $2.1 million with one of our existing financial institutions.

In October 2019, we entered into an agreement to lease approximately 14,750 square feet in a separate Seattle, Washington location, pursuant to a lease expiring in October 2029, which is subject to our ability to exercise an early termination right after the third year. In connection with the lease, the landlord has agreed to provide a tenant improvement allowance in the maximum amount of $0.7 million. The lease also requires us to pay additional amounts for operating expenses.

In October 2016, we entered into an agreement to sublease certain laboratory and office space in South San Francisco, California. The lease commenced in October 2016 and terminated in March 2019. The lease required us to pay additional amounts for operating and maintenance expenses.

In April 2018, we entered into a lease agreement to lease space in South San Francisco, California. The lease term is through March 2026 and provides for one five-year option. We will be responsible for our share of allocable operating expenses, tax expenses and utilities cost during the duration of the lease term. In connection with the lease, the landlord funded agreed-upon improvements prior to the lease commencement date of December 12, 2018. The landlord was solely responsible for the $2.4 million cost of such improvements, which we recognized as a leasehold improvement asset that depreciates beginning from the commencement date of the initial lease term, and a corresponding leasehold incentive obligation, which is amortized over the life of the lease.

As of December 31, 2019, future minimum lease payments, exclusive of operating and maintenance costs and inclusive of payments to be made under the financing obligation, were as follows (in thousands):

2020	$	4,352
2021		7,805
2022		11,638
2023		11,320
2024		11,641
Thereafter		97,147
Total future minimum lease payments	$	143,903

Rent expenses, inclusive of operating and maintenance costs, were $5.3 million, $4.1 million and $3.7 million during the year ended December 31, 2019, 2018 and 2017, respectively.

Legal Proceedings

We are subject to claims and assessments from time to time in the ordinary course of business. We will accrue a liability for such matters when it is probable that a liability has been incurred and the amount can be reasonably estimated. When only a range of possible loss can be established, the most probable amount in the range is accrued. If no amount within this range is a better estimate than any other amount within the range, the minimum amount in the range is accrued. We are not currently party to any material legal proceedings.

Indemnification Agreements

In the ordinary course of business, we may provide indemnification of varying scope and terms to vendors, lessors, customers and other parties with respect to certain matters including, but not limited to, losses arising out of breach of our agreements with them or from intellectual property infringement claims made by third parties. In addition, we have entered into indemnification agreements with members of our board of directors and certain of our executive officers that will require us to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments that we could be required to make under these indemnification agreements is, in many cases, unlimited. We have not incurred any material costs as a result of such indemnifications and are not currently aware of any indemnification claims.

11. Shareholders' Equity

Convertible Preferred Stock

Immediately prior to the completion of our initial public offering on July 1, 2019, 93,039,737 shares of convertible preferred stock then outstanding converted into an equivalent number of shares of common stock. As of December 31, 2019, no shares of convertible preferred stock were outstanding.

Preferred Stock

We are authorized to issue 10,000,000 shares of preferred stock, par value $0.0001 per share. As of December 31, 2019, no shares of preferred stock were outstanding.

Common Stock

We are authorized to issue 340,000,000 shares of common stock. Our common stock has a par value of $0.0001, no preferences or privileges and is not redeemable. Holders of our common stock are entitled to one vote for each share of common stock held. The holders of record of outstanding shares of common stock shall be entitled to receive, when, as and if declared, out of funds legally available, such cash and other dividends as may be declared from time to time. As of December 31, 2019, we had 125,238,142 shares of common stock outstanding.

We have reserved shares of common stock for the following as of December 31, 2019:

Shares issuable upon the exercise of outstanding common stock options and the vesting of outstanding common restricted stock units granted	16,651,154
Shares available for future grant under the 2019 Plan	15,396,254
Shares available for future grant under the Employee Stock Purchase Plan	1,551,917
Shares to be issued upon conversion of a common stock warrant	56,875
Total shares of common stock reserved for future issuance	33,656,200

Our 2019 Plan provides for annual increases in the number of shares that may be issued under the 2019 Plan on January 1, 2020 and on each subsequent January 1, thereafter, by a number of shares equal to the lesser of (a) 5% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (b) an amount determined by our board of directors.

Furthermore, our Employee Stock Purchase Plan ("ESPP") provides for annual increases in the number of shares available for issuance under our ESPP on January 1, 2020 and on each January 1, thereafter, by a number of shares equal to the smallest of (a) 1.0% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (b) an amount determined by the board of directors.

On January 1, 2020, our 2019 Plan and ESPP reserves automatically increased by 6,261,907 shares and 1,252,381 shares, respectively.

Common Stock Warrants

In connection with two transactions in 2012 and 2013, we granted warrants to purchase up to 55,032 shares of common stock. These warrants were exercisable at any time for a period of ten years from the date of issuance at a weighted-average exercise price of $0.37, except in the case of a warrant to purchase 20,000 shares of common stock at an exercise price of $0.45 per share that would have expired if unexercised prior to the closing of our initial public offering. On July 1, 2019, we issued 54,792 shares of common stock through both a cash and cashless exercise of the warrants. The impact of these exercises was immaterial to the financial statements.

Separately, in 2014, we issued a warrant to purchase 56,875 shares of Series C convertible preferred stock at an exercise price of $2.64. The warrant was exercisable at any time for a period of seven years from the date of issuance. Immediately prior to and in connection with the completion of our initial public offering, this convertible preferred stock warrant, which was recorded as a financial liability, was converted to a warrant to purchase the same number of shares of common stock. Upon conversion, the financial liability was reclassified to the additional paid-in capital line item on our December 31, 2019 balance sheet. The warrant to purchase 56,875 shares of common stock remains outstanding as of December 31, 2019.

12. Equity Incentive Plans

Sequenta 2008 Stock Plan, as amended

In connection with our acquisition of Sequenta in January 2015, we assumed Sequenta's Equity Incentive Plan ("2008 Plan"), including all outstanding options and shares available for future issuance under the 2008 Plan, which, prior to the completion of our initial public offering, were all exercisable for Series E-1 convertible preferred stock. Upon completion of our initial public offering, outstanding options are now exercisable for common stock. While no shares are available for future issuance under this plan, the 2008 Plan continues to govern outstanding equity awards granted thereunder.

Adaptive 2009 Equity Incentive Plan

We adopted an equity incentive plan in 2009 ("2009 Plan") that provided for the issuance of incentive and nonqualified common stock options, and other share-based awards for employees, directors and consultants. Under the 2009 Plan, the option exercise price for incentive and nonqualified stock options were not to be less than the fair market value of our common stock at the date of grant as determined by our board of directors. Options granted under this plan expire no later than ten years from the grant date, and vesting was established at the time of grant. Pursuant to the terms of the 2019 Plan, any shares subject to outstanding options originally granted under the 2009 Plan that terminate, expire or lapse for any reason without the delivery of shares to the holder thereof shall become available for issuance pursuant to awards granted under the 2019 Plan. While no shares are available for future issuance under the 2009 Plan, it continues to govern outstanding equity awards granted thereunder.

2019 Equity Incentive Plan

The 2019 Plan was approved by our shareholders on June 13, 2019 and, pursuant to the resolutions adopted by our board of directors, became effective with an initial reserve of 15,519,170 shares immediately prior to and contingent upon the closing of our initial public offering. The 2019 Plan provides for the issuance of awards in the form of options and other share-based awards for employees, directors and consultants. Under the 2019 Plan, the option exercise price per share shall not be less than the fair market value of a share of stock on the grant date of the option, as defined by the 2019 Plan, unless explicitly qualified under the provisions of Section 409A or Section 424(a) of the Internal Revenue Code of 1986. Additionally, unless otherwise specified, options granted under this plan expire no later than ten years from the grant date, and vesting is established at the time of grant. Except for certain option grants made to non-employee directors, stock options granted under the 2019 Plan generally vest over a four-year period, subject to continuous service through each applicable vesting date. As of December 31, 2019, we have authorized 15,704,914 shares of common stock for issuance under the 2019 Plan.

Changes in shares available for grant during the year ended December 31, 2019 were as follows:

	Shares Available for Grant
Shares available for grant at December 31, 2018	6,827,996
2009 Plan reserve cancelled	(3,155,968)
2019 Plan reserve established	15,519,170
Options and restricted stock units granted	(4,207,301)
Options and restricted stock units forfeited or cancelled	412,357
Shares available for grant at December 31, 2019	15,396,254

Stock option activity under the 2008 Plan, 2009 Plan and 2019 Plan during the year ended December 31, 2019, 2018 and 2017 was as follows:

	Shares Subject to Outstanding Options	Weighted-Average Exercise Price per Share	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2016	12,919,342	$ 3.28	$ 41,952
Options granted	1,604,496	6.27	
Options forfeited or cancelled	(2,207,933)	5.51	
Options exercised	(226,211)	0.98	
Options outstanding at December 31, 2017	12,089,694	3.56	36,165
Options granted	4,764,625	6.55	
Options forfeited or cancelled	(929,519)	4.86	
Options exercised	(766,870)	1.66	
Options outstanding at December 31, 2018	15,157,930	4.52	41,690
Options granted	4,194,491	9.72	
Options forfeited or cancelled	(412,357)	6.24	
Options exercised	(2,293,410)	1.97	
Options outstanding at December 31, 2019	16,646,654	$ 6.14	$ 398,379
Options vested and exercisable at December 31, 2019	10,101,496	$ 4.58	$ 255,939

The weighted-average remaining contractual life for options outstanding at December 31, 2019 was 6.8 years. The weighted-average remaining contractual life for vested and exercisable options outstanding at December 31, 2019 was 5.5 years.

The weighted-average grant date fair value of options granted was $6.87, $4.15 and $4.00 during the years ended December 31, 2019, 2018 and 2017, respectively. The total intrinsic value of options exercised was $39.1 million, $3.8 million and $1.3 million during the years ended December 31, 2019, 2018 and 2017, respectively.

As of December 31, 2019, $0.5 million was included in the prepaid expenses and other current assets line item on our balance sheet for unsettled cash proceeds related to options exercised during the year ended December 31, 2019.

As of December 31, 2016, there were 880,487 RSUs outstanding. During the year ended December 31, 2017, these RSUs were forfeited due to the related employee's termination prior to the occurrence of both a service and an event condition. During the year ended December 31, 2019, we granted 12,810 shares of RSUs at a weighted-average grant date fair value per share of $41.63; 8,310 of those shares, with a weighted-average grant date fair value per share of $41.63, vested. As of December 31, 2019, 4,500 shares of RSUs, with a weighted-average grant date fair value per share of $41.63, remain nonvested and outstanding.

For valuations of RSU grants made after the closing of our initial public offering, our board of directors determines the fair value of each share of common stock based on the closing price of our common stock on the date of grant or other relevant determination date, as reported on The Nasdaq Global Select Market.

Fair Value of Options Granted

The estimated fair value of options granted during the year ended December 31, 2019, 2018 and 2017 was estimated using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2019	2018	2017
Grant date fair value	$7.80 - $47.81	$6.55	$6.27 - $6.32
Expected term (in years)	5.27 - 6.08	6.08 - 10.00	6.08 - 10.00
Risk-free interest rate	1.4% - 2.5%	2.6% - 3.0%	1.9% - 2.4%
Expected volatility	64.3% - 72.9%	65.0% - 69.2%	67.3% - 70.5%
Expected dividend yield	—	—	—

The weighted-average volatility used in the fair value calculations of options granted during the year ended December 31, 2019, 2018 and 2017 was 68.1%, 68.1% and 70.2%, respectively.

The determination of the fair value of stock options on the date of grant using a Black-Scholes option-pricing model is affected by the estimated fair value of our common stock, as well as assumptions regarding a number of variables that are complex, subjective and generally require significant judgment to determine. The valuation assumptions were determined as follows:

Fair value of common stock—Prior to the closing of our initial public offering, the grant date fair value of our common stock was determined by our board of directors with input from management using valuation methodologies which utilize certain assumptions, including probability weighting of events, volatility, time to liquidation, a risk-free interest rate and an assumption for a discount for lack of marketability (Level 3 inputs). In determining the fair value of our common stock, the methodologies used to estimate the enterprise value were performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. For valuations of grants made after the closing of our initial public offering, our board of directors determines the fair value of each share of common stock based on the closing price of our common stock on the date of grant or other relevant determination date, as reported on The Nasdaq Global Select Market.

Expected term—The expected term of options granted to employees and non-employee directors is determined using the “simplified” method, as illustrated in ASC Topic 718, *Compensation—Stock Compensation*, as we do not have sufficient exercise history to determine a better estimate of expected term. Under this approach, the expected term is based on the midpoint between the vesting date and the end of the contractual term of the option.

Risk-free interest rate—We utilize a risk-free interest rate in the option valuation model based on U.S. Treasury zero-coupon issues, with remaining terms similar to the expected term of the options.

Expected volatility—As we do not have sufficient trading history for our common stock, the expected volatility is based on the historical volatility of our publicly traded industry peers utilizing a period of time consistent with our estimate of the expected term.

Expected dividend yield—We do not anticipate paying any cash dividends in the foreseeable future and, therefore, use an expected dividend yield of zero in the option valuation model.

Share-based compensation expense of $13.1 million, $11.1 million and $7.0 million was recognized during the year ended December 31, 2019, 2018 and 2017, respectively.

The compensation costs related to stock options and RSUs for the year ended December 31, 2019, 2018 and 2017, respectively, are included on our statements of operations as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Cost of revenue	$ 555	$ 398	$ 237
Research and development	3,934	2,896	2,375
Sales and marketing	3,480	2,891	1,344
General and administration	5,155	4,964	3,053
Total share-based compensation expense	$ 13,124	$ 11,149	$ 7,009

During the year ended December 31, 2018, there was one employee option modification to extend the option exercise period which resulted in incremental stock compensation of $0.5 million. The total grant date fair value of the stock options and RSUs that vested during the years ended December 31, 2019, 2018 and 2017, excluding the impact of modifications, approximated the share-based compensation expense recorded during the respective periods.

At December 31, 2019, unrecognized share-based compensation expense related to unvested stock options was $33.3 million, which is expected to be recognized over a remaining weighted-average period of 2.9 years. Additionally, at December 31, 2019, unrecognized share-based compensation expense related to unvested RSUs was $0.2 million, which is expected to be recognized over a remaining weighted-average period of 0.5 years.

13. Microsoft Collaboration Agreement

Summary of Agreement

In December 2017, we entered into a collaboration agreement with Microsoft Corporation ("Microsoft Agreement") to computationally derive a comprehensive TCR antigen map for purposes of developing a universal diagnostic based on a single blood test.

Contemporaneously with the Microsoft Agreement, we entered into a separate agreement to use Microsoft's Azure cloud services at standard volume pricing with a minimum Azure consumption requirement of $12.0 million over the seven-year term of the Microsoft Agreement, which we expect to meet in the ordinary course of business.

In addition, contemporaneously with entering into the Microsoft Agreement, Microsoft made a preferred stock investment of approximately $45.0 million as a part of our Series F-1 convertible preferred stock issuance.

Summary of Accounting

The terms of the Microsoft Agreement meet the criteria under ASC Topic 808, *Collaborative Arrangements* ("ASC 808"), as both parties are active participants in the activity and are exposed to significant risks and rewards dependent on the commercial success of the activity. ASC 808 does not provide guidance on how to account for the activities under the collaboration, and we determined that Microsoft did not meet the definition of a customer under ASC 606. Accordingly, we looked to other guidance to determine the accounting for the respective elements.

We determined that the preferred stock issuance and commitment to use Microsoft's Azure cloud services were made at terms consistent with market rates. All consideration received as part of the Series F-1 convertible preferred stock issuance was accounted for as part of the Series F-1 preferred stock issuance. Since the commitment to use Microsoft's Azure cloud services was at market terms and we expect to meet the commitment in the ordinary course of business during the seven-year term, we record the expenses in the period in which the services are consumed. These costs are recorded in the statement of operations based on the underlying activities for which they support.

The remaining elements of the agreement were highly interrelated, so we evaluated them in the aggregate to determine the appropriate accounting application. Specifically, we determined that the transfer of license rights between the parties, our commitment to provide data and immunomics, diagnostic and bioinformatics expertise to Microsoft and Microsoft's commitment to provide machine learning software and related development services to us were highly interrelated because they were necessary for the parties to perform the activities under the Microsoft Agreement and, therefore, should be evaluated as one unit of account.

We accounted for these collaboration activities by analogy to ASC Topic 845, *Nonmonetary Transactions*, and determined that major uncertainties exist about the realizability of the value that would be assigned to an asset received from or provided to Microsoft under the collaboration and, therefore, fair value could not be reliably measured. As a result, we did not recognize any non-monetary assets or corresponding non-monetary income or expenses pertaining to the rights provided to us or to be received by us under the Microsoft Agreement.

14. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The significant components of our deferred tax assets and liabilities for the periods presented are as follows (in thousands):

	December 31,	
	2019	2018
Deferred tax assets		
Net operating losses	$ 79,035	$ 56,555
Tax credit carryforward	11,152	6,709
Non qualifying stock options	9,150	7,861
Deferred rent	11,755	1,925
Other	3,598	2,598
Total deferred tax assets	114,690	75,648
Valuation allowance	(100,906)	(70,722)
Deferred tax assets, net of valuation allowance	13,784	4,926
Deferred tax liabilities		
Tangible and intangible assets	(13,784)	(4,926)
Net deferred taxes	$ —	$ —

ASC Topic 740, *Income Taxes*, requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on our ability to generate sufficient taxable income within the carryforward period. Because of our history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a valuation allowance. The valuation allowance increased by $30.2 million and $14.0 million during the years ended December 31, 2019 and 2018, respectively.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 ("TCJA") was signed into law, making significant changes to the Internal Revenue Code, including a decrease in the federal corporate tax rate from 35% to 21%. Taxpayers are required to recognize the effect of tax law changes in the period of enactment. The re-measurement resulted in a total decrease in these net assets equal to $25.0 million, which was fully offset by a corresponding reduction in the valuation allowance. By December 31, 2018, we completed our assessment of the impact of the changes due to the TCJA and the provisional amounts recorded are final.

Federal tax laws impose substantial restrictions on the utilization of net operating loss and credit carryforwards in the event of an ownership change, as defined in Section 382 of the Internal Revenue Code. Accordingly, our ability to utilize these carryforwards may be limited due to such ownership change. We have completed a Section 382 analysis for approximately $225.4 million of our federal operating losses and there are no permanent limitations on the utilization of our federal net operating losses as of December 31, 2018. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. Net operating losses generated prior to 2018 are eligible to be carried forward up to 20 years. As of December 31, 2019, we had U.S. federal net operating losses of $65.1 million and U.S. federal tax credits of $11.0 million. The tax credit and net operating loss carryforwards will begin to expire in 2028.

The effective tax rate of our provision for income taxes differs from the federal statutory rate for the periods presented as follows:

	Year Ended December 31,		
	2019	2018	2017
Statutory rate	21.0%	21.0%	34.0%
State tax	8.1	5.5	1.8
Stock compensation	9.8	0.5	(1.7)
Permanent items	(1.0)	0.5	(0.1)
Credits	6.1	2.7	2.7
TCJA change in federal rate	—	—	(58.4)
Other	0.3	0.1	(0.6)
Change in valuation allowance	(44.3)	(30.3)	22.3
Total	0.0%	0.0%	0.0%

We recognize, in our financial statements, the effect of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. We had unrecognized tax benefits of approximately $2.1 million as of December 31, 2019. A reconciliation of the beginning and ending amounts of unrecognized tax benefits during the years ended December 31, 2019, 2018 and 2017 are as follows (in thousands):

Balance at December 31, 2016	$ 844
Additions in 2017	187
Balance at December 31, 2017	1,031
Additions in 2018	229
Balance at December 31, 2018	1,260
Additions in 2019	792
Balance at December 31, 2019	$ 2,052

Unrecognized tax benefits may change during the next twelve months for items that arise in the ordinary course of business. We do not anticipate a material change to our unrecognized tax benefits over the next twelve months that would have an adverse effect on our operating results.

We recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. We had no accrued interest or penalties related to uncertain tax positions as of December 31, 2019 and 2018.

We file federal and certain state income tax returns, which provide varying statutes of limitations on assessments. However, because of net operating loss carryforwards, substantially all tax years since inception remain open to federal and state tax examination.

15. Net Loss Per Share Attributable to Common Shareholders

Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per share attributable to common shareholders for the year ended December 31, 2019, 2018 and 2017, respectively (in thousands, except share and per share amounts):

	Year Ended December 31,		
	2019	2018	2017
Net loss	$ (68,606)	$ (46,447)	$ (42,831)
Fair value adjustments to redemption value for Series E-1 convertible preferred stock options	(964)	102	135
Net loss attributable to common shareholders, basic and diluted	$ (69,570)	$ (46,345)	$ (42,696)
Weighted-average shares used in computing net loss per share	69,165,315	12,629,778	12,196,998
Net loss per share attributable to common shareholders, basic and diluted	$ (1.01)	$ (3.67)	$ (3.50)

Since we were in a loss position for all periods presented, basic net loss per share attributable to common shareholders is the same as diluted net loss per share attributable to common shareholders, as the inclusion of all potential shares of common stock outstanding would have been anti-dilutive. The following weighted-average common stock equivalents were excluded from the calculation of diluted net loss per share attributable to common shareholders for the year ended December 31, 2019, 2018 and 2017, respectively, as they had an anti-dilutive effect:

	Year Ended December 31,		
	2019	2018	2017
Convertible preferred stock (on as if converted basis)	46,104,469	92,783,867	88,473,431
Stock options issued and outstanding	17,183,546	14,701,626	12,644,926
Unvested restricted stock units	4,952	—	—
Common stock warrants	55,961	55,032	55,032
Convertible preferred stock warrants	28,204	56,875	56,875
Total	63,377,132	107,597,400	101,230,264

16. Retirement Plan

We maintain a salary deferral 401(k) plan ("401(k) Plan"), covering employees who have met certain eligibility requirements. Employees may defer up to 100% of their compensation to the 401(k) Plan, subject to federal limits. We did not make any discretionary contributions during the years ended December 31, 2019, 2018 and 2017.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable**.**

Item 9A. Controls and Procedures

Evaluation of disclosure controls and procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15 under the Exchange Act as of December 31, 2019. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2019.

Management's annual report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on that assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2019 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP.

This Annual Report on Form 10-K does not include an attestation report of the company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in internal control

There was not any change in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) under the Exchange Act, during the three months ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable**.**

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 of Form 10-K will be included in our definitive proxy statement to be filed with the SEC in connection with the solicitation of proxies for our 2020 Annual Meeting of Shareholders ("2020 Proxy Statement") and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 of Form 10-K will be included in our 2020 Proxy Statement 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 of Form 10-K, including with respect to or equity compensation plans, will be included in our 2020 Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 of Form 10-K will be included in our 2020 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 of Form 10-K will be included in our 2020 Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) All Financial Statements

See Index to Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

All financial statement schedules have been omitted since the required information was not applicable or was not present in amounts sufficient to require submission of the schedules, or because the information required is included in the financial statements or the accompanying notes.

(3) Exhibits

The exhibits listed in the following Index to Exhibits are filed, furnished or incorporated by reference as part of this Annual Report on Form 10-K.

Index to Exhibits

Exhibit Number	Exhibit Title	Filed/Furnished With This Report	Incorporated by Reference			
			Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Articles of Incorporation		8-K	001-38957	3.1	7/1/2019
3.2	Amended and Restated Bylaws		8-K	001-38957	3.2	7/1/2019
4.1	Seventh Amended and Restated Investors' Rights Agreement among the Registrant and certain of its shareholders, dated May 30, 2019		S-1	333-231838	4.1	5/30/2019
4.2	Warrant dated April 21, 2014, issued by the Registrant to Alexandria Equities, LLC		S-1	333-231838	4.4	5/30/2019
4.3	Description of Securities	X				
10.1†	Strategic Collaboration and License Agreement between Genentech, Inc. and the Registrant, dated December 19, 2018		S-1	333-231838	10.1	5/30/2019
10.2†	Strategic Collaboration Agreement between Microsoft Corporation and the Registrant, dated December 11, 2017		S-1	333-231838	10.2	5/30/2019
10.3†	Master Terms & Conditions of Sale between Illumina, Inc. and the Registrant, dated May 28, 2019		S-1/A	333-231838	10.3	6/17/2019
10.4	Amended and Restated Side Letter Agreement among Viking Global Equities LP, Viking Global Equities II LP, VGE III Portfolio Ltd., Viking Long Fund Master Ltd. and the Registrant, dated May 8, 2019		S-1	333-231838	10.5	5/30/2019
10.5*	Form of Amended and Restated Employment Agreement between the Registrant and certain of its executive officers		S-1	333-231838	10.7	5/30/2019

Exhibit Number	Exhibit Title	Filed/Furnished With This Report	Incorporated by Reference			
			Form	File No.	Exhibit	Filing Date
10.6*	Form of Amended and Restated Employment Agreement between the Registrant and each of Lance Baldo, MD and Francis T. Lo		S-1	333-231838	10.8	5/30/2019
10.7*	Form of Restated Non-Employee Director Change in Control Agreement between the Registrant and each of its non-employee directors		S-1	333-231838	10.9	5/30/2019
10.8*	Executive Severance Agreement between the Registrant and Chad Cohen, dated May 1, 2019		S-1	333-231838	10.10	5/30/2019
10.9*	Executive Severance Agreement between the Registrant and Lance Baldo, MD, dated April 22, 2019		S-1	333-231838	10.11	5/30/2019
10.10*	Executive Severance Agreement between the Registrant and Charles Sang, dated May 1, 2019		S-1	333-231838	10.12	5/30/2019
10.11*	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers		S-1	333-231838	10.13	5/30/2019
10.12*	Adaptive Biotechnologies Corporation Non-Employee Director Compensation Policy		S-1/A	333-231838	10.14	6/17/2019
10.13*	Adaptive Biotechnologies Corporation 2009 Equity Incentive Plan and form of award agreement thereunder		S-1	333-231838	10.15	5/30/2019
10.14*	Adaptive Biotechnologies Corporation 2019 Equity Incentive Plan and form of award agreement thereunder		10-Q	001-38957	10.12	8/13/2019
10.15*	Adaptive Biotechnologies Corporation 2019 Employee Stock Purchase Plan		S-1/A	333-231838	10.17	6/17/2019
10.16	Lease Agreement between ARE-Seattle No. 11, LLC and Adaptive TCR Corporation, dated July 21, 2011, as amended by Amendment No. 1, dated August 26, 2011, Amendment No. 2, dated June 30, 2014, Amendment No. 3, dated November 5, 2015, Amendment No. 4, dated December 23, 2015, and Amendment No. 5, dated June 6, 2016		S-1	333-231838	10.18	5/30/2019
10.17†	Sixth Amendment to Lease Agreement between Adaptive Biotechnologies Corporation and ARE-Seattle No. 11, LLC, dated August 2, 2019		8-K	001-38957	10.1	8/7/2019
10.18†	Lease Agreement between Adaptive Biotechnologies Corporation and ARE-Seattle No. 12, LLC, dated August 2, 2019		8-K	001-38957	10.2	8/7/2019
10.19†	IVD Test Kit Development and Supply Agreement between Illumina, Inc. and Adaptive Biotechnologies Corporation, effective September 23, 2019		10-Q	001-38957	10.3	11/12/2019
23.1	Consent of Independent Registered Public Accounting Firm	X				
24.1	Power of Attorney (included on the signature page)	X				

Exhibit Number	Exhibit Title	Filed/Furnished With This Report	Incorporated by Reference			
			Form	File No.	Exhibit	Filing Date
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
32.2	Certification of Principal Financial and Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
101.INS	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	X				
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X				
104	Cover Page Interactive Data File (formatted in Inline XBRL and included in Exhibit 101)	X				

* Management contract or compensation plan or arrangement.

† Portions of this exhibit have been omitted pursuant to Item 601 of Regulation S-K promulgated under the Securities Act because the information is not material and would be competitively harmful if publicly disclosed.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Seattle, State of Washington, on February 26, 2020.

Adaptive Biotechnologies Corporation

By: /s/ Chad Robins
Chad Robins
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Chad Robins, his attorney-in-fact, with the power of substitution, for him in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the SEC, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Chad Robins Chad Robins	Chief Executive Officer and Director *(Principal Executive Officer)*	February 26, 2020
/s/ Chad Cohen Chad Cohen	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 26, 2020
/s/ Kevin Conroy Kevin Conroy	Director	February 26, 2020
/s/ Eric Dobmeier Eric Dobmeier	Director	February 26, 2020
/s/ David Goel David Goel	Director	February 26, 2020
/s/ Michelle Griffin Michelle Griffin	Director	February 26, 2020
/s/ Robert Hershberg Robert Hershberg, PhD, MD	Director	February 26, 2020
/s/ Peter Neupert Peter Neupert	Director	February 26, 2020

/s/ Michael Pellini Michael Pellini, MD	Director	February 26, 2020
/s/ Andris Zoltners Andris Zoltners, PhD	Director	February 26, 2020

DESCRIPTION OF REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12
OF THE SECURITIES EXCHANGE ACT OF 1934

The following description (this "Description") of our common stock is a summary and does not purport to be complete. It is subject to, and qualified in its entirety by reference to, our Articles of Incorporation and Bylaws, each of which have been filed with the Securities and Exchange Commission. This description also summarizes relevant provisions of Washington law. We encourage you to read our Articles of Incorporation, Bylaws and the applicable provisions of Washington law for additional information.

General

Our authorized capital stock consists of 340,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share, all of which shares of preferred stock are undesignated.

Our board of directors has the authority, without further action by our shareholders (unless required by Nasdaq rules), to issue up to the authorized amount of shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. No shares of preferred stock have been issued or are outstanding as of the date of the filing of the Annual Report on Form 10-K of which this Description forms a part, and we have no present plan to issue any shares of preferred stock.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the shareholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions. In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. Our common stock is listed on The Nasdaq Global Select Market under the symbol "ADPT." The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021.

Anti-Takeover Effects of our Articles of Incorporation, Bylaws and Washington Law

Our Articles of Incorporation and Bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies

Our Articles of Incorporation provide for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our Articles of Incorporation also provide that directors may be removed only for cause and then only if the number of votes of the holders of the shares entitled to elect the director cast in favor of removing such director exceeds the number of votes cast against removal. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our remaining directors. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for shareholders to change the composition of our board of directors.

Unanimous Written Consent of Shareholders

Washington law limits the ability of shareholders to act by written consent by requiring unanimous written consent for shareholder action to be effective. This limit may lengthen the amount of time required to take shareholder actions and would prevent the amendment of our Articles of Incorporation, our Bylaws or removal of directors by our shareholders without holding a meeting of shareholders.

Meetings of Shareholders

Our Articles of Incorporation and our Bylaws provide that only our board of directors, our Chairperson of our board of directors, our Chief Executive Officer or our President may call special meetings of shareholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of shareholders. Our Bylaws limit the business that may be conducted at an annual meeting of shareholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our Bylaws have established advance notice procedures with regard to shareholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our shareholders. These procedures provide that notice of shareholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary of the date that our proxy statement was released to shareholders in connection with the previous year's annual meeting. Our Bylaws specify the requirements as to form and content of all shareholders' notices. These requirements may preclude shareholders from bringing matters before the shareholders at an annual or special meeting.

Amendment to our Articles of Incorporation and Bylaws

Any amendment of our Articles of Incorporation must first be submitted to our shareholders by us or our board of directors, and the amendment of certain articles or sections, including articles or sections relating to who may call special meetings of the shareholders, our board of directors, indemnification of our directors and officers, supermajority voting and amendments to our Bylaws, requires the affirmative vote of at least two-thirds of the outstanding shares entitled to vote on the amendment voting together as a single group. Our Bylaws may be amended by our board of directors, subject to any limitations set forth in our Bylaws, and may also be amended by the affirmative vote of at least two-thirds of the outstanding shares entitled to vote on the amendment voting together as a single group.

Undesignated Preferred Stock

Our Articles of Incorporation provide for authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our shareholders, our board of directors could cause shares of preferred stock to be issued without shareholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent shareholder or shareholder group. In this regard, our Articles of Incorporation grant our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Exclusive Forum

Our Articles of Incorporation provide that, unless we consent in writing to the selection of an alternative forum, the state courts located in King County, Washington (or, if the state courts located within King County, Washington do not have jurisdiction, the federal district court for the Western District of Washington) shall be the

sole and exclusive forum for commencing and maintaining any proceeding (1) asserting a claim based on a violation of a duty under the laws of the State of Washington by any of our current or former directors, officers or shareholders in such capacity, (2) commenced or maintained in the right of the corporation, (3) asserting a claim arising pursuant to any provision of the Washington Business Corporation Act ("WBCA"), our Articles of Incorporation or our Bylaws (as either may be amended from time to time) or (4) asserting a claim concerning our internal affairs that is not included in clauses (1) through (3) above, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants. These provisions would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction. Our Articles of Incorporation further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, subject to applicable law. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these provisions. Our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our shareholders will not be deemed to have waived our compliance with these laws, rules and regulations. Although we believe these provisions benefit us by providing increased consistency in the application of Washington law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors, officers and other employees.

Washington Anti-Takeover Law

Washington law imposes restrictions on some transactions between a corporation and significant shareholders. Chapter 23B.19 of the WBCA generally prohibits a target corporation from engaging in specified "significant business transactions" with an "acquiring person." This statute could prohibit or delay the accomplishment of mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage unsolicited attempts to acquire us. An "acquiring person" is generally defined as a person or group of persons that beneficially owns the voting shares entitled to cast votes comprising 10% or more of the voting power of the target corporation. The target corporation may not engage in "significant business transactions," as defined in Chapter 23B.19, for a period of five years after the date of the transaction in which the person became an acquiring person, unless (1) the significant business transaction or the acquiring person's purchase of shares was approved by a majority of the members of the target corporation's board of directors prior to the share acquisition causing the person to become an "acquiring person," or (2) the significant business transaction was both approved by the majority of the members of the target corporation's board of directors and authorized at a shareholder meeting by at least two-thirds of the votes entitled to be cast by the outstanding voting shares (excluding the acquiring person's shares or shares over which the acquiring person has voting control) at or subsequent to the acquiring person's share acquisition. "Significant business transactions" include, among other things:

- a merger or share exchange with, disposition of assets to or issuance or redemption of stock to or from, the acquiring person;
- a termination of 5% or more of the employees of the target corporation employed in the State of Washington as a result of the acquiring person's acquisition of 10% or more of the shares, whether at one time or over the five-year period following the share acquisition;
- a transaction in which the acquiring person is allowed to receive a disproportionate benefit as a shareholder; or
- liquidating or dissolving the target corporation.

After the five-year period, a "significant business transaction" may occur, as long as it complies with "fair price" provisions specified in the statute or is approved at a meeting of shareholders by a majority of the votes entitled to be counted within each voting group entitled to vote separately on the transaction, not counting the votes of shares as to which the acquiring person has beneficial ownership or voting control. A corporation may not opt out of this statute.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-232495) pertaining to the Sequenta Inc., 2008 Stock Plan, Adaptive Biotechnologies Corporation 2009 Equity Incentive Plan, Adaptive Biotechnologies Corporation 2019 Equity Incentive Plan, and Adaptive Biotechnologies Corporation 2019 Employee Stock Purchase Plan of our report dated February 26, 2020, with respect to the financial statements of Adaptive Biotechnologies Corporation included in this Annual Report (Form 10-K) for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Seattle, Washington
February 26, 2020

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Chad Robins, certify that:

1. I have reviewed this Annual Report on Form 10-K of Adaptive Biotechnologies 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)) 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) 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

    c) 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: February 26, 2020

By: /s/ Chad Robins
Chad Robins
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Chad Cohen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Adaptive Biotechnologies 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)) 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) 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

    c) 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: February 26, 2020

By: /s/ Chad Cohen
Chad Cohen
Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Adaptive Biotechnologies Corporation (the "Company") on Form 10-K for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: February 26, 2020

By: /s/ Chad Robins
Chad Robins
Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Adaptive Biotechnologies Corporation (the "Company") on Form 10-K for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: February 26, 2020

By: /s/ Chad Cohen
Chad Cohen
Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.