2023 Annual Report

Adaptive biotechnologies™

Dear fellow shareholders,

Adaptive continues to leverage its industry-leading capabilities to translate the immune system response to disease into paradigm-shifting clinical products.

In 2023, we substantially advanced our offerings in the clinical assessment of minimal residual disease (MRD) for blood cancers and immune medicine (IM)-driven drug discovery and development for cancer and autoimmune disease.

In MRD, we provide physicians and researchers with insight into the effectiveness of treatment for lymphoid cancers by assessing when and if a patient's immune response to disease has returned to a clinically significant level. This knowledge can transform how lymphoid cancers, such as multiple myeloma, are understood in clinical trials and treated in patients.

In IM, we are discovering novel disease-specific targets and developing immune-based pharmaceutical assets against those targets, such as T-cell receptor (TCR)-based cellular therapies and antibodies. We believe these efforts will allow us to better understand and treat therapeutically challenging conditions such as neoantigen-driven cancer and autoimmune disease.

Minimal Residual Disease (MRD)	Immune Medicine (IM)
A commercial-stage diagnostic business	**An immune-driven drug discovery business**
Highly sensitive NGS-based assessment of MRD in hematology for use in clinical practice and drug trials	Advancing transformative immune-based therapeutics in cancer and autoimmunity

Image credit: GeekWire

In this post-pandemic world, I am delighted that Adaptive continues to be an incredibly integrated and collaborative workplace. We were the winner of GeekWire's Workplace of the Year Award in 2023. I'm deeply proud of the passion, dedication, and teamwork displayed by Adapters every day. It is their ingenuity that makes us the company we are today—and the company we will strive to be over the years ahead.

Key Financial Highlights

FY'23 revenue $170.3M (MRD revenue $102.7M +18% Y/Y; IM revenue $67.5M -31% Y/Y)

FY'23 operating expenses $397.3M (+3% Y/Y including a $25.4M lease impairment charge; -4% Y/Y excluding the lease impairment charge)

Strong balance sheet with $346.4M in cash, cash equivalents and marketable securities as of December 31, 2023

Chad Robins, Chief Executive Officer and Co-founder

MRD

The MRD business is centered around the use of our highly sensitive, next generation sequencing assay to detect measurable residual disease in patients with lymphoid malignancies. It is comprised of two main pillars, the clonoSEQ® clinical test, offered to clinicians, and our clonoSEQ assay, offered to biopharmaceutical partners, to advance drug development efforts. During the last decade, we have established significant competitive advantages around clonoSEQ, including best-in-class sensitivity, broad payer coverage, clinical evidence, guideline inclusion, and biopharmaceutical utilization of MRD as a surrogate endpoint in clinical trials.

Tiffany's story

Tiffany, a mother, wife, and now-retired pediatric nurse practitioner, was diagnosed with multiple myeloma nearly 10 years ago.

She embarked on an eight-month journey of induction therapy, chemotherapy infusion and a stem cell transplant. During that period, her life stopped. She took a leave of absence from work. She worried about being there for her children. After more than 6 years of maintenance therapy, Tiffany's oncologist recommended MRD testing with clonoSEQ, which confirmed she was MRD-negative and allowed her to discontinue maintenance therapy. For the first time in nearly a decade, she was able to take a deep breath, and look to the future.

clonoSEQ® is the gold standard in hematology MRD

Clinical test volume

>50%

Year-over-year growth from 2022

Payer coverage

300M

Covered lives today from 80M in 2020

Pharma studies

>140

75 studies using clonoSEQ assay technology as an endpoint

Total unique patients[1]

>51K

Patients tested today from 10K in 2020

Significant advances in 2023 include:

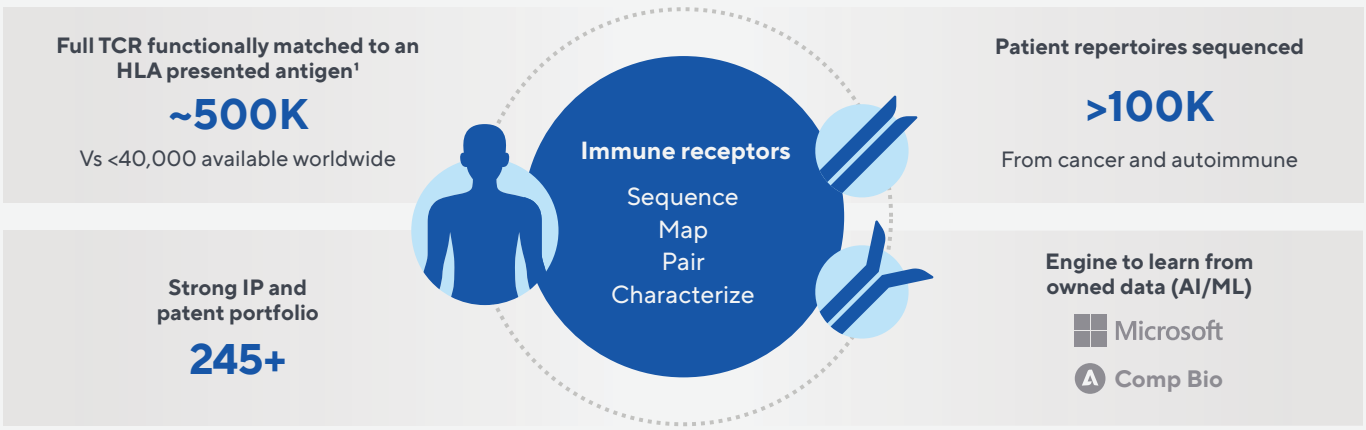
- We grew clonoSEQ test volume by 53% year-over-year. Blood-based testing is a key driver of the growth in the community setting, increasing 8 percentage points over the year to make up 39% of clonoSEQ tests.
- Payer coverage for the test grew to 300 million lives in B-cell acute lymphoblastic leukemia (B-ALL) and multiple myeloma, 200 million lives in chronic lymphocytic leukemia (CLL) and 70 million lives in diffuse large B-cell lymphoma (DLBCL).
- MRD Pharma revenue, excluding milestones, increased by 1% from 2022 against a slowdown in pharma services, reflecting broader macroeconomic factors impacting the biopharmaceutical industry.
- As of December 31, 2023, clonoSEQ assay technology was being used in 143 active trials conducted by 43 biopharmaceutical partners, including 75 trials in which it represented a clinical endpoint (10 of which it is being used as a primary endpoint).

[1]US clinical patients

Immune Medicine

For more than a decade, Adaptive has been generating a treasure trove of valuable immune receptor data, including over 100,000 signatures of cancer and autoimmune disease and approximately 500,000 matches of TCRs to disease-related antigens. Our IM business leverages these data to develop and train artificial intelligence and machine learning models to accelerate target and drug discovery efforts in cancer and autoimmunity—either on our own or with a partner. In cancer, we remain focused on supporting Genentech, Inc. in the development and commercialization of TCR-based cancer cell therapy product candidates. In autoimmunity, we have advanced our technology to support the development of more precise therapies for the millions of patients with these diseases, such as multiple sclerosis.

Adaptive Immune Medicine is the gold standard in immune receptor discovery



Significant advances in 2023 include:

- In drug discovery, we made significant progress under the Genentech Agreement with respect to both the shared and personalized product programs. For the shared products, we completed an assessment of efficacy and safety data which enabled selection of a TCR candidate to advance as a potential therapeutic product candidate. The first FDA Investigational New Drug (IND) application clearance under our Genentech Agreement was obtained for this candidate in 2023.

- For our fully personalized approach, blood samples from 165 cancer patients have been screened. A proof of concept was completed by identifying and characterizing patient specific TCRs to unique tumor mutations. The 2023 completion of our personalized process workflow under regulated conditions enables us to initiate end-to-end testing for future clinical readiness.

- In autoimmune diseases, we continued our drug discovery efforts in multiple sclerosis (MS), Crohn's disease, type 1 diabetes, and rheumatoid arthritis, and we discovered a novel therapeutic target in MS. We plan to validate this novel MS self-antigen as a therapeutic target and assess potential therapeutic modalities against it in the next few years.

[1]HLA: human leukocyte antigens

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, 2023

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.)**
1165 Eastlake Avenue East Seattle, Washington	**98109**
(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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

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

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

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 30, 2023 (the last business day of the Registrant's most recently completed second fiscal quarter), was approximately $756,000,000.

As of February 23, 2024, the Registrant had 145,092,271 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 2024.

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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 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 expressed or implied 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;
- the success of developing, commercializing and achieving commercial market acceptance of clonoSEQ, Adaptive Immunosequencing, T cell receptor ("TCR")-based cellular therapies, antibody-based therapeutics products and additional products beyond our portfolio;
- the potential for our identified research priorities to advance our proprietary immune medicine ("IM") platform or our future products;
- the success, cost and timing of our research and 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;
- our ability to identify research priorities and apply a risk-mitigated strategy to efficiently discover and develop products and services, including new targets in autoimmunity and neurodegenerative disorders;
- our ability to obtain and maintain regulatory approval of our products;
- the pricing and reimbursement of our products following approval where required;
- our ability to obtain equipment and materials (including reagents or other materials that may also require additional internal validation) from our suppliers, and in some cases single suppliers;
- 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 if successful, commercialization;
- our ability to manage operating expenses;
- the size and growth potential of the markets for our products, and our ability to serve those markets, either alone or in combination with others;
- the rate and degree of market acceptance of our products;
- our financial performance;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our immune medicine platform, products, and related technologies and the direction of such protection;
- regulatory developments in the United States ("U.S.") 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

Throughout our history, we have advanced the field of immune 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 the immune system detects and treats disease in that patient. We capture these insights in our dynamic clinical immunomics database and related antigen annotations, which are underpinned by computational biology and machine learning, and use them to develop and commercialize clinical products and services that can be tailored to the needs of individual patients.

In 2023, we continued to pursue our business around two main areas: clinical assessment of minimal residual disease ("MRD") in lymphoid malignancies and immune medicine ("IM")-driven drug discovery and development. We believe the total addressable market for the MRD business is $5.1 billion, $4.4 billion of which is derivable from clinical testing. The IM business focuses its research and development investments on catalysts that achieve strategic priorities, including continued support of our partner, Genentech, Inc. ("Genentech"), in its development of TCR-based cell therapies in oncology as well as the discovery of novel druggable targets in autoimmunity.

The MRD business focuses on the use of our highly sensitive, next-generation sequencing ("NGS") assay to measure MRD in patients with hematologic malignancies. It is comprised of our clonoSEQ clinical diagnostic test, offered to clinicians, and our clonoSEQ assay, offered to biopharmaceutical partners, to advance drug development efforts ("MRD Pharma").

clonoSEQ is the first test authorized by the Food and Drug Administration ("FDA") for the detection and monitoring of MRD in patients with multiple myeloma ("MM"), B cell acute lymphoblastic leukemia ("ALL") and chronic lymphocytic leukemia ("CLL") and is also available as a CLIA-validated laboratory developed test ("LDT") for patients with other lymphoid cancers, including diffuse large B-cell lymphoma ("DLBCL"). We believe clonoSEQ is the test of choice in MRD testing for hematologic malignancies with industry leading sensitivity. With the use of clonoSEQ, we are transforming how lymphoid cancers are treated by working with providers, pharmaceutical partners and payors.

The IM business leverages our proprietary ability to sequence, map, pair and characterize TCRs and B cell receptors ("BCRs") at scale. We have created a powerful data engine to drive the development of novel therapies. These datasets, which we own, include over 100,000 signatures of cancer and autoimmune disease and approximately 500,000 matches of TCRs to disease-related antigens.

Our sizable data and differentiated capabilities uniquely positions our IM business to discover novel targets and develop therapeutic candidates, such as TCR-based therapies and antibodies, against these targets. Our goal is to better understand and treat challenging conditions such as autoimmune disease and cancer. The tremendous potential of IM in drug discovery is demonstrated by our worldwide collaboration and license agreement with Genentech (the "Genentech Agreement"). Under the Genentech Agreement, we will continue development of TCR-based cell therapies in cancer. In 2023, a first FDA-cleared investigational new drug ("IND") for a shared antigen cell therapy product candidate was secured by Genentech. This milestone also established an important proof of concept for our first discovered TCR to be used in a cell therapy product candidate and supports our work towards a TCR-based fully personalized approach. The IM business also applies the potential of our immune medicine platform in the treatment of autoimmune diseases, such as multiple sclerosis ("MS"), Crohn's disease, type 1 diabetes and rheumatoid arthritis.

Selected 2023 Results

In 2023, our revenue was $170.3 million compared to $185.3 million in 2022, with the reduction primarily reflecting a decline in the amortization of the upfront payment from Genentech, a slowdown in pharma services largely due to broader macroeconomic factors impacting the biopharmaceutical industry and no MRD milestones. At the same time, our operating expenses were significantly leveraged as a result of continued streamlining of our operations during the year. Operating expenses were $397.3 million during 2023, of which $25.4 million represented non-cash impairment charges, as compared to $385.5 million during 2022. As of December 31, 2023, cash, cash equivalents and marketable securities was $346.4 million.

MRD Highlights

- We grew clonoSEQ test volume by 53% year over year. Clinical test revenue increased by 53% over 2022. Payor coverage for the test has grown to 300 million lives in ALL and MM, 200 million lives in CLL and 70 million lives in DLBCL.

- We integrated the clonoSEQ clinical diagnostic test via the Epic System Corporation's ("Epic") comprehensive electronic medical record ("EMR") system into the records systems of four accounts in 2023 to enable easier test ordering, with a fifth account nearing launch.
- Our MRD Pharma revenue, excluding milestones, increased by 1% from 2022, attributable primarily to the slowdown in pharma services due to broader macroeconomic factors impacting the biopharmaceutical industry.
- As of December 31, 2023, our clonoSEQ assay was being used in 143 active trials being conducted by 43 biopharmaceutical partners, including 75 trials in which it represented a clinical endpoint (primary endpoint in 10 trials).

IM Highlights

- In Drug Discovery, we made significant progress under the Genentech Agreement with respect to both the Shared Products and Personalized Product. For the Shared Products, we completed an assessment of efficacy and safety data which enabled selection of a TCR candidate to advance as a potential therapeutic product candidate. The first FDA IND clearance under our Genentech Agreement was obtained for this candidate in 2023. In addition, fully characterized TCR data packages against validated neoantigen targets have also been provided to Genentech for further evaluation.
- For our fully personalized approach, blood samples from 165 cancer patients have been screened. A Personalized Product proof of concept was completed by identifying and characterizing patient specific TCRs to unique tumor mutations. In 2023, we successfully built our personalized process workflow under regulated conditions in our South San Francisco lab. This foundation enables us to initiate end-to-end testing in preparation for future clinical readiness of our fully personalized process.
- In autoimmune diseases, we continued our drug discovery efforts in MS, Crohn's disease, type 1 diabetes and rheumatoid arthritis, and discovered a novel therapeutic target in MS. Validation of this novel MS self-antigen as a therapeutic target and assessment of potential therapeutic modalities against this target are planned to occur over the next few years.

Our Immunosequencing Platform

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

Our immunosequencing platform combines a suite of proprietary chemistry, computational biology 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.

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.

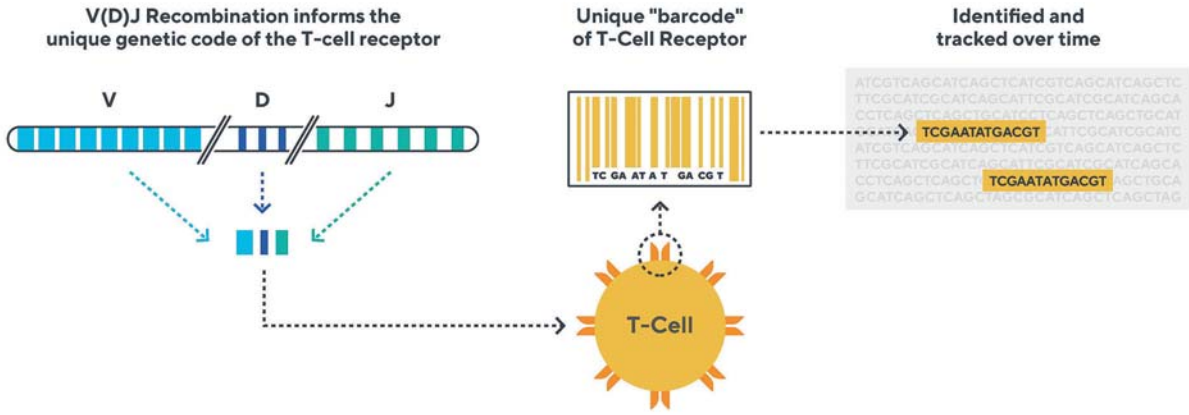
The innate and adaptive immune systems both play a role in human immunity. However, the adaptive immune system alone provides a specific response to signals of disease, or antigens. These disease specific antigens are primarily fragments of proteins that are recognized as foreign, such as proteins from a virus. However, antigens can be recognized as foreign even if they are not from a virus or pathogen. In cancer cells, tumor associated antigens ("TAAs") are normal proteins that are aberrantly expressed in a tumor; neoantigens are mutated versions of normal proteins that are specific to the cancer and not found in healthy normal cells. Both TAAs and neoantigens are recognized by the immune system as foreign. For autoimmune disorders, the immune system loses the ability to distinguish between 'self' and 'non-self' and mistakenly recognizes normal protein fragments ("self-antigens") as foreign, which results in attacking 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 cell 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 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 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, as summarized in the table below:

Properties	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 the natural properties of the immune system to develop clinical products, the enormous diversity and scale of the adaptive immune system must be taken into consideration, including the ability to accurately and reliably measure the relative frequency of each disease-specific T (or B) 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 technology was built and validated to address this need.

Our immune medicine platform combines proprietary chemistry, computational biology and machine learning to generate clinical immunomics data that we use 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. To that end, we developed a combination of technologies to perform the following key functions that broaden our understanding of immune-mediated biology:

- *Sequencing.* Our proprietary NGS-based immunosequencing methods provide sequences for single chains of "Y-shaped" TCRs or BCRs, which enables understanding of the quantity and diversity of T cells and B cells in a biological sample. Together with our massive clinical immunomics database of immune receptor sequences, our sequencing capabilities provide deep insights into individual and collective immune responses at a scale that is thousands of times greater than was previously possible.
- *Antigen Identification.* We have developed powerful approaches to identify disease-related antigens which trigger a T-cell response, even at levels of one T-cell in a million (as may occur in autoimmune disorders).

- Human leukocyte antigen ("HLA")-presented disease specific antigens. By applying proprietary screening methods, we can identify TCRs which cluster around a presumably identical HLA-presented antigen and identify that antigen by a process we call "de-orphanization". Our massive database of TCRs and healthy control samples enables us to rapidly confirm whether such antigens are disease-specific, even if the antigen or its relationship to the disease was previously unknown.
- Antigen-TCR mapping. MIRA (Multiplexed Identification of TCR Antigen Specificity) maps millions of TCRs to thousands of clinically relevant Class I and Class II antigens. MIRA is another proprietary method which enables us to elucidate *in silico* what potential diseases a patient's immune system has been exposed to or is actively fighting.

- *Pair.* pairSEQ provides 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.* Our platform characterizes binding, functionality and safety properties of antigen-specific, paired TCRs or BCRs. Our high-throughput sequencing and antibody discovery process allows us to select from a diversity of potent, naturally occurring, full length human receptors. We identify and focus on a subset of therapeutic-grade candidates to designate and further develop as TCR or antibody based therapeutic products.

Our Products and Pipeline (MRD)

The MRD business area focuses on the use of our highly sensitive, FDA-authorized NGS assay to measure MRD in patients with hematologic malignancies. It is comprised of our clonoSEQ clinical diagnostic test, offered to clinicians, and our clonoSEQ assay offered to biopharmaceutical partners to advance drug development efforts.

We believe clonoSEQ is the test of choice in MRD testing for hematological malignancies with industry leading 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 assess treatment response, predict long-term patient outcomes, monitor disease burden over time and detect potential relapse.

With the use of clonoSEQ, we are transforming how lymphoid cancers are treated by working with biopharmaceutical partners, providers and payors. For instance, with the use of clonoSEQ we have the potential to accelerate the development of drugs in lymphoid cancers, assist physicians with critical clinical decisions and enable treatment decisions which may lower payor cost through the discontinuation of costly drugs that are no longer needed.

The Technology

clonoSEQ is our FDA-authorized, NGS 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 we perform in clonoSEQ 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 polymerase chain reaction ("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.

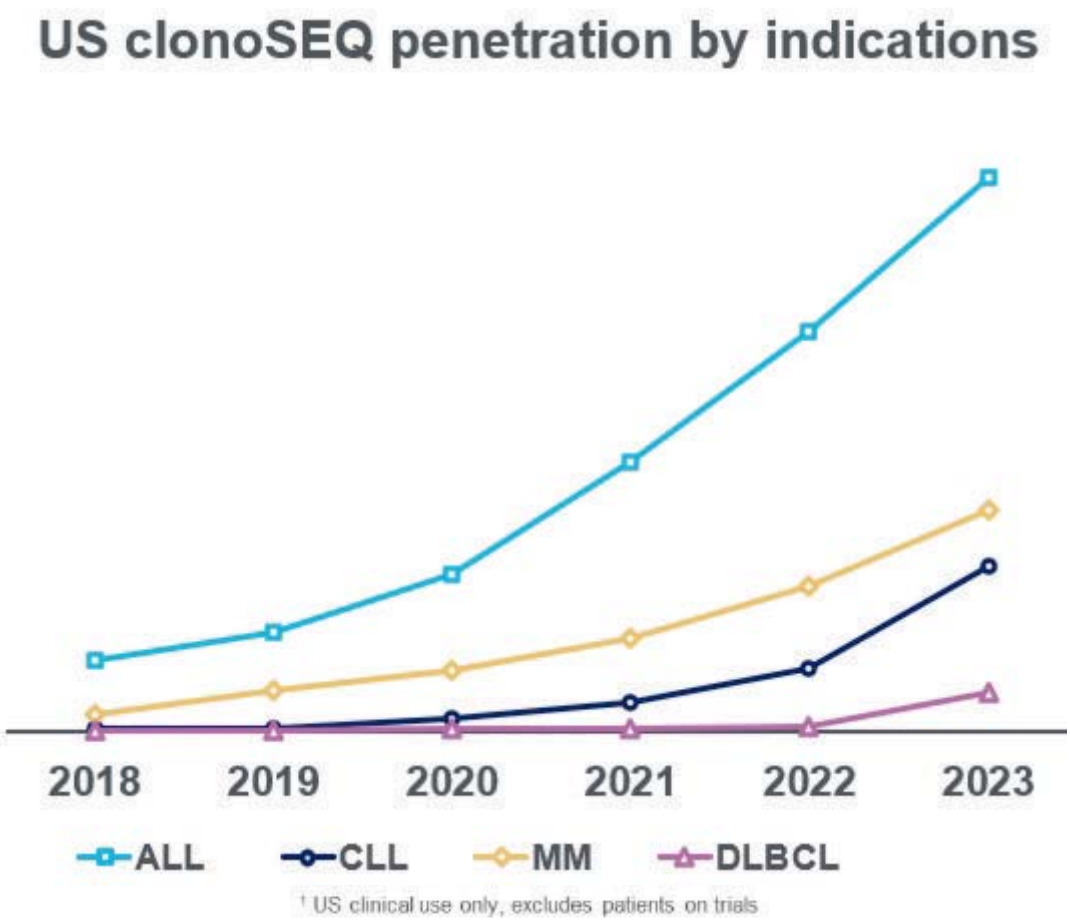
clonoSEQ

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. We believe clonoSEQ has broad applicability across all lymphoid malignancies, including ALL, CLL, MM, and Non-Hodgkins Lymphoma ("NHL") conditions (DLCBL, mantle cell lymphoma ("MCL"), and cutaneous T-cell lymphoma ("CTCL").

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. In August 2020, the clonoSEQ label was expanded to include patients with CLL from bone marrow and blood samples.

In 2022, the assay was launched as a CLIA-validated LDT to detect MRD in blood for patients with DLBCL by measuring circulating tumor DNA ("ctDNA"), which provides patients and clinicians with a powerful blood-based prognostic tool. We are pursuing FDA clearance of our DLBCL test to support clinical adoption and increase its usage by our biopharmaceutical partners.

Clinical penetration with clonoSEQ has grown significantly[1] as illustrated below.



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. clonoSEQ is now incorporated in NCCN guidelines and used by all 33 NCCN cancer centers. Over the years since, we have secured additional payor coverage for clonoSEQ aligned with our FDA label with Medicare, national private payors and large regional plans, expanding coverage to 300 million covered lives for ALL and MM, 200 million covered lives for CLL and 70 million covered lives for DLBCL.

In November 2021, MolDX published its local coverage decision ("LCD") for MRD testing. This LCD not only affirmed the importance of MRD and clonoSEQ coverage in ALL, MM and CLL in bone marrow and blood, but it also provided a clear and efficient pathway for seeking expanded clonoSEQ coverage through technical assessments in NHL.

In July 2022, coverage expansion continued as we secured Medicare coverage for DLBCL, the most common form of NHL. We secured clonoSEQ coverage with Medicare for DLBCL patients regardless of line of therapy, treatment regimen or testing timepoint. clonoSEQ is the first and only MRD test to receive Medicare coverage in DLBCL. We anticipate receiving Medicare coverage for another NHL condition, MCL, in early 2024.

In October 2022, we entered into a partnership with Epic to integrate clonoSEQ into Epic's EMR system, which we believe will enable easier test ordering and results access for the clonoSEQ test. In 2023, clonoSEQ became integrated into the EMRs of five customers and we expect significant growth in customer integrations in 2024, including through an additional EMR collaboration with Flatiron Health, Inc. entered into in February 2024.

We have a multi-pronged strategy to deepen penetration of clonoSEQ and improve our commercial and operational infrastructure:

- Increase clinical testing in blood to facilitate adoption for clinicians in the community setting and increase frequency of testing across treatment settings.
- Expand into new patient populations mainly within NHL subtypes, starting with DLBCL, MCL and CTCL.
- Expand patient use bases by continuing to generate clinical evidence in clonoSEQ utility at multiple points along the patient continuum of care.

In parallel, we continue to enhance customer experience with EMR integration, optimize payor coverage and leverage our operating infrastructure to drive margin improvements.

Through 2023, clonoSEQ is also being used by 43 biopharmaceutical companies in 143 active clinical trials, representing (depending on the disease) between 9% and 44% penetration (peak for MM) of active industry sponsored clinical trials in lymphoid cancers as of December 31, 2023. We continue to deepen our commercial investments to expand clinical adoption of clonoSEQ and have increased the strength of our specialized sales and customer support organization and supporting infrastructure in the U.S. We have also successfully transferred certain sequencing technology under non-exclusive licenses to multiple labs in other parts of the world.

Evolving Clinical Utility Data

We believe that the value of clonoSEQ as a decision-making tool may enable clinicians to select the best patient treatment options based on MRD status. Some examples of recent expanded clinical use cases and drug development advances include:

- PERSEUS is a phase 3 randomized study of Daratumumab + VRd (Velcade, Revlimid, and dexamethasone) versus VRd alone in patients with newly diagnosed MM who are eligible for ASCT. MRD was assessed by clonoSEQ in 355 patients in the D-RVd group and 354 patients in the VRd alone group. Deep and durable MRD negativity was achieved with D-VRd, and 64% of patients receiving maintenance in the D-VRd group discontinued Daratumumab after achieving sustained MRD negativity per the protocol. Not only has MRD been shown to be prognostic but it also informs clinical care in the sustained MRD negativity group.
- In an MRD-adapted study from the University of Wisconsin, MRD status assessed by clonoSEQ in peripheral blood was used to determine the relationship between early response and outcomes, as well as to guide maintenance therapy in patients with previously untreated MCL. The data were presented in a poster presentation titled Minimal Residual Disease (MRD) Testing by Next Generation Sequencing (NGS) after Two Cycles (CY) of Non-Intensive Chemoimmunotherapy Is Predictive of Remission Duration and Need for Maintenance Therapy (MT) in Previously Untreated Mantle Cell Lymphoma (MCL): A Wisconsin Oncology Network Study (Abstract 4407). In this study of 21 patients, those with a complete response who were MRD negative by clonoSEQ after induction and consolidation therapy were not given maintenance therapy. In patients without a complete response or with persistent MRD positivity, obinutuzumab maintenance was given for 8 cycles. Patients were followed for greater than or equal to two years from therapy completion. In patients achieving MRD negative status after induction and consolidation, omission of obinutuzumab maintenance did not result in worsening progression free survival ("PFS") compared to those that did receive maintenance. Additionally, MRD status post cycle two of induction was prognostic.

Additional prospective studies are underway, and many have shared interim data at industry conferences. As more studies read out, we expect there may be greater adoption of MRD in clinical decision making, which could result in more patients benefiting from clonoSEQ and greater frequency of testing for each patient helped.

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 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.

MRD Pharma

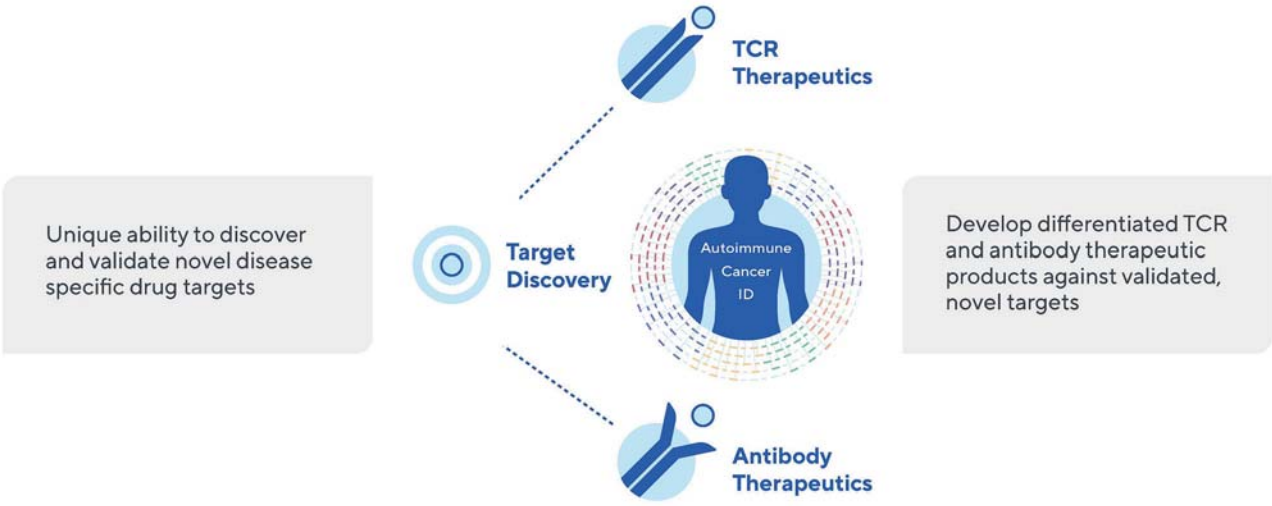
The MRD Pharma business area focuses on offering our clonoSEQ assay to biopharmaceutical partners to advance drug development efforts. Given the broad penetration of clonoSEQ, we believe there is a significant growth opportunity for our MRD Pharma business, as we aim to replicate clonoSEQ's success in other indications. For example, clonoSEQ is currently identified as an endpoint in approximately 30% of U.S.-based clinical trials being conducted by biopharmaceutical companies in MM.

Our Products and Pipeline (Immune Medicine)

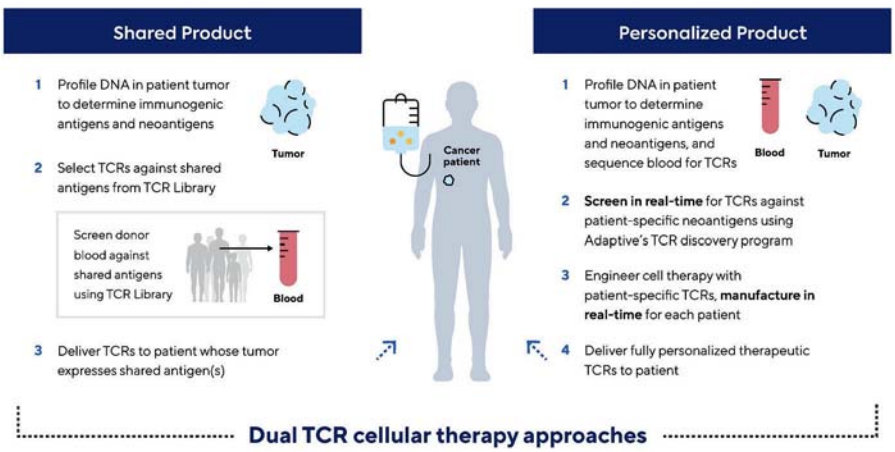
The goal of our IM business is to scale our target discovery and drug discovery efforts to bring transformative therapies into the clinic either on our own or with a partner. The engine driving the IM platform is our immunosequencing technology that allows us to tap into the massive diversity of the immune repertoire at unparalleled scale and specificity. Our immunosequencing approach utilizes multiplex, bias-controlled PCR to accurately and quantitatively sequence, map, pair and characterize millions of TCRs and BCRs at scale. The proprietary datasets we have generated to date include over 100,000 signatures of disease (such as cancer and autoimmune conditions) and approximately 500,000 matches of paired TCRs to disease-related antigens.

Drug Discovery

We are focusing our drug discovery programs to develop therapies on our own or in partnership. In these respects, our proprietary data and capabilities uniquely position IM to discover and develop therapeutic candidates such as TCR-based modalities, antibodies and potentially vaccines to better understand immune-mediate biology and treat challenging conditions such as cancer and autoimmune disorders.



The tremendous potential of IM in drug discovery is demonstrated by the Genentech Agreement. Two product development pathways for T cell immunotherapies in cancer are being pursued under the Genentech Agreement in which Genentech intends to use TCRs discovered and characterized 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 many cancer patients ("Shared Products"). We have completed an assessment of efficacy and safety data which enabled selection of a TCR candidate to progress as a potential therapeutic product candidate for which FDA IND clearance was secured by Genentech in 2023. Fully characterized TCR data packages against additional validated antigen targets have also been provided to Genentech for further evaluation.

- *Personalized Product.* The personalized product will use patient-specific TCRs identified by real-time screening of TCRs specific to each patient's unique cancer mutations ("Personalized Product"). Blood from 165 cancer patients has been screened. A Personalized Product proof of concept was completed by identifying and characterizing patient specific TCRs to unique tumor mutations. In 2023, we successfully built our personalized process workflow under regulated conditions. This foundation enables us to initiate end-to-end testing in preparation for future clinical readiness of our fully personalized process.

Under the Genentech Agreement, IM supports Genentech in the development of two categories of TCR-based cancer cell therapies for the treatment of patients with solid tumors. The first neoantigen-directed cell therapy product candidate was recently FDA IND cleared with plans to enter the clinic.

The IM business is also advancing a pipeline of potential immune-based therapies to novel targets in autoimmune disorders such as MS, Crohn's disease, type 1 diabetes and rheumatoid arthritis. In autoimmunity, the immune system attacks self-antigens, which are human proteins normally found in our body. Specifically, T cells lose their ability to distinguish 'self' from 'non-self' antigens which may cause disease. In MS, for example, we have discovered a novel self-antigen that we are validating as a potential therapeutic target. MS is a T-cell mediated disease involving mostly unknown self-antigens for which current treatments lack specificity to disease-causing targets, leading to suboptimal efficacy and risk of significant side effects. We have identified and validated specific TCRs that are shared and clustered in MS patients, which enabled the discovery of this particular self-antigen, which we believe is likely to play a causative role in MS. Validation of the self-antigen as a therapeutic target is ongoing and drug discovery to select the best therapeutic modality to drug this target and designate a therapeutic candidate is planned to occur over the next few years.

Expanding on our capabilities in finding HLA-presented, disease specific epitopes that T cells hit naturally, we are also identifying causative target antigens of interest for therapeutic development in inflammatory bowel disease conditions, which includes Crohn's disease, as well as other autoimmune disorders such as rheumatoid arthritis and type 1 diabetes, where there is a high unmet need for more targeted and specific therapies.

Our Competitive Strengths

We 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 for us and our collaborators.* 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 believe that we have a differentiated ability to perform these functions at an unprecedented scale to develop novel clinical diagnostic and therapeutic products.

- *Our clinical immunomics database provides a robust product development engine.* Using the adaptive immune system as our product source-code, we are building a dynamic clinical immunomics database that is machine learning/AI-enabled. We 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. The combination of our large, quality data and our ability to generate additional insights creates a data foundation which we will continue to leverage to accelerate our target and drug discovery efforts.

- *We are well capitalized and on a path to profitability for our MRD business area.* As of December 31, 2023, we had $346.4 million in cash, cash equivalents and marketable securities. In 2023, we focused on reducing our operating expense growth rate. For the MRD business, we estimate positive adjusted EBITDA by the end of 2025 and expect to be cash flow breakeven by the end of 2026.

- *Clinical applicability spans diagnostic and therapeutic product potential.* Our ability to accumulate, synthesize and process billions of immunomic datapoints to generate multiple clinical applications across disease areas provides optionality to our commercial pipeline. Each of our products also has broad applicability, enabling robust product lifecycle extensions.

- *Transformational collaborations with industry leaders validate our platform.* Our collaborations with industry-defining leaders such as Genentech and Microsoft Corporation ("Microsoft") validate our unique approach to advancing the promise of immune 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.
- *Expanding regulatory and reimbursement expertise will help inform future clinical product development.* Having obtained FDA marketing authorization and expanded coverage to 300 million covered lives for multiple indications of clonoSEQ from Medicare, national private payors and large regional plans, we believe we have developed valuable core capabilities that will facilitate future product development through to regulatory approval and reimbursement.
- *Strong intellectual property protects our immune medicine platform and its applications.* As of December 31, 2023, we had filed over 800 patent applications, more than 450 of which were issued and active as of that date, covering improvements in sequencing methods and new ways to leverage adaptive immune receptors for our MRD and IM business areas.

Our Strategy

Our focus is to leverage our immune medicine platform and competitive strengths to develop transformative clinical solutions that are accessible to patients with a range of diseases.

- *Powering the age of immune medicine.* We contribute to the immune medicine field by generating a large quantity and quality of immunomics data that facilitates 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 that enables novel target discovery and the development of personalized and immune-based therapeutic products.
- *Increase blood-based testing with clonoSEQ in ALL, MM, CLL, and DLBCL*. As noted, a study reported at the American Society of Hematology annual meeting in 2023 demonstrated that MRD negativity confirmed by clonoSEQ in the blood of MM patients in early treatment for MM correlated well with PFS. Testing with blood is less invasive for patients and less expensive as compared to MRD testing from bone marrow samples. Therefore, blood-based MRD testing may enable more frequent monitoring of patients over longer periods of time. We believe continued validation of clonoSEQ in blood will increase usage, particularly by clinicians in the community setting who perform fewer bone marrow aspirations.
- *Expand clonoSEQ in NHL.* 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 increased adoption across lymphoid malignancies. We are already cleared in ALL and MM from bone marrow and CLL from bone marrow and blood. At the same time, we are increasing marketing support for clonoSEQ usage as a CLIA-validated lab-developed testing service, where samples for any lymphoid cancer indication and a range of sample types (including blood) are acceptable, and payor coverage is already in place for blood-based testing in ALL, MM, CLL and a form of NHL, DLBCL. NHL represents 50% of all newly diagnosed patients with lymphoid malignancies in the U.S., and DLBCL represents 30% of NHL patients. clonoSEQ has Medicare coverage for all DLBCL patients.
- *Improve our margins for clonoSEQ.* We continue to enhance our average selling price ("ASP") for clonoSEQ while increasing the efficiencies of operations in our production laboratories and managing our overall operating expenses.
- *Entrench our products in clinical drug development with biopharmaceutical collaborators.* Maintain our platform as the gold standard for the validation of potential immune-driven clinical discoveries in late-stage clinical trials, including designation of clonoSEQ as a basis for clinical endpoints.
- *Leverage our foundational technology to address clinical therapeutic challenges in key disease states, such as cancer and autoimmune disorders.* We believe that by leveraging our established capabilities, we can scale our target and drug discovery efforts and aim to successfully develop differentiated immune medicine-based therapies, including TCR-based therapies and prophylactic or therapeutic antibodies and potentially vaccines against novel druggable targets to treat patients with cancer or autoimmune disorders.
- *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 with expertise in biology, chemistry, bioinformatics, software, drug discovery, development and commercialization, into clinical products.

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 and, in 2023, we received a $10.0 million milestone payment for FDA IND acceptance of the first cell therapy product candidate under our Genentech Agreement. We also may be eligible to receive approximately $1.8 billion over time, including payments of up to $65.0 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. The Genentech Agreement accounted for 25%, 34% and 40% of our revenue for the year ended December 31, 2023, 2022 and 2021, respectively.

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 (the “Microsoft Agreement”) to map TCR sequences to the antigens they bind with 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 with. 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.

Revenue Interest Purchase Agreement

In September 2022, we entered into a Revenue Interest Purchase Agreement (the "Purchase Agreement") with OrbiMed Royalty & Credit Opportunities IV, LP ("OrbiMed"), an affiliate of OrbiMed Advisors LLC, as collateral agent and administrative agent for the purchasers party thereto (the “Purchasers”). Pursuant to the Purchase Agreement, we received $124.4 million from the Purchasers (the "First Payment"), net of expenses. We will also be entitled to receive up to $125.0 million in subsequent installments as follows: (i) $75.0 million upon our request occurring no later than September 12, 2025 (the “Second Payment”) and (ii) $50.0 million upon our request in connection with certain permitted acquisitions occurring no later than September 12, 2025 (the “Third Payment”), in each case subject to certain funding conditions. To secure our obligations under the Purchase Agreement, we and our subsidiaries have granted OrbiMed a security interest in our core platform technology assets, subject to certain customary exclusions, as defined in the Purchase Agreement.

As consideration for such payments, the Purchasers will have a right to receive certain revenue interests (the "Revenue Interests") from us based on a percentage (the "Applicable Payment Percentage") of all GAAP revenue (the "Revenue Base"). If only the First Payment has been made, the Applicable Payment Percentage shall be five percent of the quarterly Revenue Base. If both the First Payment and Second Payment have been made, the Applicable Payment Percentage shall be eight percent of the quarterly Revenue Base. If each of the First Payment, Second Payment and Third Payment have been made, the applicable payment percentage applied to the Revenue Interest shall be ten percent of the quarterly Revenue Base. Payments in respect of the Revenue Interests shall be made quarterly within 45 days following the end of each fiscal quarter (each, a "Revenue Interest Payment"). If OrbiMed has not received Revenue Interest Payments in the aggregate equal to or greater than the sum of its invested capital (the "Cumulative Purchaser Payments") on or prior to September 12, 2028, the revenue interest rate shall be increased to a rate which, if applied retroactively to our cumulative Revenue Base, would have resulted in Revenue Interest Payments equal to the sum of all Cumulative Purchaser Payments.

OrbiMed will be entitled to 100% of the Revenue Interest Payments until it has received a total cumulative value of 165% of the Cumulative Purchaser Payments (the "Return Cap"), unless full repayment of the amount of the Return Cap has not been made by September 12, 2032, in which case the Return Cap shall be increased to 175% of the Cumulative Purchaser Payments.

We incurred interest expense of $13.8 million and $4.2 million under the Purchase Agreement for the year ended December 31, 2023 and 2022, respectively.

Processing and Manufacturing

We process both clinical and research use samples in our laboratory in Seattle, Washington. Our Seattle laboratory is CLIA-certified, College of American Pathologists ("CAP")-accredited and International Organization for Standardization ("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 and sequence immune receptors in samples submitted to us, 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.

For our TCR-Antigen Map and drug discovery initiatives, we conduct our 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 or building to 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. For example, we have purchased the Illumina NextSeq System, and Illumina, Inc. ("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 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 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 internally focused and may also be pursued in collaboration with one or more biopharmaceutical companies.

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, 2023, we owned or controlled more than 450 active issued patents and more than 55 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 granted patent protection generally expires in years ranging from 2029 to 2040.

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, 2023, our intellectual property portfolio consisted of the following:

- More than 800 patent applications filed worldwide directly or in conjunction with a co-owner or licensor since 2009;
- More than 55 pending patent applications;
- More than 450 issued patents across our immune medicine platform, including more than 145 patents related to diagnostic approaches in lymphoid malignancies;
- 24 patent families directed to methods and tools useful in our immune medicine platform for non-target specific immunosequencing and research;
- 17 patent families directed to methods and tools useful in diagnosis, prognosis and disease monitoring, including clonoSEQ, certain diagnostic methods and the TCR-Antigen Map;
- 12 patent families directed to methods and tools useful in drug discovery, including our drug discovery screening processes, MIRA and pairSEQ;
- 3 patent families directed to therapeutic antibodies and novel antigen targets;
- 1 patent family directed to SARS-CoV-2 vaccines;
- 3 patent families directed to gene sequencing technology; and
- 28 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 Hutchinson Cancer Research Center (“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 U.S.

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 more than 31 additional patent applications, many of which have been granted as of December 31, 2023, 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. More than 28 related patent applications have since been filed, many of which have been granted as of December 31, 2023, 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, ribonucleic acid 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. More than 112 patents have been granted in the portfolio as of December 31, 2023, 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 B cell-based clonoSEQ diagnostic test for assessing how disease burden changes in response to treatment or during remission) and T-Detect (our T cell-based diagnostic tests). Multiple patents have been granted from additional applications relating to MRD assessment, diagnostic methods and diagnostically significant TCRs filed by us, including U.S. Patent Nos. 9,824,179 and 11,047,008. Additional patent applications are pending to TCR-based diagnostic signals in specific indications, including COVID-19.

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 algorithmic-based methods to characterize antigen specificities.

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. Several patents have been granted as of December 31, 2023, 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. Over fifty related patent applications have been filed, nearly half of which have matured into granted patents as of December 31, 2023, 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. More than 20 related patent applications have been filed, most of which have been granted as of December 31, 2023, including U.S. Patent No. 10,221,461.

Therapeutic Antibodies

We developed a therapeutic antibody discovery process called TruAB from which neutralizing antibodies have been and are being produced against target antigens in conditions such as SARS-CoV-2, influenza, Respiratory Syncytial Virus, inflammatory bowel disease and MS. Patent applications to a number of these antibodies have been filed and are pending.

Vaccines

Together with our partner Nykode Therapeutics, we filed a patent application which is pending and directed to COVID-19 vaccines, the development of which was informed by our immunosequencing-based drug discovery efforts.

Therapeutic TCRs

We have a granted patent application to TCRs responsive to WT-1 antigens with potential utility in cell therapy against WT-1 related cancers. We are also pursuing a patent application to TCRs responsive to other cancer antigens which are of interest in our collaboration with Genentech.

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 U.S. 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 U.S., 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 NHL, 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 U.S. 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's 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 Relating 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 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 clinical diagnostics, clonoSEQ faces competition primarily from institutions performing flow cytometry in-house, particularly outside of the U.S. We may also face competition from companies developing early cancer detection testing products for indications that do not currently compete with clonoSEQ, such as methods for MRD assessment directed at solid tumors.

In drug discovery, clinical trials in the field of immune 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, Adaptive Immunosequencing, is a research use only ("RUO") tool in the U.S. 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 exempt from most regulatory controls, 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. If the FDA determines an RUO product is adulterated and misbranded, enforcement may also include a warning letter, seizure, an injunction and/or criminal fines for FDCA violations.

Clinical Diagnostics in the U.S.

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 in September 2018, which classified clonoSEQ and future DNA-based tests to measure MRD in hematological malignancies as Class II devices, as explained further below. In August 2020, we received FDA clearance for clonoSEQ, following a 510(k) submission, for CLL in bone marrow as well as blood samples. We also received FDA clearance in 2021 for ALL from blood samples, launched a NHL (DLBCL) test under CLIA as a LDT and are actively advancing validation studies in certain other NHL sub-types.

In the U.S., 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. In vitro diagnostic products ("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.

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

- compliance with the FDA's QSR, which requires manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;
- labeling regulations, which prohibit the promotion of products for uncleared, or unapproved uses, or "off-label" uses, and impose other restrictions on labeling; and
- obligations to investigate and report to the FDA adverse events, including deaths, or serious injuries that may have been or were caused by a medical device and malfunctions in the device that would likely cause or contribute to a death or serious injury if it were to recur.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include sanctions, including but not limited to, warning letters; fines, injunctions, and civil penalties; recall or seizure of the device; operating restrictions, partial suspension or total shutdown of production; refusal to grant 510(k) clearance or premarket approvals ("PMAs") of new devices; withdrawal of clearance or approval; and civil or criminal prosecution.

Position in the European Union

In the European Union ("EU"), IVDs can be placed on the market by obtaining a "CE mark," which demonstrates conformity via a self-certification with the *In vitro* Diagnostic Medical Device Directive ("IVDD"). clonoSEQ obtained a CE mark in May 2019 for all B-cell malignancies with blood and bone marrow. The requirements under the IVDD 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 U.S. However, unlike the U.S., 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 by May 2026, subject to the applicable transitional provisions before full compliance is required. To that end, we submitted an application for IVDR approval of clonoSEQ in 2023. 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.

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.

LDTs in the U.S.

The FDA has historically exercised enforcement discretion to not regulate most LDTs. As such, LDTs have not been subject to FDA's marketing clearance and approval processes, or post-marketing controls, for medical devices. LDTs are generally considered to be tests that are designed, developed, validated and used within a single laboratory. Laboratories certified as "high complexity" under CLIA may develop, manufacture, validate and run LDTs. clonoSEQ is available as an LDT for use in assessing MRD for other lymphoid malignancies, including NHL and use in other specimen types, at our Seattle, Washington laboratory.

In that respect, Congress introduced legislation to establish a framework for the FDA to oversee marketing of in vitro clinical tests ("IVCTs"), such as test kits and LDTs (the Verifying Accurate Leading-edge IVCT Development Act, or "VALID Act"). Under the VALID Act, FDA would oversee IVCTs, requiring pre-market review for high-risk IVCTs which expose patients to serious or irreversible harm and novel IVCTs. As currently drafted, existing LDTs at the time of VALID Act passage would be grandfathered as approved. For new low risk IVCTs, developers would submit a representative IVCT to the FDA for review and issuance of a technology certification for the specific IVCT reviewed and later developed test within the scope of the certification. It is not certain whether or in what form the VALID Act bill will pass Congress, but passage could increase the stringency of regulatory review required for our LDT products. If the VALID Act does not pass, the FDA may decide to exercise enforcement discretion for LDTs, especially if it perceives an LDT as posing a risk to patients. Therefore, the regulatory path for marketing of LDTs is subject to uncertainty given the FDA's latitude in interpreting and applying its laws and policies.

Federal and State Privacy, Security and Breach Notification Laws

Many state and federal laws govern the processing of personal 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.

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. Although we have and maintain a system for compliance with privacy laws and regulations, failure to comply with them could expose us to potential FTC enforcement action and fines.

In addition, certain state laws govern the privacy and security of health information and personal information. Some of the state laws governing health information privacy and security are more stringent than HIPAA (including providing for patient enforcement of these state laws) and often differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. There has also recently been an influx of state privacy and security laws that introduce similar compliance complexities, including the Washington state My Health My Data Act, the California Consumer Privacy Act in combination with the California Privacy Rights Act and associated regulations and the Colorado Privacy Act. In addition, there are state breach notification laws in every state, as well as in the District of Columbia, Guam and Puerto Rico. Failure to comply with these laws, where applicable, can result in the imposition of significant civil or criminal penalties and private litigation as further detailed in the "Risk Factors" section.

In addition to laws that directly impose privacy and data protection obligations on companies, there is also a growing interest in laws and regulations that govern data areas that are related to, but not completely related to data privacy. One area of these laws relates to use and testing of genetic and genomic data. In addition to the federal Genetic Information Nondiscrimination Act, there are a number of state laws that have recently passed (e.g., the California Genetic Information Privacy Act) and that continue to make appearances on states' legislative schedules. There have been similar draft bills at the state level that would regulate machine learning, artificial intelligence, the Internet of Things, and human specimen use.

General Data Protection Regulation in the EU and other International Privacy Laws

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 is a comprehensive privacy law, meaning that it applies to all types of personal information, including the human resources record of employees and even the Internet Protocol addresses of people using online services.

Many other countries and regions also have privacy and data protection laws, some of which are modeled after the European framework. This includes countries within Europe that are not part of the EEA, such as the United Kingdom and Switzerland, and therefore operate under different privacy and data protection frameworks.

In response to the advancements in artificial intelligence and machine learning, there are also global efforts to regulate the use of these technologies. One prominent law that is pending finalization is the European Union's AI Act.

Federal, State and Foreign Fraud and Abuse Laws

In the U.S., 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 U.S., 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 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 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 U.S. The FCPA also requires companies whose securities are listed in the U.S. to meet its accounting provisions, which were designed to operate in tandem with the anti-bribery provisions, and 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. In 2016, France passed an anti-bribery and compliance law ("Sapin II"), and the French anti-corruption agency ("AFA") was 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 significant fines for companies and executives. If we were to have future growth in the European market, this law could potentially become applicable to us.

U.S. Physician Referral Prohibitions

The Physician Self-Referral Law ("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. Penalties for violating the Stark Law include the return of funds received for all prohibited referrals, fines, civil monetary penalties and possible exclusion from federal health care programs. In addition to the Stark Law, many states have their own self-referral bans, which may extend to all self-referrals, regardless of the payor. 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 U.S.

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 U.S., 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.

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 covered recipients, defined to include doctors, dentists, optometrists, podiatrists, chiropractors, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, certified nurse-midwives, 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.

There are also state transparency and gift ban laws that require manufacturers to provide reports to state governments on pricing and marketing information. Several states have enacted legislation requiring medical device manufacturers to, among other things, establish marketing compliance programs, file periodic reports with the state, and make periodic public disclosures on sales and marketing activities, and such laws may also prohibit or limit certain other sales and marketing practices. These laws may adversely affect our sales, marketing and other activities by imposing administrative and compliance burdens on us. Although we have a system for tracking and reporting "sunshine" law required information, if we fail to do so as required, we could be subject to government enforcement action and potential penalties.

Coverage and Reimbursement Generally

Reimbursement and billing requirements of applicable laws and payors for diagnostic services are highly complex. Laboratories must bill various payors, such as private third-party payors, including managed care organizations ("MCO") and state and federal health care programs, such as Medicare and Medicaid, and each may have different billing requirements. Depending on the reimbursement arrangement and applicable law, the party that reimburses us for our services may be a third party who provides coverage to the patient, such as an insurance company or MCO, a state or federal healthcare program, or the patient. Additionally, the audit requirements we must meet to ensure compliance with applicable laws and regulations, as well as our internal compliance policies and procedures, add further complexity to the billing process. As such, we are at risk of being paid less or no part of our price for our products for reasons including:

- variability in coverage and information requirements among various payors;
- patient financial assistance programs;
- missing, incomplete or inaccurate billing information provided by ordering physicians;
- billings to payors with whom we do not have contracts;
- disputes with payors as to which party is responsible for payment; and
- disputes with payors as to the appropriate level of reimbursement.

In addition, we may not be free to determine the price charged for our products. For instance, the No Surprises Act ("NSA") was enacted on December 27, 2020 and took effect on January 1, 2022. One of the goals of the NSA is to protect patients from "surprise" medical bills resulting from gaps in coverage for services provided by out-of-network providers, such as laboratories, related to patient visits at in-network facilities. The NSA limits the amount out-of-network laboratories may charge a patient for laboratory services ordered during an in-network facility visit. In addition, the NSA establishes an independent dispute resolution process for determining the amount of reimbursement for the laboratory service in the event that the laboratory and insurer cannot agree on a rate.

Certain countries, including a number of member states of the EU, set prices and make reimbursement decisions for diagnostics and pharmaceutical products. 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. We may therefore be constrained in our pricing strategies in markets outside of the U.S.

For additional information on coverage and reimbursement in the U.S., 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 U.S. 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.

Our People and Culture

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

As of December 31, 2023, we had 709 full-time employees of which 132 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. This plays an invaluable role in our ability to execute at all levels in our organization. Our core values are used in candidate screening, rewards and recognition criteria 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 from 2018 to 2022 by the Puget Sound Business Journal as one of Washington State's Best Places to Work. We were also nationally certified as a Great Place to Work in 2021 and 2022.

We pride ourselves on inclusive team building, product design and gender diversity at all levels of management. We are committed to creating and maintaining a culture of belonging.

We strive to provide compensation and benefits that are competitive to market and create incentives to attract and retain employees. Our compensation package includes market-competitive base pay, performance-based short-term incentives, health care, retirement benefits, paid time off and family leave. In addition, we offer employees the benefit of equity ownership in the Company through restricted stock unit awards. We also provide access to a variety of health and wellness resources.

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, a San Francisco, California-based company that was also developing an NGS test for MRD. Our principal executive offices are located at 1165 Eastlake Avenue East, Seattle, Washington 98109, 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 consolidated 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.

Summary of Risk Factors

Generally, the risks described below relate to the following:

- our significant net losses since inception, expected net losses in the future and need for significant investments in products and services, as well as our ability to manage operating expenses in light of profitability goals;
- our collaboration with Genentech and ability to develop and commercialize cellular therapeutics, including our ability to achieve milestones and realize the intended benefits of the collaboration;
- our laboratory operations, including errors or defects in our products or services and our reliance on a limited number of suppliers, and in some cases single suppliers, for our equipment and materials, some of which include reagents or other materials that may also require additional internal validation prior to use;
- our limited experience with the development and commercialization of therapeutic products, including cellular therapies and antibodies;
- our ability to leverage our immune medicine platform to discover, develop and commercialize target antigens and therapeutic products may not be successful;
- our expected and potential reliance on collaborators for development and clinical testing of therapeutic product candidates, which may fail at any time due to a number of possible unforeseen events;
- market acceptance of our products and services;
- our ability to increase our capacity, manage the evolution of our products and services, stay current in our rapidly changing industry and otherwise manage our growth;
- the loss of any member of our senior management team, or of the support of key opinion leaders;
- the extensive regulation of our industry, including reimbursement coverage decisions;
- the validity of our patents, protection of our trade secrets and related intellectual property matters; and
- the effects of health epidemics in regions where we or third parties on which we rely have significant laboratory operations, manufacturing facilities, concentrations of clinical trial sites or other business operations.

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 year ended December 31, 2023, 2022 and 2021, we incurred a net loss of $225.3 million, $200.4 million and $207.3 million, respectively. As of December 31, 2023, we had an accumulated deficit of $1.1 billion. 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, revenue as well as entry into the Purchase Agreement. We expect to continue to incur significant expenses and operating losses 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.

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.

Our strategy is to leverage our immune medicine platform to discover, develop and potentially commercialize additional diagnostic and therapeutic products and services for various disease states. In particular, for clonoSEQ we are attempting to generate sufficient clinical evidence to support the utility of MRD in additional lymphoid cancers beyond ALL, MM, CLL, and DLBCL while also demonstrating the clinical utility of blood as a sample type for all lymphoid cancers. If we are unable to generate compelling evidence supporting clonoSEQ use in other indications or sample types, we may not succeed in expanding our clonoSEQ product platform.

In our immune medicine business, our focus on target antigen discovery and development of therapeutic products, including antibodies and cellular therapies, faces significant challenges in the identification, validation, development, clinical testing and marketing approval of new products. If we or our collaborators are unable to discover novel targets and develop transformative immune-based therapies, we may not succeed in commercializing new therapeutic products.

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.

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. For example, we continually expand our immunomics database and antigen-annotated TCR-Antigen Map with a view toward continually advancing target antigen discovery to leverage in developing therapies such as prophylactic or therapeutic antibodies. 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 therapeutic products.

We are also attempting to leverage our immune medicine platform to discover and develop potential antibody therapies, which have been informed by our previous investment in producing, collecting and analyzing data related to COVID-19. Our efforts in this area are early and continue to evolve and mature as we augment our databases and pool of knowledge. As we continue to collect and analyze additional data, we may find that our initial hypotheses regarding any disease state which is a target for antibody discovery is not supported by a larger data set or further analysis. If our beliefs regarding the effectiveness of our antibody discovery and development capabilities are incorrect, that could have a material adverse effect on the market for our products.

Developing new products 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. Therapeutic 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 (if any) 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 clearance, authorization or approval pathways at the FDA and other regulatory authorities are likely to involve significant time, as well as additional research, development and clinical study expenditures. The FDA or other regulatory authorities may not clear, authorize or approve any future product we develop. Even if we develop a product 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 may never be commercially successful. Additionally, development of any product may be disrupted or made less viable by the development of competing products.

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

Our efforts to develop products leveraging our antigen-annotated TCR-Antigen Map may not be successful, and it may not yield the insights we expect at all or on a timetable that allows development or commercialization of new diagnostic and therapeutic products.

We are using our immunosequencing capabilities, proprietary computational modeling and machine learning to map TCR sequences to the antigens they bind. However, we may not be successful in developing a sufficiently comprehensive TCR-Antigen Map for development of new therapies for any number of reasons including difficulty accessing required sample sets to validate signals and complications in advancing algorithmic-based methods that accurately define TCR signatures to be validated.

In addition, even with the aid of machine learning, we expect the TCR-Antigen Map to take us several years to fully develop as planned. The TCR-Antigen Map we are developing therefore may not yield clinically actionable insights on a timetable that is commercially viable for our products or our collaborators' products, or at all. Our goal is to leverage the TCR-Antigen Map in connection with drug discovery and development.

We have established proof of concept for identification of disease-specific signals from TCRs produced in patients with SARS-CoV-2, acute Lyme disease, Crohn's disease, celiac disease and MS. We have also identified early signals in ulcerative colitis and rheumatoid arthritis and we will seek to confirm those signals in ongoing validation work.

In pursuit of discovering and developing new drugs, we will leverage our immunomics database and further develop our TCR-Antigen Map through the discovery of potential new drug targets (antigens). Once we have a validated target, we will use our immune medicine platform and our growing TCR-Antigen Map to support development of TCR-based, antigen-based, and antibody-based therapeutic modalities.

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, which expires in 2024.

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, products derived from our novel technologies may have product level errors. If we are unable to make meaningful progress in our TCR-Antigen Map and successfully use it to develop and commercialize new therapeutic products or services, our business and results of operations will suffer.

We utilize artificial intelligence in data and document generation, which may impact reliability of our data.

We do not use artificial intelligence as an element of any product or service but do use it to assist in generation of datasets and documentation as well as to assist in training computational models. As with many innovations, the use of artificial intelligence presents risks and challenges, including flawed, insufficient or biased datasets. Challenges inherent to the use of artificial intelligence could adversely impact the reliability of our data and subject us to delays and competitive harm, regulatory action, or legal liability, as well as brand or reputational harm.

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 the 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 up to 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. For instance, in 2021, Genentech suspended development of a drug against our first shared antigen target candidate in response to published data, followed by its selection of an alternative candidate. 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 suspend development of product candidates or 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 U.S. 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 laboratory facilities or resources to accommodate all the requirements that we currently anticipate needing to be successful. 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 meeting the needs of existing customers, collaborators and suppliers and securing 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 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 advance those product candidates into the clinic, 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 have limited experience with the development and commercialization of antibody-based therapeutics, and future such products may never be successfully developed and commercialized by us or our collaborators.

We have limited experience with the development of clinically applicable antibodies, and no experience with the commercialization, marketing and distribution of antibody-based therapeutic products. Our antibody-based therapeutic product candidates are at an early stage of discovery and development. We and any of our collaborators we work with to develop and commercialize therapeutic antibody products may not be able to do so.

We currently use, and in the future expect to continue using, collaborators for several aspects of our operations as well as to commercially leverage our drug discovery platform, and if we cannot maintain current and enter new relationships with collaborators when necessary or desirable to do so, our business will suffer.

We have limited resources to conduct our operations in both the MRD and IM business areas, and have not yet fully established infrastructure for sales, marketing or distribution in connection with all of our current or potential products. 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. For example, 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 the Microsoft Agreement, which has provided us with access to Microsoft's research and machine learning technologies that we are using to develop our TCR-Antigen Map.

We are pursuing several additional industry and academic collaborations to access patient cohorts that could accelerate our TCR-Antigen Map signal generation and validation for our immune-based diagnostics or drug discovery product or services pipeline. 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.

We are also pursuing, and may in the future pursue, drug discovery and development opportunities with our pharmaceutical services collaborators to develop and commercialize TCR-based, antigen-based, and antibody-based therapeutic modalities. Many of these collaborations provide us with upfront and milestone payments. We may not succeed in identifying therapeutic assets in these collaborations and our collaborators may not succeed in developing and commercializing such assets, which may cause us not to realize the expected monetary benefits of the collaborations.

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 and TCR-Antigen Map. All of the risks relating to product 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, 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 or our collaborators 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 medicine therapeutics, including cellular therapies in oncology, but significant additional research and development activities, validations, and clinical trials could be required before we and, as pertinent, 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 based on pharmaceutical 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. 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 therapeutics, including T-cell based cellular therapies and antibodies, 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 therapeutic products or services, we must demonstrate that our products are both safe and effective for use in each target disease indication. Clinical studies will be necessary to demonstrate that a product is safe and effective. Clinical testing and other validation efforts are expensive and can take many years to complete, the outcome of which 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, 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 or omissions. 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 and variation between testing runs. Refinements to our processes may initially result in unanticipated issues that reduce the efficiency or increase variability. In particular, DNA 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, which may negatively impact customer turnaround time. Therefore, inefficient or variable processes can cause variability in our operating results and damage our reputation.

In addition, our development laboratory operations could result in any number of errors or defects. Our quality assurance system or product development processes 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 development 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 liability claims for damages related to errors or defects in our products. 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, 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, even in markets that we expect to be primarily self-pay, 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, 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, reagents, equipment and other materials that we use in our laboratory operations and product development. An interruption in our laboratory operations, kit distribution, technology transfer, or development activities 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 such an event, 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. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. Internal changes in processes or compositions of our reagents or other materials may also require validation efforts by us and supply of new materials from our suppliers which could impact timing of production and levels of inventory while such changes are being implemented.

For example, 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. 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, materials or other equipment could impact our ability to do business.

We believe there are only a few other equipment manufacturers that are currently capable of supplying the equipment necessary for our laboratory operations and product development, 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 we use in immunosequencing, potentially including our 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.

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

Our 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. Competition for experienced sales and marketing personnel is intense, and new members of our sales organization may require intense training to apply their experience and expertise to our products and services. 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.

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. We face similar risks in our pharmaceutical services collaborations where milestone payments to us are dependent on successful commercialization of drugs by our collaborators.

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, 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 therapeutic products;
- 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, or improvements to current products, may be greater than we anticipate;
- we may not have sufficient capacity in our laboratories 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, or improvements to current products, 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 our products 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 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 products and harming our business and results of operations. Any delays in the development of our products 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 in development.

We may need to expand our workforce, commercial infrastructure and laboratory operations over time to support demand for our products. We may encounter difficulties in managing this and in meeting fluctuations in this demand.

We may need to further expand our workforce, commercial infrastructure and laboratory operations to support demand for our products. If we are unable to support fluctuations in the demand for our products and services, including ensuring that we have adequate capacity to meet potential increased demand as well as other customer requirements (such as turnaround time and service level), our business could suffer. As of December 31, 2023, we had 709 full-time employees and we may be required to increase the number of employees, including potential contingent employees as needed to address demand fluctuations. 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. 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.

Due to the technical proficiency required from much of our workforce, we may not be able to effectively recruit, train, and retain 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 and contingent workers, inability to execute on hiring plans and reduced productivity among remaining employees and contingent workers.

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, including therapeutic products;
- 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;
- the ability of our clinical sales teams to continue converting physicians from using incumbent products in the market to clonoSEQ and new diagnostic products and services we may develop;
- our ability to continue driving 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;
- our relationships, and any associated exclusivity terms, with collaborators;
- our ability to manage our growth and operating expenses;
- 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 any 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 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, including adverse safety events reported for any of our products.

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, and the number of individuals who have developed or are at a higher risk of developing certain autoimmune disorders, as well as the proportion of patients in each market whose needs can be addressed by our or our collaborators' products, 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 may prove to be incorrect. If the actual number of patients who would benefit from our products, 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 our competitors, we may not be able to successfully commercialize our products.

The biotechnology and pharmaceutical industries in the field of 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 diagnostic, pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions across various components of our platform and current and potential product offerings. Due to the significant interest and growth in immune medicine more broadly, we expect the intensity of the competition to increase.

For instance, in clinical diagnostics, our clonoSEQ MRD test faces competition from both conventional and next-generation flow cytometry performed either in-house by our target customers or by reference labs, as well as from labs and institutions advancing research-use-only MRD technologies for clinical applications and commercial-stage oncology diagnostics companies extending the application of their solid tumor (ctDNA) MRD products into the hematology MRD space. In drug discovery, clinical trials of immune 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 clinical diagnostic and drug discovery products, obtain required regulatory and other clearances, authorizations or approvals, obtain or enforce patents covering our discoveries and launch our products before our competitors. Moreover, our competitors may succeed in developing clinical diagnostics and therapies that circumvent our intellectual property rights. Our competitors may succeed in developing and commercializing therapies or diagnostic products that are more accurate, more convenient to use or more cost-effective than our products or could 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 products 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 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 obsolete. For example, there have been numerous advances in technologies relating to life sciences research and the diagnosis and treatment of cancer, and autoimmune disorders. There have also been advances in technologies used to computationally analyze very large amounts of biologic information. Our future success will depend on our ability to keep pace with 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. If we do not update our platform and products to reflect new scientific knowledge about DNA sequencing, immunology, computational biology, software development, new disease diagnostics and therapies or the diseases we seek to treat, our products and technology could become obsolete so products and services 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 our co-founders and executive officers. 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 sciences and technology businesses, particularly near our facilities 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 strategies. 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.

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, 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 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.

In addition to the risks directly relevant to our vendors, systems, and information technology, there are risks associated with the outside vendors and third parties with whom they subcontract. For example, our third-party billing and collections provider depends upon technology and telecommunications systems provided by outside vendors. Subcontractors can be a vector of vulnerability, as any weaknesses in their organization's technical and organizational controls could affect vendor operations as well as data management, in turn impacting our own operations and ability to safeguard critical data.

Information technology and telecommunications systems are vulnerable to attack in a variety of forms and from a variety of sources, including telecommunications or network failures, malicious human acts (such as ransomware) 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 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.

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. 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 that could develop if our facilities are inoperable, for even a short period of time, or to replace or repair inventory such as reagents or customer samples 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. 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 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 continued progress in establishing payor coverage and reimbursement arrangements with domestic and international commercial third-party payors and government payors for our clonoSEQ diagnostic test;
- the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts;
- our rate of progress in supporting the development of cellular therapies developed under the Genentech Agreement;
- our rate of progress in, and research and development expenses 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. 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 for changes in ownership through June 30, 2023 and continue to monitor for changes that could trigger a limitation. Based on this analysis, we do not expect to have any permanent limitations on the utilization of our federal NOLs. Under the Tax Cuts and Jobs Act of 2017 (the "TCJA"), federal NOLs incurred in 2018 and future years may be carried forward indefinitely, but the deductibility of such federal NOLs is subject to an annual limitation. NOLs 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, 2023. Accordingly, management applied a full valuation allowance against net deferred tax assets as of December 31, 2023.

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.

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 U.S., 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. Changes in these economic conditions can arise suddenly, such as in the case of the recent rise in inflation. A severe or prolonged economic downturn, as result of a global pandemic or otherwise, 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. For instance, we have observed a slowdown in pharmaceutical services due to macroeconomic factors impacting the biopharmaceutical industry. A weak or declining economy could also 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 increase with the volume of material and sample transfers and 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 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 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 have completed a technology transfer process for research use to international sites including France, Germany, Italy, the United Kingdom, Spain, and Australia, 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.

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, including potential liability arising out of third parties' negatively impacted data privacy rights. 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.

Our business could be adversely affected by the effects of health epidemics, such as the recent COVID-19 pandemic, in regions where we or third parties on which we rely have significant laboratory operations, manufacturing facilities, concentrations of clinical trial sites or other business operations. Such epidemics could materially affect our operations as well as the business or operations of our manufacturers, contract research organizations or other third parties with whom we do or will need to conduct business.

Our business could be adversely affected by global pandemics or health epidemics in regions where we have concentrations of clinical trial sites or other business operations, and such pandemics or epidemics could cause significant disruption in the operations of third-party manufacturers, suppliers, general contractors and sub-contractors related to capital projects and CROs upon whom we do or will need to rely.

Quarantines, stay at home orders and similar government orders, or the perception that such orders, shutdowns or other restrictions on business operations could occur, whether related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing or supplier facilities in the U.S. and other countries, or the availability or cost of materials, which would disrupt our supply chain.

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 pharmaceutical therapies, including certain LDTs, and related services, which are regulated by the FDA under the FDCA and the FTC;
- 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, EKRA, 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 clinical diagnostics and pharmaceutical 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 are subject to interpretation by the courts and governmental agencies. Our failure to comply could lead to civil or criminal penalties, exclusion from participation in state and federal health care programs, or prohibitions or restrictions on our laboratories' ability to provide or receive payment for our services. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position, or that a private party could file suit under the qui tam provisions of the federal False Claims Act or a similar state law. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations, and other private third-party payors.

The insurance coverage and reimbursement status of newly approved products, in a new category of diagnostics and therapeutics, is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for current or future products could limit our ability, and that of our collaborators, to fully commercialize our products 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 therapeutics that we and our collaborators plan to develop and sell. In addition, because our clinical diagnostics and some of our potential therapeutic products will 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 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. If we adopt a self-pay strategy with respect to any products or services, we may experience similar difficulties in the establishment or maintenance of sufficiently high pricing. 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 U.S., many significant decisions about reimbursement for new diagnostics and medicines are typically made by CMS, an agency within the HHS, and its contractors. CMS and its contractors decide whether and to what extent a new diagnostic or medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS policies to a substantial degree. It is difficult to predict what CMS and its contractors 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. These inherent limitations could affect our ability to realize revenues from our clinical products, including new indications addressed for clonoSEQ.

Outside the U.S., 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, including the U.S. and the EU, are pursuing 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. 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 U.S. 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 introduced the Lower Drug Costs Now Act of 2019 to reduce the cost of drugs. This blueprint contains certain measures that HHS is already working to implement. In addition, the No Surprises Act ("NSA") took effect in January 2022. One of the goals of the NSA is to protect patients from "surprise" medical bills resulting from gaps in coverage for services provided by out-of-network providers, such as laboratories, related to patient visits at in-network facilities. The NSA limits the amount out-of-network laboratories may charge a patient for laboratory services ordered during an in-network facility visit and establishes an independent dispute resolution process for determining the amount of reimbursement for the laboratory service in the event that the laboratory and insurer cannot agree on a rate. To the extent the NSA limits the price charged for our diagnostic products or cellular therapeutics, the commercial viability of those products may be adversely affected.

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 U.S., 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.

Some of the provisions of the ACA have been subject to judicial and Congressional challenges. 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. In addition, 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.

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 marketing authorization requirements of the FDA and equivalent foreign and state regulatory authorities for our products and services whose sale is subject to their authority 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 did 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, such as the Clinical Laboratory Evaluation Program for New York State, 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 and possibly also other authorizations or approvals 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 provided on a RUO basis, not for use in the diagnosis or treatment of disease. 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. If the FDA were to disagree with our RUO classification or modify its approach to regulating RUO products, 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 cleared version of clonoSEQ as a test for MRD in certain blood cancers, we also currently offer LDT versions of this test for other indications. 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 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, recently introduced legislation, 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 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-cleared clonoSEQ test, any enforcement action the FDA takes might not be limited to the FDA-cleared clonoSEQ test and could encompass our LDT testing service.

For each product we are developing that requires FDA premarket review or equivalent regulatory approval, the FDA or other regulatory authority 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 U.S., we may be required to obtain either clearance, marketing authorization or approval from the FDA and state regulatory authorities with jurisdiction over such products, unless an exemption applies or, in the case of the FDA, it 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 from the FDA 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 clearance 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 U.S. 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 and suppliers, but it is not always possible to identify and deter 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 HHS 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 diagnostic 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 eligible 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 January 2020, CMS revised the 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. CMS revised the NCD to extend specific coverage for germline (inherited) testing. CMS stated that it is continuing to make other technical, clarifying and conforming changes in the NCD manual and they are also clarifying the existing policy related to diagnostic tests for Somatic (Acquired) Cancer. If CMS were to make material revisions to policy, this could potentially impact the scope of clonoSEQ coverage.

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. 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. If we offer tests with specific codes, this apparatus will 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.

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 products, 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 or any future products 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 medical device reporting 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. 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. In addition, renumeration may not be offered or provided to beneficiaries under the monetary penalty law provision prohibiting inducements to beneficiaries.
- 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.

- The Criminal Health Care Fraud Statute, 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 or specific intent to violate the Criminal Health Care Fraud Statute.
- 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 subject to significant fines 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 applied to each 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 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. 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 and imposing strict obligations on organizations to safeguard genetic data and the results of any such testing.
- 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 for payments and other transfers of value made to these practitioners. 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 U.S. 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 private right of action under the CCPA and other similar state laws, 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 substantial per violation civil monetary penalties for each provision of HIPAA that is violated up to a statutory cap and, in certain circumstances, significant criminal penalties with fines per violation and potential imprisonment. A single breach can result in findings of violations of multiple provisions, leading to possible penalties in excess of any applicable cap for violations in a calendar year. Any person who knowingly obtains or discloses PHI in violation of HIPAA may face a significant criminal penalty 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 or related third-party private rights of action 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, New York and Massachusetts, have implemented similar privacy laws and regulations (such as the California Confidentiality of Medical Information Act, California Consumer Privacy Act and California Privacy Rights Act) that impose restrictive requirements regulating the use and disclosure of personal information, while other states are considering adoption of similar provisions. These laws and regulations are not necessarily preempted by HIPAA, but they have a wider scope and 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. 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.

We currently operate in some and may eventually operate in additional countries outside of the U.S. whose laws may in some cases be more stringent than the requirements in the U.S. For example, the EU has specific requirements relating to cross-border transfers of personal data to certain jurisdictions, including to the U.S. 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 are becoming more complex and may result in greater penalties. For instance, the GDPR governs 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 after becoming aware of 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 substantial fines in a lump sum or a percentage of our worldwide annual turnover of our preceding fiscal year, whichever is higher, and other administrative penalties. Compliance with the GDPR requires us to put in place and maintain additional policies, procedures and documentation as the law and updates to it require, which may result in other substantial expenditures. This may be onerous and adversely affect our business. 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.

The GDPR also imposes strict rules on the transfer of personal data out of the EU to the U.S. 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 to the GDPR, we continue to expand our business into several countries that have or are developing data privacy laws. Compliance with such laws may be onerous and adversely impact expansion of our business.

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.

In addition, within the U.S., an increasing number of states and the federal government are considering or have proposed adoption of new data privacy laws. While not all of these bills become law, they add significant uncertainty about additional obligations or potential penalties which we may face in conducting our business. These uncertainties are confounded by parallel changes in laws adjacent to privacy, such as those impacting machine learning and artificial intelligence or data use, and we may incur substantial expense or experience disruption as related to compliance with these laws, which would adversely affect our ability to conduct our business.

Security and cybersecurity 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, 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, including policies and procedures to safeguard us from various types of cybersecurity threats, such data is currently accessible through multiple channels and we may experience one or more data or cybersecurity 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.

In addition, a growing number of states are considering or have adopted cybersecurity requirements for cloud-based provision of services which we may be required to comply with as a condition of doing business with government-affiliated organizations, such as state universities. Implementation of the controls required by such laws can be onerous and may affect our ability to provide services to government-affiliated organizations in such states, adversely affecting our results of operations.

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 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 therapeutics discovery 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 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 therapeutic products;
- 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 U.S. 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 and have in-licensed 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, 2023, we own or have rights to more than 450 active patents and patent applications filed in the U.S., Europe and elsewhere. Of these, there are more than 55 pending patent applications. 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 U.S. 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 diagnostic methods and biological molecules.

The patent position of companies engaged in the development and commercialization of clinical diagnostic tests (like our clonoSEQ diagnostic test) and of biologic material (such as TCRs) 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, naturally-occurring molecules 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 U.S. 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 U.S., 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 U.S., 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 U.S., or from selling or importing products made using our inventions in and into the U.S. 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 U.S. 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 U.S. 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 U.S. 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 addition, a third party that files a patent application 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 U.S. 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.

Third parties may also submit prior art to the USPTO during patent prosecution to attack the validity of a patent and it is also possible in the U.S. and other countries for third parties to challenge granted patents through Patent Office proceedings such as, in the U.S., post-grant review, inter partes review and derivation proceedings. In the U.S., a lower evidentiary standard is imposed in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim. As such, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The 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 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, including with respect to naturally occurring biological molecules such as the immune cell receptors which are a focus of our immune medicine platform. 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 U.S. 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 U.S., 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 U.S. 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 U.S. 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 a third party license in relation to certain sequencing technology and if we lose these licenses then we may be subjected to future litigation.

We are a party to a license agreement that grants 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 licensor to obtain, maintain and enforce patent protection for our licensed intellectual property. Our licensor 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 agreement.

In addition, the agreement under which we currently license intellectual property or technology from third parties is complex and certain provisions in such agreements may be susceptible to multiple interpretations.

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 U.S. 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, our corporate logo, clonoSEQ, pairSEQ and other trademarks in the U.S., the EU and a number of other countries and are seeking to register additional trademarks, including our new corporate logos and certain slogans. As we apply to register our unregistered trademarks in the U.S. 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 U.S., 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.

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 U.S., 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 by us or the opponent from Opposition Proceedings at the European Patent Office related to four of our patents: EP2364368, EP2387627, EP3059337, and EP3144673. 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. One or more 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 U.S., 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 and Capital Structure

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

The market price of our common stock has been and is likely to continue to be highly volatile, with a 52-week high closing price of $10.11 and a 52-week low closing price of $3.46, 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 U.S. 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. Any decline in the market price of our common stock may impair our ability to raise capital through the sale of equity securities.

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.

Our Purchase Agreement with OrbiMed could limit cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operations.

Our obligations under the Purchase Agreement could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- requiring the dedication of a portion of our cash flow from operations to service the Purchase Agreement obligations, which will reduce the amount of cash available for other purposes, and if our cash inflows and capital resources are insufficient to allow us to make required payments, we may have to reduce or delay additional investments in our operations or seek additional capital;

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital; and
- if we fail to comply with the terms of the Purchase Agreement, resulting in an event of default that is not cured or waived, the Purchasers could seek to enforce their security interest.

In addition, the Purchase Agreement contains customary affirmative and negative non-financial covenants and events of default, including covenants and restrictions that, among other things, grant a first-position security interest in our core assets and restrict our ability to incur liens, incur additional indebtedness, make loans and investments, make certain restricted payments or transfer core assets. Additionally, the Purchasers under the Purchase Agreement have an option (the "Put Option") to terminate the Purchase Agreement and to require us to repurchase future Revenue Interests at a price of 120% to 175% of Cumulative Purchaser Payments, less the sum of all Revenue Interest Payments made by us to the Purchasers prior to such date, upon enumerated events such as a bankruptcy event, a material judgment against us, a material divestiture or a change of control. The triggering of the Put Option, including by our failure to comply with these covenants, could permit the Purchasers to declare certain amounts to be immediately due and payable.

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.

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 consolidated 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 consolidated 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. 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 and potentially impair our ability to raise capital through the sale of equity securities.

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.

We are subject to financial reporting and other requirements for which our accounting and other management systems and resources may not be adequately prepared.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"), we are 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. Our compliance with Section 404 necessitates that we incur substantial accounting expense and expend significant management efforts. We will continue to dedicate internal resources, potentially engage outside consultants, and 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. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.

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.

Evolving expectations around corporate responsibility practices, specifically related to environmental, social and governance ("ESG") matters, may expose us to reputational and other risks.

Investors, shareholders, customers, suppliers and other third parties are increasingly focusing on ESG and corporate social responsibility endeavors and reporting. Certain institutional investors, investment funds, other influential investors, customers, suppliers and other third parties are also increasingly focused on ESG practices. In particular, third party proxy advisory services which focus on shareholder rights provisions, such as majority voting, annual election of directors, and overboarding of outside directors, have recommended against voting for our directors in past elections as a result of our governance profile.

Companies that do not adapt to or comply with the evolving investor or stakeholder expectations and standards, or which are perceived to have not responded appropriately, may suffer from reputational damage and result in the business, financial condition and/or stock price of a company being materially and adversely affected. Further, this increased focus on ESG issues may result in new regulations and/or third-party requirements that could adversely impact our business, or certain shareholders reducing or eliminating their holdings of our stock. Additionally, an allegation or perception that we have not taken sufficient action in these areas could negatively harm our reputation.

Companies across all industries are facing increasing scrutiny relating to their ESG policies. If we are perceived to have not responded appropriately to the growing concern for governance issues, investors may reconsider their capital investment as a result of their assessment of our practices, and our reputation, business, financial condition, results of operations and cash flows may be adversely affected.

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 or cause shareholders to incur additional costs to bring claims in the forums designated in our Articles of Incorporation.

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. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a jurisdiction other than those designated in the exclusive forum provision, and the provision may not be enforced by a court in that jurisdiction. It is unclear 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 most of 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 1C. Cybersecurity

As trusted partners to healthcare providers, patients, biopharmaceutical companies, academic and non-profit institutions, business partners and employees, we appreciate the importance of maintaining a comprehensive and trustworthy information security program. Our information security program is fully integrated into our operations, and a hallmark of our program is its cross-functional approach with our internal privacy objectives and stakeholders.

Our cybersecurity program is based on the ISO 27001 security controls set, and in particular, it focuses on the principles of confidentiality, integrity and availability. We maintain an ISO 27001 certification with a fully integrated set of operational policies and procedures to adhere to the 14 domains of ISO 27001. This includes but is not limited to the organization of information security to assign roles and responsibilities within Adaptive, access control to restrict employees' access to view only that information that is relevant to their roles, information security incident management, and compliance to broadly ensure alignment with applicable laws and regulations. We perform an annual risk assessment conducted by an outside assessor and operate a vendor risk assessment program for third party vendors to evaluate how their systems may impact our business in the event of a cybersecurity incident. We also provide annual, mandatory cybersecurity training for employees to equip our workforce with the knowledge to identify and respond to cybersecurity threats, such as phishing attempts.

The internal body with executive oversight of our cybersecurity program is our Privacy and Information Security Steering Committee ("PISSC"), which applies a multidisciplinary framework to cybersecurity risks and risk assessment by integrating information security, privacy and human resources expertise, oversight and reporting. The PISSC is made up of our Head of Security, Privacy Officer, Chief Operations Officer, Chief Financial Officer, General Counsel and Chief People Officer and meets on a quarterly basis. Our Head of Security is a senior information security professional with more than 20 years of experience implementing and leading security programs. Our Head of Security holds an undergraduate degree in computer science, has a Six Sigma certification in Total Quality Management and is a Certified Information Systems Security Professional ("CISSP").

Our board of directors is kept apprised of cybersecurity risks and assessments through regular presentations to the Audit Committee regarding our information security and privacy governance and reports on information security and privacy incidents. Cybersecurity threats, including as a result of any past cybersecurity incidents, have not materially affected us, including our business strategy, results of operations or financial condition. For more information regarding how cybersecurity risks may affect us, see the "Risk Factors" section.

Item 2. Properties

Our corporate headquarters is located in Seattle, Washington, where we lease approximately 100,000 square feet. The lease expires in August 2033, subject to our option to twice extend the lease for five years. In a separate Seattle, Washington location, we lease approximately 65,500 square feet pursuant to a lease that expires October 2032, subject to our option to twice extend the lease for five years. Both of our Seattle, Washington locations contain office and laboratory space.

We also lease approximately 27,000 square feet of a warehouse in Bothell, Washington. The lease expires in October 2031, subject to an early termination option in 2028 and an option to twice extend the lease for five years.

Additionally, we lease approximately 33,300 square feet of laboratory and office space in South San Francisco, California, pursuant to an amended lease that expires March 2026, subject to our option to extend the lease for five years.

We also lease approximately 3,100 square feet of office space in New York City, New York, pursuant to a lease that expires November 2025.

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

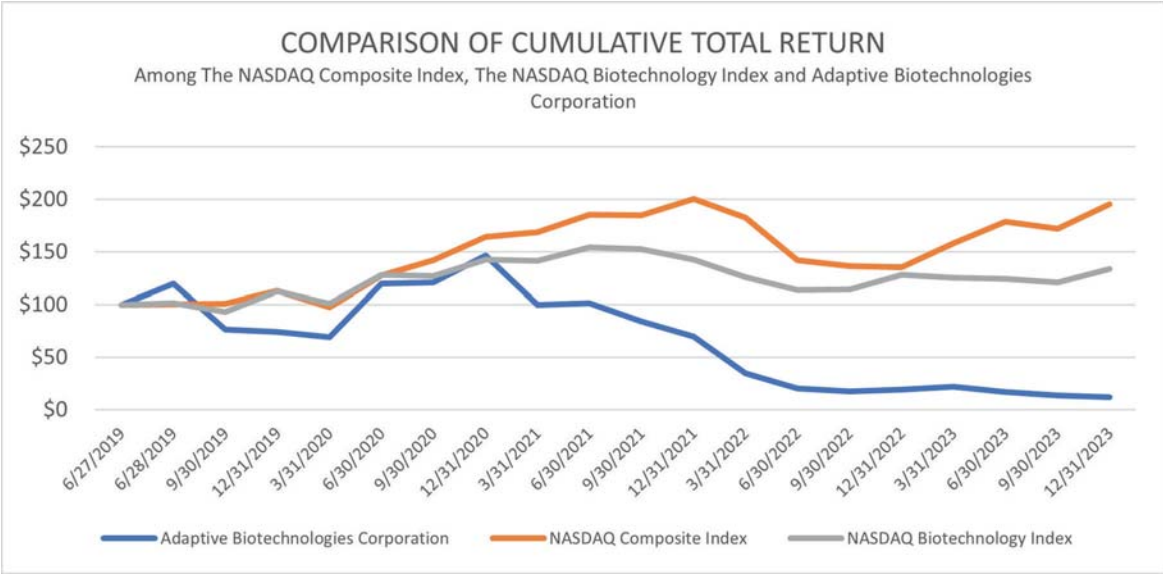
As of February 23, 2024, there were approximately 85 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of shareholders, we are unable to estimate the total number of shareholders represented by these record holders.

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.

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 in our common stock at the market close on June 27, 2019, which was our initial trading day. Data for the NASDAQ Composite Index and the NASDAQ Biotechnology Index assume reinvestment of dividends. The 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. [Reserved]

Not applicable.

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 the consolidated 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 Securities and Exchange Commission ("SEC") from time to time. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties relating to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. 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 2023 and 2022 items and year-to-year comparisons between 2023 and 2022. Discussions of 2021 items and year-to-year comparisons between 2022 and 2021 may be found in Part II, Item 7 under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 14, 2023.

Overview

We are advancing the field of immune 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 the immune system detects and treats disease in that patient. We capture these insights in our dynamic clinical immunomics database and related antigen annotations, which are underpinned by computational biology and machine learning, and use them to develop and commercialize clinical products and services that can be tailored to the needs of individual patients. Our existing and future commercial products and services are aligned to two business areas which we refer to as MRD and Immune Medicine.

Our current product and service offerings in MRD related to the MRD market are our clonoSEQ clinical diagnostic test, offered to clinicians, and our clonoSEQ or MRD assay, offered to biopharmaceutical partners to advance drug development efforts ("MRD Pharma"). 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, B cell ALL and CLL, and is also available as a CLIA-validated laboratory developed test for patients with other lymphoid cancers, including DLBCL. With the use of clonoSEQ, we are transforming how lymphoid cancers are treated by working with providers, pharmaceutical partners and payors.

Immune Medicine leverages our proprietary ability to sequence, map, pair and characterize TCRs and BCRs at scale to drive opportunities in cancer, autoimmune disorders, infectious diseases and neurodegenerative disorders. Our core research product, Adaptive Immunosequencing, serves as our underlying research and development engine and generates revenue from biopharmaceutical and academic customers. Leveraging our collaboration with Microsoft, we are creating the TCR-Antigen Map. We are using the TCR-Antigen Map to identify and validate disease signatures to improve the diagnosis and treatment of many diseases. In Drug Discovery, we use our proprietary capabilities to discover new drug targets and leverage our validated TCR and BCR discovery approaches to discover and develop TCR or antibody therapeutic assets. Drug Discovery includes the Genentech Agreement. Part of our strategy within Immune Medicine is to develop a diagnostic test for many diseases from a single blood test, known as T-Detect. In 2022, we decided to defer further commercialization of T-Detect until we have strong enough data in multiple disease states to impact physician behavior with a clear path to reimbursement.

We recognized revenue of $170.3 million and $185.3 million for the year ended December 31, 2023 and 2022, respectively. Net loss attributable to Adaptive Biotechnologies Corporation was $225.3 million and $200.2 million for the year ended December 31, 2023 and 2022, respectively. We have funded our operations to date principally from the sale of convertible preferred stock and common stock and, to a lesser extent, revenue and proceeds from the Purchase Agreement. As of December 31, 2023 and 2022, we had cash, cash equivalents and marketable securities of $346.4 million and $498.2 million, respectively.

Components of Results of Operations

Revenue

We derive revenue by providing diagnostic and research services in our Immune Medicine and MRD business areas. Our Immune Medicine revenue consists of revenue generated from (1) providing sample testing services for our commercial research product, Adaptive Immunosequencing, to biopharmaceutical customers and academic institutions; (2) our collaboration agreements with Genentech and other biopharmaceutical customers in areas of drug and target discovery; and (3) for prior years, providing our T-Detect COVID tests to clinical customers. Our MRD revenue consists of revenue generated from (1) providing our clonoSEQ report to clinical customers; (2) providing MRD sample testing services to biopharmaceutical customers and certain academic institutions, including investigator-led clinical trials; and (3) providing our clonoSEQ report or results to certain international laboratory sites through technology transfers. We disclose our clonoSEQ test volume, which includes the number of clonoSEQ reports and results we have provided to ordering physicians in the U.S. and international technology transfer sites. These volumes do not include sample results from our biopharmaceutical customers or academic institutions utilizing our MRD services.

For our research customers, which include biopharmaceutical customers and academic institutions for both our Adaptive Immunosequencing and MRD services, delivery of the respective test results may include some level of professional support and analysis. Terms with biopharmaceutical customers generally include non-refundable payments made in advance of services ("upfront payments"), which we record as deferred revenue. For all research 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. In periods where our sample estimates are reduced or a customer project is cancelled and, in either case, we have remaining related deferred revenue, we recognize revenue using a cumulative catch-up approach based on the proportion of samples delivered to date relative to the total samples expected to be delivered. Certain of our MRD revenue arrangements with biopharmaceutical customers include cash consideration from the achievement of regulatory milestones of the respective biopharmaceutical customers' therapeutics. Such revenue is constrained from recognition until it becomes probable that such milestone will be achieved.

Under certain agreements with our biopharmaceutical customers who seek access to our platform to support their therapeutic development activities, revenues are generated from research and development support services that we provide. These agreements may include substantial non-refundable upfront payments, which we recognize over time as we perform the respective services. Revenue recognized from these activities relate primarily to the Genentech Agreement.

For our clinical customers, we primarily derive revenue from providing our clonoSEQ report to ordering physicians. We bill commercial, government and medical institution payors based on reports delivered to ordering physicians. Amounts paid for clonoSEQ by commercial, government and medical institution payors vary based on respective reimbursement rates and patient responsibilities, which may differ from our targeted list price. 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.

For our clonoSEQ coverage under Medicare, we bill an episode of treatment when we deliver the first eligible test report. 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 recognition commences at the time the initial billable test report 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 either as we deliver our estimate of the remaining tests in a patient's treatment cycle or when the likelihood becomes remote that a patient will receive additional testing.

We expect our Immune Medicine revenue to decrease in the short term primarily due to our expected reduction in revenue generated from the Genentech Agreement. Over the long term, we expect our Immune Medicine revenue to increase as we or our collaborators advance therapies to commercialization. Our Immune Medicine revenue may fluctuate from period to period due to the timing of expenses incurred, changes in estimates of total anticipated costs related to the Genentech Agreement and other events not within our control, including the recognition of milestones under the Genentech Agreement and the timing of receipt of customer samples from our biopharmaceutical customers.

We expect our MRD revenue to increase in the long term as we continue to increase our MRD clinical testing volume through increased penetration in our existing covered patient populations, expansion into new patient populations and as we optimize payor coverage. Our MRD revenue may fluctuate period to period due to the uncertain timing of receipt of our biopharmaceutical customer samples, which may cause uncertainty in the delivery of our products and services, the recognition of milestones related to regulatory approvals of our biopharmaceutical customers' therapeutics and changes in estimates of our clinical revenue reimbursement rates.

Cost of Revenue

Cost of revenue includes the cost of materials, personnel-related expenses (including salaries, benefits and share-based compensation), shipping and handling expenses, equipment costs, allocated facility costs associated with processing samples and professional support costs related to our service revenue activities. Allocated facility costs include depreciation of laboratory equipment, as well as 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 the Genentech Agreement are a component of our research and development expenses.

We expect cost of revenue to increase in absolute dollars as we grow our sample testing volume, but the cost per sample to decrease over the long term due to the efficiencies we may gain as assay volume increases from improved utilization of our laboratory capacity, automation and other value engineering initiatives. If our sample volume throughput is reduced, cost of revenue as a percentage of total revenue may be adversely impacted due to fixed overhead costs.

Research and Development Expenses

Research and development expenses consist of laboratory materials costs, personnel-related expenses (including salaries, benefits and share-based compensation), equipment costs, allocated facility and information technology costs and contract service expenses. Research and development activities support further development and refinement of existing assays and products, discovery of new technologies and investments in our immune medicine platform. We also include in research and development expenses the costs associated with software development of applications to support future commercial opportunities, as well as development activities to support laboratory scaling and workflow. 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 have not historically tracked research and development expenses by specific product candidates.

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

We expect research and development expenses to decrease in the short term and 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 include personnel-related expenses (including salaries, benefits and share-based compensation) for commercial sales, product and 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 and information technology costs.

We expect sales and marketing expenses to remain relatively consistent in the short term. In the long term, we expect sales and marketing expenses to increase in absolute dollars as we 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 include personnel-related expenses (including salaries, benefits and share-based compensation) for our personnel in executive, legal, finance and accounting, human resources and other administrative functions, including third-party clinical billing services. In addition, these expenses include insurance costs, external legal costs, accounting and tax service expenses, consulting fees and allocated facility and information technology costs.

We expect general and administrative expenses to remain relatively consistent in the short term and to decrease as a percentage of revenue in the long term.

Impairment of Right-of-Use and Related Long-Lived Assets Expenses

Impairment of right-of-use and related long-lived assets expenses include our impairment charge for certain leased office and laboratory space, as well as impairment costs for related leasehold improvements. See Note 10, *Leases* of the accompanying notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for details regarding our impairment assessments and considerations.

Interest Expense

Interest expense includes costs associated with our revenue interest liability related to the Purchase Agreement and noncash interest costs associated with the amortization of the related deferred issuance costs. We impute interest expense using the effective interest rate method. We calculate an effective interest rate which will amortize our related obligation to zero over the anticipated repayment period. A significant increase or decrease in or changes in timing of forecasted revenue will prospectively impact our interest expense.

Statements of Operations Data and Other Financial and Operating Data

The following table sets forth our statements of operations data and other financial and operating data for the periods presented (in thousands, except share and per share amounts):

	Year Ended December 31,		
	2023	2022	2021
Statements of Operations Data:			
Revenue	$ 170,276	$ 185,308	$ 154,344
Operating expenses			
Cost of revenue	75,553	57,909	49,301
Research and development	122,117	141,756	142,343
Sales and marketing	88,579	95,603	95,465
General and administrative	83,934	88,527	74,502
Amortization of intangible assets	1,699	1,699	1,699
Impairment of right-of-use and related long-lived assets	25,429	—	—
Total operating expenses	397,311	385,494	363,310
Loss from operations	(227,035)	(200,186)	(208,966)
Interest and other income, net	15,531	4,056	1,668
Interest expense	(13,800)	(4,238)	—
Net loss	(225,304)	(200,368)	(207,298)
Add: Net loss attributable to noncontrolling interest	54	177	19
Net loss attributable to Adaptive Biotechnologies Corporation	$ (225,250)	$ (200,191)	$ (207,279)
Net loss per share attributable to Adaptive Biotechnologies Corporation common shareholders, basic and diluted	$ (1.56)	$ (1.40)	$ (1.48)
Weighted-average shares used in computing net loss per share attributable to Adaptive Biotechnologies Corporation common shareholders, basic and diluted	144,383,294	142,515,917	140,354,915
Other Financial and Operating Data:			
Adjusted EBITDA[(1)]	$ (116,413)	$ (121,589)	$ (151,743)

[(1)] Adjusted EBITDA is a non-GAAP financial measure that we define as net loss attributable to Adaptive Biotechnologies Corporation adjusted for interest and other income, net, interest expense, income tax (expense) benefit, depreciation and amortization expense, impairment costs for right-of-use and related long-lived assets, restructuring expense and share-based compensation expense. Please refer to "Adjusted EBITDA" below for a reconciliation between Adjusted EBITDA and net loss attributable to Adaptive Biotechnologies Corporation, the most directly comparable GAAP financial measure, and a discussion about the limitations of Adjusted EBITDA.

Comparison of the Years Ended December 31, 2023 and 2022

Revenue

	Year Ended December 31,		Change		Percent of Revenue	
(in thousands, except percentages)	2023	2022	$	%	2023	2022
Immune Medicine revenue						
Service revenue	$ 24,959	$ 31,777	$ (6,818)	(21)%		
Collaboration revenue	42,578	66,387	(23,809)	(36)		
Total Immune Medicine revenue	67,537	98,164	(30,627)	(31)	40%	53%
MRD revenue						
Service revenue	102,739	81,144	21,595	27		
Regulatory milestone revenue	—	6,000	(6,000)	(100)		
Total MRD revenue	102,739	87,144	15,595	18	60%	47%
Total revenue	$170,276	$185,308	$(15,032)	(8)	100%	100%

The $30.6 million decrease in Immune Medicine revenue was primarily due to a $20.2 million decrease in revenue generated from the Genentech Agreement which resulted from decreased collaboration expenses partially offset by the $8.2 million of revenue recognized in connection with the regulatory milestone achieved in May 2023. There was also a $9.1 million decrease in revenue generated from our biopharmaceutical customers, $3.6 million of which was driven by the completion of our development activities for two of our collaboration agreements in 2022, and a $1.4 million decrease in revenue generated from our T-Detect COVID clinical customers resulting from our deferral of commercializing T-Detect.

The $15.6 million increase in MRD revenue was primarily due to an $18.2 million increase in revenue generated from providing clonoSEQ to clinical customers and a $2.8 million increase in revenue generated from providing MRD sample testing services to investigator-led clinical trials. These increases were partially offset by a $6.0 million decrease in revenue recognized upon the achievement of regulatory milestones by some of our biopharmaceutical customers. Our clonoSEQ test volume increased by 53% to 56,496 tests delivered in the year ended December 31, 2023 from 36,871 tests delivered in the year ended December 31, 2022.

Cost of Revenue

	Year Ended December 31,		Change		Percent of Revenue	
(in thousands, except percentages)	2023	2022	$	%	2023	2022
Cost of revenue	$ 75,553	$ 57,909	$ 17,644	30%	44%	31%

The $17.6 million increase in cost of revenue was primarily attributable to an $8.6 million increase related to higher usage of our production laboratory to process revenue samples versus research and development samples, a $5.1 million increase in overhead costs largely driven by laboratory relocation and consolidation activities, a $2.8 million increase in materials cost resulting from increased revenue sample volume and a $1.2 million increase in shipping and handling expenses.

Research and Development

	Year Ended December 31,		Change		Percent of Revenue	
(in thousands, except percentages)	2023	2022	$	%	2023	2022
Research and development	$122,117	$141,756	$(19,639)	(14)%	72%	76%

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

	Year Ended December 31,		
(in thousands)	2023	2022	Change
Research and development materials and allocated production laboratory expenses	$ 20,243	$ 43,706	$ (23,463)
Personnel expenses	74,385	68,177	6,208
Allocable facilities and information technology expenses	11,617	8,856	2,761
Software and cloud services expenses	3,394	2,678	716
Depreciation and other expenses	12,478	18,339	(5,861)
Total	$ 122,117	$ 141,756	$ (19,639)

The $19.6 million decrease in research and development expenses was primarily attributable to a $23.5 million decrease in cost of materials and allocated production laboratory expenses, which was driven primarily by decreased investments in T-Detect and TCR-Antigen Map development activities, as well as decreased investments in drug discovery efforts, including collaboration efforts with Genentech. There was also a $3.1 million decrease in consultant costs and a $2.5 million decrease in costs related to collaboration studies and clinical trials, which were the primary drivers of the $5.9 million decrease in depreciation and other expenses. These decreases were partially offset by a $6.2 million increase in personnel costs, a $2.8 million increase in allocable facility expenses and a $0.7 million increase in software and cloud services expenses.

Sales and Marketing

	Year Ended December 31,		Change		Percent of Revenue	
(in thousands, except percentages)	2023	2022	$	%	2023	2022
Sales and marketing	$ 88,579	$ 95,603	$ (7,024)	(7)%	52%	52%

The $7.0 million decrease in sales and marketing expenses was primarily attributable to a $5.0 million decrease in marketing expenses, which was largely driven by reduced clonoSEQ marketing activities and our deferral of commercializing T-Detect, a $3.8 million decrease in personnel costs and a $1.0 million decrease in consultant costs. These decreases were partially offset by a $2.4 million increase in computer and software expenses and a $0.8 million increase in building, facility and depreciation related expenses.

General and Administrative

	Year Ended December 31,		Change		Percent of Revenue	
(in thousands, except percentages)	2023	2022	$	%	2023	2022
General and administrative	$ 83,934	$ 88,527	$ (4,593)	(5)%	49%	48%

The $4.6 million decrease in general and administrative expenses was primarily attributable to an $8.0 million decrease in building, facility and depreciation related expenses, driven largely by office space transitions made to support laboratory consolidation activities, a $2.0 million decrease in consultant costs and a $1.6 million decrease in insurance costs. These decreases were partially offset by a $2.7 million increase in personnel costs, driven primarily by increased share-based compensation, a $1.6 million increase in legal and accounting fees, a $1.3 million increase in computer and software expenses and a $1.2 million increase in third-party billing service fees.

Impairment of Right-of-Use and Related Long-Lived Assets

	Year Ended December 31,		Change		Percent of Revenue	
(in thousands, except percentages)	2023	2022	$	%	2023	2022
Impairment of right-of-use and related long-lived assets	$ 25,429	$ —	$ 25,429	*%	15%	0%

* Not applicable

The $25.4 million increase in impairment of right-of-use and related long-lived assets expenses was attributable to us vacating certain leased space in Seattle, Washington in October 2023 and the resulting impairment of related leasehold improvements.

Interest and Other Income, Net

	Year Ended December 31,		Change	
(in thousands, except percentages)	2023	2022	$	%
Interest and other income, net	$ 15,531	$ 4,056	$ 11,475	283%

The $11.5 million increase in interest and other income, net was primarily attributable to an increase in net interest income and investment amortization driven by increased interest rates and related yields of our invested cash and cash equivalents and marketable securities.

Interest Expense

	Year Ended December 31,		Change	
(in thousands, except percentages)	2023	2022	$	%
Interest expense	$ (13,800)	$ (4,238)	$ (9,562)	226%

The $9.6 million increase in interest expense was attributable to the Purchase Agreement entered into in September 2022.

Adjusted EBITDA

Adjusted EBITDA is a non-GAAP financial measure that we define as net loss attributable to Adaptive Biotechnologies Corporation adjusted for interest and other income, net, interest expense, income tax (expense) benefit, depreciation and amortization expense, impairment costs for right-of-use and related long-lived assets, restructuring expense and share-based compensation expense.

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;
- interest expense, which is an ongoing element of our costs to operate;
- 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 noncash component of employee compensation expense;
- right-of-use and related long-lived assets impairment costs; and
- the impact of earnings or charges resulting from matters we consider not to be reflective, on a recurring basis, of our ongoing operations, such as our March 2022 restructuring and reduction in workforce.

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 net loss attributable to Adaptive Biotechnologies Corporation, the most directly comparable GAAP financial measure, to Adjusted EBITDA for the periods presented (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Net loss attributable to Adaptive Biotechnologies Corporation	$ (225,250)	$ (200,191)	$ (207,279)
Interest and other income, net	(15,531)	(4,056)	(1,668)
Interest expense[1]	13,800	4,238	—
Depreciation and amortization expense	22,231	20,920	13,953
Impairment of right-of-use and related long-lived assets[2]	25,429	—	—
Restructuring expense[3]	—	2,023	—
Share-based compensation expense[4]	62,908	55,477	43,251
Adjusted EBITDA	$ (116,413)	$ (121,589)	$ (151,743)

[1] Represents costs associated with our revenue interest liability and noncash interest costs associated with the amortization of the related deferred issuance costs. See Note 11, *Revenue Interest Purchase Agreement* of the accompanying notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for details on the Purchase Agreement.
[2] Represents impairment costs for right-of-use and related long-lived assets. See Note 10, *Leases* of the accompanying notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for details on our impairment expense.
[3] Represents expenses recognized in conjunction with restructuring activities. See Note 16, *Restructuring* of the accompanying notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for details on our restructuring expense.
[4] Represents share-based compensation expense related to stock option, restricted stock unit and market-based restricted stock unit awards. See Note 14, *Equity Incentive Plans* of the accompanying notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for details on our share-based compensation expense.

Liquidity and Capital Resources

We have incurred losses since inception and have incurred negative cash flows from operations since inception through the year ended December 31, 2018, and again in the years ended December 31, 2020, 2021, 2022 and 2023. As of December 31, 2023, we had an accumulated deficit of $1.1 billion.

We have funded our operations to date principally from the sale of convertible preferred stock and common stock, and, to a lesser extent, revenue and proceeds from the Purchase Agreement. Pursuant to the Purchase Agreement entered into in September 2022, we received net cash proceeds of $124.4 million, after deducting issuance costs. We are also entitled to receive up to $125.0 million in subsequent installments as follows: (i) $75.0 million upon our request occurring no later than September 12, 2025 and (ii) $50.0 million upon our request in connection with certain permitted acquisitions occurring no later than September 12, 2025, in each case subject to certain funding conditions. As of December 31, 2023, we had cash, cash equivalents and marketable securities of $346.4 million.

We believe 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.

If our available cash, cash equivalents and marketable securities balances and anticipated cash flows are insufficient to satisfy our liquidity requirements, we may request an additional installment under the Purchase Agreement, 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. This additional capital may not be available on reasonable terms, or at all.

We plan to utilize the existing cash, cash equivalents and marketable securities on hand primarily to fund our continued research and development initiatives related to drug discovery, our commercial and marketing activities associated with clonoSEQ and our continued investments in streamlining our laboratory operations. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to capital preservation and liquidity. Currently, our funds are held in money market funds and marketable securities consisting of U.S. government treasury and agency securities, commercial paper and corporate bonds.

While we may experience variability in revenue in the near term, over the long-term we expect revenue from our current and future products and services to grow. Accordingly, we expect our accounts receivable and inventory balances to increase. Our levels of accounts receivable may fluctuate relative to our revenue for a number of reasons, including the timing of milestone triggers and related payment of those milestones, as well as reductions in revenue derived from the upfront payment received under the Genentech Agreement and an increase in revenue generated from clinical customers, which may result in more billings in arrears as opposed to upfront payments. 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.

Contractual Obligations

Our contractual obligations as of December 31, 2023 include operating lease obligations of $121.3 million, which reflects the minimum commitments for our office and laboratory spaces in Seattle, Washington and South San Francisco, California and our warehouse lease in Bothell, Washington. See Note 10, *Leases* of the accompanying notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for more information, including the timing of cash payments related to these lease obligations. In connection with one of our lease agreements, we have an existing letter of credit of $2.1 million with one of our existing financial institutions.

Additionally, pursuant to the Purchase Agreement, the Purchasers have a right to receive Revenue Interests from us based on the Applicable Payment Percentage of the Revenue Base. If only the First Payment has been made, the Applicable Payment Percentage shall be five percent of the quarterly Revenue Base. If both the First Payment and Second Payment have been made, the Applicable Payment Percentage shall be eight percent of the quarterly Revenue Base. If each of the First Payment, Second Payment and Third Payment have been made, the applicable payment percentage applied to the Revenue Interest shall be ten percent of the quarterly Revenue Base. Revenue Interest Payments shall be made quarterly within 45 days following the end of each fiscal quarter. If OrbiMed has not received Revenue Interest Payments in the aggregate equal to or greater than the Cumulative Purchaser Payments on or prior to September 12, 2028, the revenue interest rate shall be increased to a rate which, if applied retroactively to our cumulative Revenue Base, would have resulted in Revenue Interest Payments equal to the sum of all Cumulative Purchaser Payments. OrbiMed will be entitled to 100% of the Revenue Interest Payments until it has received the Return Cap, unless full repayment of the amount of the Return Cap has not been made by September 12, 2032, in which case the Return Cap shall be increased to 175% of the Cumulative Purchaser Payments. As projected revenues change from our initial estimates, the amount of the obligation and timing of payment is likely to change. See Note 11, *Revenue Interest Purchase Agreement* of the accompanying notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for more information.

We also have minimum commitments for laboratory material suppliers, which are generally fulfilled within one year, software and service license commitments, which are generally fulfilled within one to three years, and royalty commitments.

Cash Flows

The following table summarizes our uses and sources of cash for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (156,324)	$ (183,945)
Net cash provided by investing activities	129,647	2,905
Net cash provided by financing activities	2,245	132,265

Operating Activities

Cash used in operating activities during the year ended December 31, 2023 was $156.3 million, which was primarily attributable to a net loss of $225.3 million and a net change in operating assets and liabilities of $46.2 million, partially offset by noncash share-based compensation of $62.9 million, noncash impairment of right-of-use and related long-lived assets of $25.4 million, noncash depreciation and amortization of $13.0 million, noncash lease expense of $6.9 million, noncash interest expense related to the Purchase Agreement of $5.3 million and inventory reserve expense of $1.4 million. The net change in operating assets and liabilities was primarily due to a $29.3 million reduction in deferred revenue driven largely by revenue recognized from the Genentech Agreement, an $8.7 million decrease in operating lease right-of-use assets and liabilities, a $5.4 million reduction in accounts payable and accrued liabilities, a $2.8 million increase in inventory and a $1.9 million increase in prepaid expenses and other current assets driven largely by an increase in prepaid software charges. These changes were partially offset by a $2.0 million decrease in accounts receivable, net.

Cash used in operating activities during the year ended December 31, 2022 was $183.9 million, which was primarily attributable to a net loss of $200.4 million and a net change in our operating assets and liabilities of $71.5 million, partially offset by noncash share-based compensation of $55.5 million, noncash depreciation and amortization of $21.7 million, noncash lease expense of $7.2 million, a research and development inventory reserve charge of $2.6 million and noncash interest expense related to the Purchase Agreement of $1.0 million. The net change in our operating assets and liabilities was primarily due to a $56.5 million reduction in deferred revenue driven largely by revenue recognized from the Genentech Agreement, an increase in accounts receivable, net of $22.6 million, $7.1 million of which was attributed to growth in receivables related to clonoSEQ with the remaining increase driven largely by growth in receivables from biopharmaceutical customers, and a $4.1 million decrease in operating lease right-of-use assets and liabilities. These changes were partially offset by a $7.1 million increase in accounts payable and accrued liabilities, a $3.6 million decrease in prepaid expenses and other current assets and a $0.8 million decrease in inventory.

Investing Activities

Cash provided by investing activities during the year ended December 31, 2023 was $129.6 million, which was primarily attributable to proceeds from maturities of marketable securities of $569.9 million, partially offset by purchases of marketable securities of $429.6 million and purchases of property and equipment of $10.7 million.

Cash provided by investing activities during the year ended December 31, 2022 was $2.9 million, which was primarily attributable to proceeds from maturities of marketable securities of $298.0 million, partially offset by purchases of marketable securities of $278.8 million and purchases of property and equipment of $16.3 million.

Financing Activities

Cash provided by financing activities during the year ended December 31, 2023 was $2.2 million, which was attributable to proceeds from the exercise of stock options.

Cash provided by financing activities during the year ended December 31, 2022 was $132.3 million, which was primarily attributable to $124.4 million in proceeds from the Purchase Agreement, net of issuance costs, as well as $7.9 million in proceeds from the exercise of stock options.

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 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 for changes in ownership through June 30, 2023 and continue to monitor for changes that could trigger a limitation. Based on this analysis, we do not expect to have any permanent limitations on the utilization of our federal NOLs. Under the TCJA, federal NOLs incurred in 2018 and future years may be carried forward indefinitely, but the deductibility of such federal NOLs is subject to an annual limitation. NOLs 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, 2023. Accordingly, management applied a full valuation allowance against net deferred tax assets as of December 31, 2023.

Critical Accounting Policies and Estimates

We have prepared the consolidated financial statements in accordance with GAAP. Our preparation of these consolidated 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 consolidated 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 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, imputing interest for the Purchase Agreement, the provision for income taxes, including related reserves, the analysis of goodwill impairment and the recoverability and impairment of long-lived assets, 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, *Significant Accounting Policies* of the accompanying notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies are critical to the judgments and estimates used in the preparation of the consolidated financial statements.

Revenue Recognition

Our 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.

As we fulfill our obligations under these agreements, 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.

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 Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers.* For our biopharmaceutical customers, our performance obligations may 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 not constrained to the extent 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 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. For our collaboration with Genentech, we estimate the extent of progress using a proportional performance model that uses an input method based on costs incurred relative to the total estimated costs of research and development efforts to pursue both the Shared Products and Personalized Product pathways. These estimates are based on our internal estimates and development timeframes, which are subject to revision based on the potential outcomes for both product pathways, decisions made by Genentech, regulatory feedback or other factors not currently known. 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.

For agreements where we provide our clonoSEQ report to ordering physicians, we have identified one performance obligation: the delivery of a clonoSEQ report.

For arrangements with our commercial payors, the payment from the respective payors may vary based on the various reimbursement rates and patient responsibilities. As such, 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.

Revenue Interest Liability, Net and Related Imputed Interest

The revenue interest liability balance associated with the Purchase Agreement that we entered into in September 2022 with OrbiMed is presented net of unamortized issuance costs on the consolidated balance sheets. We impute our associated interest expense using the effective interest rate method. We calculate an effective interest rate which will amortize our related obligation to zero over the anticipated repayment period. The effective interest rate may vary during the term of the agreement depending on a number of factors, including changes in forecasted GAAP revenues. We evaluate the effective interest rate quarterly based on both achieved and forecasted revenues, utilizing the prospective method. The estimates of future revenues and resulting Revenue Interest Payments are based on key assumptions including population, penetration, probability of success and sales price, among others. A significant increase or decrease in or changes in timing of forecasted revenue will prospectively impact our interest expense and the time period for repayment. As of December 31, 2023, a hypothetical ten percent increase in forecasted quarterly revenue would not result in a material change in projected annual interest expense.

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, revenue growth and cash flow trends. 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. If impairment exists, the carrying value of the goodwill is reduced to fair value through an impairment charge recorded in the consolidated statements of operations. To date, we have not recognized any impairment of goodwill.

Recoverability and Impairment of Long-Lived Assets

We review long-lived assets for impairment annually or whenever events or circumstances indicate the carrying amount of an asset group may not be recoverable. To test for recoverability, we compare the carrying amount of the asset group to projected future net undiscounted cash flows. If the carrying amount is found to be unrecoverable, we then assess the asset group's fair value. We utilize the income approach to measure fair value, which requires management to make estimates regarding cash flow projections and discount rates. The extent to which the asset group's carrying amount exceeds its fair value represents the impairment cost to be recognized. Impairment losses, if incurred, are classified within the consolidated statements of operations in accordance with the use of the asset group, if not separately stated within its own financial statement line item. We recognized $25.4 million in impairment expense related to certain right-of-use and related leasehold improvement assets during the year ended December 31, 2023.

Recent Accounting Pronouncements

See Note 2, *Significant Accounting Policies* of the accompanying notes to the consolidated 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, 2023 and 2022, we had cash and cash equivalents of $65.1 million and $90.0 million, respectively, held primarily in cash deposits and money market funds. As of December 31, 2023, we had short-term marketable securities of $281.3 million, held in U.S. government treasury and agency securities, commercial paper and corporate bonds. As of December 31, 2022, we had short-term marketable securities of $408.2 million, held in U.S. government treasury securities, corporate bonds and commercial paper. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates in the U.S. As of December 31, 2023, a hypothetical 100 basis point increase in interest rates would have resulted in a $1.2 million decline in fair value of our available-for-sale securities, as compared to a $1.5 million decline as of December 31, 2022. 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 Consolidated Financial Statements

As of December 31, 2023 and 2022 and

For the Years Ended December 31, 2023, 2022 and 2021

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 consolidated balance sheets of Adaptive Biotechnologies Corporation (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 29, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matter

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

	Genentech Agreement
Description of the Matter	As more fully described in Note 3 of the consolidated financial statements, the Genentech Agreement revenue is estimated to be recognized over a period of approximately nine years from the effective date. The non-refundable consideration of $310.0 million is recognized using a proportional performance model through an input method based on costs incurred relative to the total estimated costs of research and development efforts. For the year ended December 31, 2023, total revenue recognized was $42.6 million and the related deferred revenue at December 31, 2023 totaled $54.7 million. Auditing management's estimate of the total expected research and development costs at completion is complex and requires judgment as a result of the uncertainties of the ultimate progression of the customized product paths, timing and path of development and commercialization decisions, which are controlled by Genentech.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls over the Company's process to evaluate the progress of the collaboration and the likely path of future development based on significant decisions made by Genentech communicated through the joint committees and any resulting impacts on the total costs of research and development efforts for the collaboration. To test the estimate of total expected research and development costs, we performed audit procedures that included, among others, observing the quarterly meetings with accounting and the Company collaboration managers discussing the status of the collaboration and the future development for the customized product paths, and investigating any changes to the development path. We also reviewed supporting documentation to corroborate progress and status of the overall timeline, including meeting minutes from the joint committees.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2015
Seattle, Washington
February 29, 2024

Adaptive Biotechnologies Corporation
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 65,064	$ 90,030
Short-term marketable securities (amortized cost of $281,122 and $412,282, respectively)	281,337	408,166
Accounts receivable, net	37,969	40,057
Inventory	14,448	14,453
Prepaid expenses and other current assets	11,370	9,440
Total current assets	410,188	562,146
Long-term assets		
Property and equipment, net	68,227	83,447
Operating lease right-of-use assets	52,096	80,763
Restricted cash	2,932	2,398
Intangible assets, net	5,128	6,827
Goodwill	118,972	118,972
Other assets	3,591	2,064
Total assets	$ 661,134	$ 856,617
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 7,719	$ 8,084
Accrued liabilities	8,597	12,424
Accrued compensation and benefits	13,685	15,935
Current portion of operating lease liabilities	9,384	9,230
Current portion of deferred revenue	48,630	64,115
Total current liabilities	88,015	109,788
Long-term liabilities		
Operating lease liabilities, less current portion	89,388	98,772
Deferred revenue, less current portion	44,793	58,599
Revenue interest liability, net	130,660	125,360
Total liabilities	352,856	392,519
Commitments and contingencies (Note 12)		
Shareholders' equity		
Preferred stock: $0.0001 par value, 10,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock: $0.0001 par value, 340,000,000 shares authorized at December 31, 2023 and 2022; 145,082,271 and 143,105,002 shares issued and outstanding at December 31, 2023 and 2022, respectively	14	14
Additional paid-in capital	1,452,502	1,387,349
Accumulated other comprehensive gain (loss)	215	(4,116)
Accumulated deficit	(1,144,332)	(919,082)
Total Adaptive Biotechnologies Corporation shareholders' equity	308,399	464,165
Noncontrolling interest	(121)	(67)
Total shareholders' equity	308,278	464,098
Total liabilities and shareholders' equity	$ 661,134	$ 856,617

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

Adaptive Biotechnologies Corporation
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2023	2022	2021
Revenue	$ 170,276	$ 185,308	$ 154,344
Operating expenses			
Cost of revenue	75,553	57,909	49,301
Research and development	122,117	141,756	142,343
Sales and marketing	88,579	95,603	95,465
General and administrative	83,934	88,527	74,502
Amortization of intangible assets	1,699	1,699	1,699
Impairment of right-of-use and related long-lived assets	25,429	—	—
Total operating expenses	397,311	385,494	363,310
Loss from operations	(227,035)	(200,186)	(208,966)
Interest and other income, net	15,531	4,056	1,668
Interest expense	(13,800)	(4,238)	—
Net loss	(225,304)	(200,368)	(207,298)
Add: Net loss attributable to noncontrolling interest	54	177	19
Net loss attributable to Adaptive Biotechnologies Corporation	$ (225,250)	$ (200,191)	$ (207,279)
Net loss per share attributable to Adaptive Biotechnologies Corporation common shareholders, basic and diluted	$ (1.56)	$ (1.40)	$ (1.48)
Weighted-average shares used in computing net loss per share attributable to Adaptive Biotechnologies Corporation common shareholders, basic and diluted	144,383,294	142,515,917	140,354,915

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

Adaptive Biotechnologies Corporation
Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,		
	2023	2022	2021
Net loss	$ (225,304)	$ (200,368)	$ (207,298)
Other comprehensive income (loss)			
Change in unrealized gains and losses on investments	4,331	(2,979)	(2,030)
Comprehensive loss	(220,973)	(203,347)	(209,328)
Add: Comprehensive loss attributable to noncontrolling interest	54	177	19
Comprehensive loss attributable to Adaptive Biotechnologies Corporation	$ (220,919)	$ (203,170)	$ (209,309)

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

Adaptive Biotechnologies Corporation
Consolidated Statements of Shareholders' Equity
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Noncontrolling Interest	Total Shareholders' Equity
	Shares	Amount					
Balance at December 31, 2020	137,646,896	$ 14	$ 1,253,971	$ 893	$ (511,612)	$ —	$ 743,266
Issuance of common stock upon exercise of common stock warrant	54,162	—	—	—	—	—	—
Issuance of common stock for cash upon exercise of stock options	3,674,057	—	26,484	—	—	—	26,484
Vesting of restricted stock units	18,750	—	—	—	—	—	—
Share-based compensation	—	—	43,251	—	—	—	43,251
Capital contributions for Digital Biotechnologies, Inc.	—	—	300	—	—	129	429
Other comprehensive loss	—	—	—	(2,030)	—	—	(2,030)
Net loss	—	—	—	—	(207,279)	(19)	(207,298)
Balance at December 31, 2021	141,393,865	14	1,324,006	(1,137)	(718,891)	110	604,102
Issuance of common stock for cash upon exercise of stock options	1,406,500	—	7,866	—	—	—	7,866
Vesting of restricted stock units	304,637	—	—	—	—	—	—
Share-based compensation	—	—	55,477	—	—	—	55,477
Other comprehensive loss	—	—	—	(2,979)	—	—	(2,979)
Net loss	—	—	—	—	(200,191)	(177)	(200,368)
Balance at December 31, 2022	143,105,002	14	1,387,349	(4,116)	(919,082)	(67)	464,098
Issuance of common stock for cash upon exercise of stock options	470,405	—	2,245	—	—	—	2,245
Vesting of restricted stock units	1,506,864	—	—	—	—	—	—
Share-based compensation	—	—	62,908	—	—	—	62,908
Other comprehensive income	—	—	—	4,331	—	—	4,331
Net loss	—	—	—	—	(225,250)	(54)	(225,304)
Balance at December 31, 2023	145,082,271	$ 14	$ 1,452,502	$ 215	$ (1,144,332)	$ (121)	$ 308,278

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

Adaptive Biotechnologies Corporation
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2023	2022	2021
Operating activities			
Net loss	$ (225,304)	$ (200,368)	$ (207,298)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation expense	20,532	19,221	12,254
Noncash lease expense	6,920	7,227	7,028
Share-based compensation expense	62,908	55,477	43,251
Intangible assets amortization	1,699	1,699	1,699
Investment amortization	(9,184)	741	7,233
Impairment of right-of-use and related long-lived assets	25,429	—	—
Inventory reserve	1,387	2,638	—
Noncash interest expense	5,300	985	—
Other	172	(19)	(78)
Changes in operating assets and liabilities			
Accounts receivable, net	2,032	(22,648)	(7,362)
Inventory	(2,838)	817	(5,200)
Prepaid expenses and other current assets	(1,930)	3,551	1,286
Accounts payable and accrued liabilities	(5,407)	7,111	3,940
Operating lease right-of-use assets and liabilities	(8,676)	(4,050)	8,522
Deferred revenue	(29,291)	(56,496)	(57,727)
Other	(73)	169	(275)
Net cash used in operating activities	(156,324)	(183,945)	(192,727)
Investing activities			
Purchases of property and equipment	(10,697)	(16,349)	(61,746)
Purchases of marketable securities	(429,558)	(278,778)	(316,544)
Proceeds from maturities of marketable securities	569,902	298,032	559,500
Net cash provided by investing activities	129,647	2,905	181,210
Financing activities			
Proceeds from exercise of stock options	2,245	7,890	26,717
Proceeds from revenue interest purchase agreement, net of issuance costs	—	124,375	—
Proceeds from initial capital contributions for Digital Biotechnologies, Inc.	—	—	429
Net cash provided by financing activities	2,245	132,265	27,146
Net (decrease) increase in cash, cash equivalents and restricted cash	(24,432)	(48,775)	15,629
Cash, cash equivalents and restricted cash at beginning of year	92,428	141,203	125,574
Cash, cash equivalents and restricted cash at end of year	$ 67,996	$ 92,428	$ 141,203
Noncash investing activities			
Purchases of equipment included in accounts payable and accrued liabilities	$ 687	$ 1,719	$ 682
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 8,985	$ 494	$ —

The accompanying notes are an integral part of these consolidated 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 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 the immune system detects and treats disease in that patient. We capture these insights in our dynamic clinical immunomics database and related antigen annotations, which are underpinned by computational biology and machine learning, and use them to develop and commercialize clinical products and services that can be tailored to the needs of individual patients. We have 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 and autoimmune disorders.

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.

2. Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The consolidated financial statements include the accounts of Adaptive Biotechnologies Corporation, Adaptive Biotechnologies B.V., our wholly-owned subsidiary, and Digital Biotechnologies, Inc., a corporate subsidiary we have 70% ownership interest in. The remaining interest in Digital Biotechnologies, Inc., held by certain of our related parties and their related family trusts, are shown in the consolidated financial statements as noncontrolling interest. All intercompany transactions and balances have been eliminated upon consolidation.

Use of Estimates

The preparation of consolidated 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 consolidated 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, imputing interest for our revenue interest purchase agreement (the "Purchase Agreement") that we entered into in September 2022, the provision for income taxes, including related reserves, the analysis of goodwill impairment and the recoverability and impairment of long-lived assets, 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.

Segment Information

We have determined that our chief executive officer is the chief operating decision maker ("CODM"). The CODM regularly reviews operating results and other financial information presented on a consolidated basis. While revenue is reviewed at levels lower than the consolidated entity, resource allocation decisions are made by the CODM based on the results presented at the consolidated entity level, which is determined to be a single reporting unit. The consolidated entity operates as one operating segment and represents one reportable segment. We present disaggregated revenue from contracts with customers by market opportunity and type of arrangement. See Note 3, *Revenue*.

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 had a restricted cash balance of $2.9 million and $2.4 million as of December 31, 2023 and 2022, respectively. Our restricted cash primarily relates to certain balances we are required to maintain under lease arrangements for some of our property and facility leases.

Investments in Marketable Securities

Marketable securities are classified as available-for-sale, consist of United States ("U.S.") government treasury and agency securities, corporate bonds and commercial paper and are reported at fair value. Unrealized holding gains and losses are reflected as a separate component of shareholders' equity 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.

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. In certain cases, where there is limited activity or less transparency around valuation inputs, financial instruments are classified as Level 3 within the valuation hierarchy.

Our financial instruments consist of Level 1 and Level 2 assets and have included Level 3 liabilities in the past. 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, 2023 and 2022.

Concentrations of Risk

We are subject to a concentration of risk from a limited number of suppliers, or in certain 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 treasury and agency securities, corporate bonds and commercial paper with high-quality accredited financial institutions.

Significant customers are those that represent more than ten percent of our total revenue or accounts receivable, net balances for the periods and as of each consolidated balance sheet date presented, respectively.

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 dates presented were as follows:

	Revenue			Accounts Receivable, Net	
	Year Ended December 31,			December 31,	
	2023	2022	2021	2023	2022
Customer A	*%	*%	*%	*%	15.8%
Customer B	*	11.6	*	*	19.5
Genentech, Inc. and Roche Group	27.8	36.4	41.9	*	*

* less than 10%

Accounts Receivable

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

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. Long-term inventory of $2.8 million and $1.4 million was included within the other assets balance on the consolidated balance sheet as of December 31, 2023 and 2022, respectively.

Property and Equipment

Property and equipment consists of computer equipment, computer software, laboratory equipment, leasehold improvements, furniture and office equipment and assets under construction. 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 years to 7 years
Leasehold improvements	Shorter of estimated useful life or remaining lease term
Computer equipment and software	3 years to 5 years
Furniture and office equipment	5 years to 7 years

We review long-lived assets for impairment annually or 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, if incurred, are classified within the consolidated statements of operations in accordance with the use of the asset, if not separately stated within its own financial statement line item. See Note 10, *Leases* for more information regarding the leasehold improvements impairment loss recognized during the year-ended December 31, 2023.

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.

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. If impairment exists, the carrying value of the goodwill is reduced to its fair value through an impairment charge recorded in the consolidated statements of operations. To date, we have not recognized any impairment of goodwill.

Leases

We determine if an arrangement contains a lease at inception. We have operating lease agreements for the laboratory, office and warehouse facilities that we occupy. Operating lease right-of-use ("ROU") assets and operating lease liabilities are recognized at the date the underlying asset becomes available for our use and are based on the present value of the future minimum lease payments over the lease term. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. As our leases generally do not provide an implicit interest rate, the present value of our future minimum lease payments is determined using our incremental borrowing rate. This rate is an estimate of the collateralized borrowing rate we would incur on our future lease payments over a similar term and is based on the information available to us at the lease commencement date, or as of January 1, 2020 for commenced leases that existed as of our adoption of Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842) ("ASC 842").

Certain of our leases contain options to extend or terminate the lease; lease terms are adjusted for these options only when it is reasonably certain we will exercise these options. Our lease agreements do not contain residual value guarantees or covenants.

We have made a policy election regarding our real estate leases not to separate nonlease components from lease components, to the extent they are fixed. Nonlease components that are not fixed are expensed as incurred as variable lease expense. Our leases for laboratory, office and warehouse facilities typically include variable nonlease components, such as common-area maintenance costs. We have also elected not to record on the consolidated balance sheets a lease that has a lease term of twelve months or less and does not contain a purchase option that we are reasonably certain to exercise.

We review our right-of-use assets for impairment annually or whenever events or circumstances indicate the carrying amount of an asset group may not be recoverable. Impairment losses are classified within the consolidated statements of operations in accordance with the use of the asset, if not separately stated within its own financial statement line item. See Note 10, *Leases* for more information regarding the right-of-use asset impairment loss recognized during the year-ended December 31, 2023.

Lease expense is recognized on a straight-line basis over the terms of the leases. Incentives granted under our facilities leases, including rent holidays, are recognized as adjustments to lease expense on a straight-line basis over the terms of the leases.

Revenue Interest Liability, Net and Related Imputed Interest

The revenue interest liability balance associated with the Purchase Agreement that we entered into in September 2022 is presented net of unamortized issuance costs on the consolidated balance sheets. We impute our associated interest expense using the effective interest rate method. We calculate an effective interest rate which will amortize our related obligation to zero over the anticipated repayment period. The effective interest rate may vary during the term of the agreement depending on a number of factors, including changes in forecasted GAAP revenues. We evaluate the effective interest rate quarterly based on both achieved and forecasted revenues, utilizing the prospective method. A significant increase or decrease in or changes in timing of forecasted revenue will prospectively impact our interest expense and the time period for repayment.

Revenue Recognition

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.

We derive revenue by providing diagnostic and research services in our Immune Medicine and Minimal Residual Disease ("MRD") business areas. Our Immune Medicine revenue consists of revenue generated from (1) providing sample testing services for our commercial research product, Adaptive Immunosequencing, to biopharmaceutical customers and academic institutions; (2) our collaboration agreements with Genentech, Inc. ("Genentech") and other biopharmaceutical customers in areas of drug and target discovery; and (3) for prior years, providing our T-Detect COVID tests to clinical customers. Our MRD revenue consists of revenue generated from (1) providing our clonoSEQ report to clinical customers; (2) providing MRD sample testing services to biopharmaceutical customers and certain academic institutions, including investigator-led clinical trials; and (3) providing our clonoSEQ report or results to certain international laboratory sites through technology transfers.

For research customers who utilize either Adaptive Immunosequencing or our MRD services, 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: (1) the delivery of our Adaptive Immunosequencing or MRD data for customer provided samples; and (2) related data analysis. We recognize revenue for both identified performance obligations as sample results are delivered to the customer. In periods where our sample estimates are reduced or a customer project is cancelled and, in either case, we have remaining related deferred revenue, we recognize revenue using a cumulative catch-up approach based on the proportion of samples delivered to date relative to the total samples expected to be delivered.

For agreements where we provide our clonoSEQ report to ordering physicians, we have identified one performance obligation: the delivery of a clonoSEQ report. We bill and receive payments for these transactions from commercial, government and medical institution payors. 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.

Regarding our clonoSEQ coverage under Medicare, we bill an episode of treatment when we deliver the first eligible test report. 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 recognition commences at the time the initial billable test report 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. Any unrecognized revenue from the initial billable test is recorded as deferred revenue and is recognized either as we deliver our estimate of the remaining tests in a patient's treatment cycle or when the likelihood becomes remote that a patient will receive additional testing.

The contract transaction price for agreements we enter into with biopharmaceutical customers to further develop and commercialize their therapeutics may consist of a combination of non-refundable upfront fees, separately priced MRD testing fees and milestone fees earned upon our customers' achievement of certain regulatory approvals. Depending on the contract, these agreements include single or multiple performance obligations. Such performance obligations include providing services to support our customers' therapeutic development efforts, including regulatory support for our technology intended to be utilized as part of our customers' registrational trials, developing analytical plans for our data, participating on joint research committees, assisting in completing a regulatory submission and providing MRD testing services related to customer-provided samples for our customers' regulatory submissions. Generally, the support services, excluding MRD testing services, are not distinct within the context of the contract and thus are accounted for as a single performance obligation. 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 MRD testing services. When MRD sample testing services are separately priced customer options, we assess if a material right exists and, if not, the customer option to purchase additional MRD sample testing services is not considered part of the contract. We recognize revenue related to MRD testing services 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, 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 using a cost-based model based on estimates of effort completed. Selecting the measure of progress and estimating progress to date requires significant judgment. Except for any non-refundable upfront fees, the other forms of compensation represent variable consideration. At contract inception, we fully constrain any consideration related to regulatory milestones, as the achievement of such milestones is subject to third-party regulatory approval and the customers' own submission decision-making. Variable consideration related to 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 will not occur. Milestone payments for regulatory approvals, which are not within our customers' control, 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, as well as the level of effort and investment required to achieve the respective milestone.

In 2021, we executed an intellectual property license agreement that includes variable consideration related to sales-based royalties. Any consideration related to such royalties will be recognized as revenue at the later of when (i) the related sales occur or (ii) the performance obligation to which some or all of the sales-based royalty has been allocated has been satisfied (or partially satisfied).

Contract Balances

In certain circumstances, billing may occur prior to services being performed. Upfront payments are recorded as deferred revenue, or contract liabilities. We classify deferred revenue as current when 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 service and collaboration activities, excluding those related to our worldwide collaboration and license agreement with Genentech, 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, a 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. We also recognize revenue when our estimate of total samples to be provided under certain of our agreements is reduced or, in the case of contract balances related to Medicare, when the likelihood becomes remote that a patient will receive additional testing. See Note 3, *Revenue* for our deferred revenue policy related to our worldwide collaboration and license agreement with Genentech.

Share-Based Compensation

Share-based compensation includes compensation expense for stock option, restricted stock unit and market-based restricted stock unit grants made 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 grant date fair value of stock option and market-based restricted stock unit grants using the Black-Scholes option-pricing model and the Monte Carlo valuation model, respectively.

Advertising

Advertising costs are expensed as incurred. Advertising expenses were $8.6 million, $13.7 million and $22.4 million for the year ended December 31, 2023, 2022 and 2021, respectively.

Cost of Revenue

Cost of revenue includes the cost of materials, personnel-related expenses (including salaries, benefits and share-based compensation), shipping and handling expenses, equipment costs, allocated facility costs associated with processing samples and professional support costs related to our service revenue activities. Allocated facility costs include depreciation of laboratory equipment, as well as 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 consist of laboratory materials costs, personnel-related expenses (including salaries, benefits and share-based compensation), equipment costs, allocated facility and information technology costs and contract service expenses. Research and development activities support further development and refinement of existing assays and products, discovery of new technologies and investments in our immune medicine platform. We also include in research and development expenses the costs associated with software development of applications to support future commercial opportunities, as well as development activities to support laboratory scaling and workflow. Additionally, a component of our research and development expenses are costs supporting clinical and analytical validations to obtain regulatory approval for future clinical products and services. 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. Costs to support our worldwide collaboration and license agreement with Genentech are also a component of our research and development expenses.

Sales and Marketing Expenses

Sales and marketing expenses include personnel-related expenses (including salaries, benefits and share-based compensation) for commercial sales, product and 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 and information technology costs.

Impairment of Right-of-Use and Related Long-Lived Assets Expenses

Impairment of right-of-use and related long-lived assets expenses include our impairment charge for certain leased office and laboratory space, as well as impairment costs for related leasehold improvements.

Interest Expense

Interest expense includes costs associated with our revenue interest liability and noncash interest costs associated with the amortization of the related deferred issuance costs. We impute interest expense using the effective interest rate method. We calculate an effective interest rate which will amortize our related obligation to zero over the anticipated repayment period. A significant increase or decrease in or changes in timing of forecasted revenue will prospectively impact our interest expense.

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 consolidated 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 consolidated 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 the effect of income tax positions only if those positions are more likely than not of being sustained upon examination.

Net Loss Per Share Attributable to Adaptive Biotechnologies Corporation Common Shareholders

We calculate basic net loss per share attributable to our common shareholders by dividing net loss attributable to us by our weighted-average number of shares of common stock outstanding for the period. The diluted net loss per share attributable to our 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, outstanding common stock warrants, outstanding stock options, nonvested restricted stock units outstanding and the maximum nonvested market-based restricted stock units outstanding eligible to be earned are considered common stock equivalents but have been excluded from the calculation of diluted net loss per share attributable to our common shareholders, as their effect is anti-dilutive.

New Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting* (Topic 280): *Improvements to Reportable Segment Disclosures*, which intends to enhance reportable segment disclosures about significant segment expenses. This guidance is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted and the guidance is to be applied retrospectively. We are currently evaluating the impact of this guidance on our consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes* (Topic 740): *Improvements to Income Tax Disclosures*, which primarily intends to enhance the rate reconciliation and income taxes paid disclosures. This guidance is effective for annual periods beginning after December 15, 2024. Early adoption is permitted and the guidance is to be applied prospectively; retrospective application is permitted. We are currently evaluating the impact of this guidance on our consolidated financial statements.

3. Revenue

We disaggregate our revenue from contracts with customers by business area and type of arrangement, 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 disaggregated revenue for the periods presented (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Immune Medicine revenue			
Service revenue	$ 24,959	$ 31,777	$ 24,482
Collaboration revenue	42,578	66,387	63,651
Total Immune Medicine revenue	67,537	98,164	88,133
MRD revenue			
Service revenue	102,739	81,144	56,211
Regulatory milestone revenue	—	6,000	10,000
Total MRD revenue	102,739	87,144	66,211
Total revenue	$ 170,276	$ 185,308	$ 154,344

During the year ended December 31, 2023, we recognized $0.6 million in Immune Medicine service revenue related to cancelled customer contracts. Additionally, during the year ended December 31, 2023, we recognized $5.6 million in MRD service revenue related to Medicare reimbursements resulting from our determination that the likelihood of additional testing for specific patients was remote, cancelled customer contracts and changes in estimates of total samples to be provided under certain of our agreements.

During the year ended December 31, 2022, we recognized $0.7 million in Immune Medicine service revenue related to cancelled customer contracts. Additionally, during the year ended December 31, 2022, we recognized $5.2 million in MRD service revenue related to Medicare reimbursements resulting from our determination that the likelihood of additional testing for specific patients was remote, changes in estimates of total samples to be provided under certain of our agreements and cancelled customer contracts.

During the year ended December 31, 2021, we recognized $5.8 million in MRD service revenue related to changes in estimates of total samples to be provided under certain of our agreements, Medicare reimbursements resulting from our determination that the likelihood of additional testing for specific patients was remote, a change in our estimate of expected cumulative tests per patient for one of our covered indications and cancelled customer contracts.

As of December 31, 2023, we could receive up to an additional $440.0 million in milestone payments in future periods if certain regulatory approvals are obtained by our customers' therapeutics in connection with MRD data generated from our MRD product.

Genentech Collaboration Agreement

In December 2018, we entered into a worldwide collaboration and license agreement with Genentech (the "Genentech Agreement") 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 ($10.0 million of which was achieved in May 2023), 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 Genentech Agreement, we are pursuing two product development pathways for novel T cell therapeutic products 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 Genentech 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 Accounting Standards Codification ("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 Topic 606, *Revenue from Contracts with Customers* ("ASC 606") to account for the activities related to the Genentech Agreement.

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 Products 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 Genentech 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. 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 resulting from 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 given their achievement was highly dependent on factors outside our control. As a result, these payments were fully constrained and were not included in the initial transaction price. In May 2023, one of the regulatory milestones was achieved, resulting in a $10.0 million addition to the transaction price, $7.7 million of which was recognized as revenue in the three months ended June 30, 2023, with the remainder included in deferred revenue to be recognized as revenue over the remaining research and development period. We continue to exclude 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 Products and Personalized Product pathways. When any of the potential regulatory and development milestones are no longer fully constrained and are included in the transaction price, such amounts will be recognized using the cumulative catch-up method based on proportional performance at such time. We currently expect to recognize revenue generated from the Genentech Agreement over a period of approximately nine years from the effective date. This estimate of the research and development period considers pursuit options of development activities supporting both the Shared Products and 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.

In total, we recognized $42.6 million, $62.8 million and $62.0 million in Immune Medicine collaboration revenue during the year ended December 31, 2023, 2022 and 2021, respectively, related to the Genentech Agreement. Costs related to the Genentech Agreement are included in research and development expenses.

4. Deferred Revenue

Deferred revenue from the Genentech Agreement represents $13.6 million and $41.1 million of the current and non-current deferred revenue balances on the consolidated balance sheet, respectively, as of December 31, 2023 and $31.8 million and $55.5 million of the current and non-current deferred revenue balances on the consolidated balance sheet, respectively, as of December 31, 2022. We expect our current deferred revenue to be recognized as revenue within 12 months. We expect the majority of our non-current deferred revenue to be recognized as revenue over a period of approximately four years from December 31, 2023. 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 various research and development activities.

Changes in deferred revenue during the year ended December 31, 2023 were as follows (in thousands):

Deferred revenue balance at December 31, 2022	$	122,714
Additions to deferred revenue during the period		44,471
Revenue recognized during the period		(73,762)
Deferred revenue balance at December 31, 2023	$	93,423

As of December 31, 2023, $53.2 million was recognized as revenue that was included in the deferred revenue balance at December 31, 2022.

5. Fair Value Measurements

The following tables set forth the fair values of financial assets as of December 31, 2023 and 2022 that were measured at fair value on a recurring basis (in thousands):

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Financial assets				
Money market funds	$ 45,123	$ —	$ —	$ 45,123
Commercial paper	—	10,630	—	10,630
U.S. government treasury and agency securities	—	264,426	—	264,426
Corporate bonds	—	6,281	—	6,281
Total financial assets	$ 45,123	$ 281,337	$ —	$ 326,460

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Financial assets				
Money market funds	$ 38,502	$ —	$ —	$ 38,502
Commercial paper	—	9,969	—	9,969
U.S. government treasury securities	—	385,848	—	385,848
Corporate bonds	—	12,349	—	12,349
Total financial assets	$ 38,502	$ 408,166	$ —	$ 446,668

Level 1 securities include highly liquid money market funds, for 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 treasury and agency securities, corporate bonds and commercial paper, and are valued based on recent trades of securities in inactive markets or on quoted market prices of similar instruments and other significant inputs derived from or corroborated by observable market data.

6. Investments

Available-for-sale investments consisted of the following as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Short-term marketable securities				
Commercial paper	$ 10,630	$ —	$ —	$ 10,630
U.S. government treasury and agency securities	264,214	232	(20)	264,426
Corporate bonds	6,278	3	—	6,281
Total short-term marketable securities	$ 281,122	$ 235	$ (20)	$ 281,337

	December 31, 2022			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Short-term marketable securities				
Commercial paper	$ 9,969	$ —	$ —	$ 9,969
U.S. government treasury securities	389,898	14	(4,064)	385,848
Corporate bonds	12,415	—	(66)	12,349
Total short-term marketable securities	$ 412,282	$ 14	$ (4,130)	$ 408,166

All the U.S. government treasury and agency securities, corporate bonds and commercial paper designated as short-term marketable securities have an effective maturity date that is equal to or less than one year from the respective consolidated 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 consolidated balance sheet date.

Accrued interest receivable is excluded from the amortized cost and estimated fair value of our marketable securities. Accrued interest receivable of $1.0 million and $0.8 million was presented separately within the prepaid expenses and other current assets balance on the consolidated balance sheet as of December 31, 2023 and 2022, respectively.

The following table presents the gross unrealized holding losses and fair values for investments in an unrealized loss position, and the length of time individual securities have been in a continuous loss position, as of December 31, 2023 (in thousands):

	Less Than 12 Months		12 Months Or Greater	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
U.S. government treasury and agency securities	$ 48,100	$ (20)	$ —	$ —
Total available-for-sale securities	$ 48,100	$ (20)	$ —	$ —

We periodically review our available-for-sale securities to assess for credit impairment. Some of the factors considered in assessing impairment include the extent to which the fair value is less than the amortized cost basis, adverse conditions related to the security, an industry or geographic area, changes to security ratings or sector credit ratings and other relevant market data.

As of December 31, 2023, we did not intend, nor were we more likely than not to be required, to sell our available-for-sale investments before the recovery of their amortized cost basis, which may be maturity. Based on our assessment, we concluded all impairment as of December 31, 2023 to be due to factors other than credit loss, such as changes in interest rates. A credit allowance was not recognized and the impairment of our available-for-sale securities was recorded in other comprehensive loss.

7. Property and Equipment, Net

Property and equipment, net as of December 31, 2023 and 2022 consisted of the following (in thousands):

	December 31,	
	2023	2022
Laboratory equipment	$ 49,567	$ 43,592
Computer equipment	7,970	7,766
Furniture and office equipment	3,820	5,342
Computer software	1,965	1,069
Construction in progress	3,405	7,625
Leasehold improvements	74,734	72,403
Total property and equipment, at cost	141,461	137,797
Less: Accumulated depreciation	(73,234)	(54,350)
Property and equipment, net	$ 68,227	$ 83,447

Depreciation expense was $20.5 million, $19.2 million and $12.3 million for the year ended December 31, 2023, 2022 and 2021, respectively. See Note 10, *Leases* for details regarding the impairment loss we recognized for certain leasehold improvements for the year ended December 31, 2023.

8. 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, 2023 and 2022 consisted of the following (in thousands):

	December 31, 2023		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquired developed technology	$ 20,000	$ (14,970)	$ 5,030
Purchased intellectual property	325	(227)	98
Balance at December 31, 2023	$ 20,325	$ (15,197)	$ 5,128

	December 31, 2022		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquired developed technology	$ 20,000	$ (13,304)	$ 6,696
Purchased intellectual property	325	(194)	131
Balance at December 31, 2022	$ 20,325	$ (13,498)	$ 6,827

The developed technology was acquired in connection with our acquisition of Sequenta, Inc. in 2015. The remaining balance of the acquired developed technology and the purchased intellectual property is expected to be amortized over the next 3.0 years.

As of December 31, 2023, expected future amortization expense for intangible assets was as follows (in thousands):

2024	$ 1,703
2025	1,699
2026	1,699
2027	27
Total future amortization expense	$ 5,128

9. Accrued Liabilities

Accrued liabilities as of December 31, 2023 and 2022 consisted of the following (in thousands):

	December 31,	
	2023	2022
Professional fees	$ 4,920	$ 4,744
Clinical and contract research organization costs	863	1,533
Travel and entertainment	154	233
Tax liabilities	59	194
Purchases of property and equipment	687	1,680
Computer and software	1,151	2,385
Other	763	1,655
Total accrued liabilities	$ 8,597	$ 12,424

10. Leases

We have operating lease agreements for laboratory, office and warehouse facilities that we occupy in various locations.

In July 2011, we entered into a non-cancelable lease agreement with an, at the time, minority shareholder for office and laboratory space in Seattle, Washington. The lease terms were subsequently amended multiple times, most recently in August 2019, when we expanded the existing premises to approximately 65,500 square feet. Cash payment for rent of the expanded premises commenced January 2020, four months after the landlord delivered 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 October 2032, subject to our option to twice extend the lease for five years. The amended lease also requires us to pay additional amounts for operating and maintenance expenses.

In October 2023, we vacated this leased space. As such, we assessed the right-of-use asset and related leasehold improvements (together, the "asset group") for impairment by first comparing the carrying amount of the asset group to future net undiscounted cash flows projected to be generated over the remaining lease term. These projections include management's estimates of cash inflows from potential sublease income and outflows for operating and maintenance expenses. The carrying amount was found to be unrecoverable, thus we assessed the asset group's fair value. The extent to which the asset group's carrying amount exceeds its fair value represents the impairment cost to be recognized. Fair value was determined using the income approach, whereby we discounted estimated net cash flows using a rate commensurate with our estimated incremental borrowing rate. As a result of this assessment, which included unrecoverable operating and maintenance costs, we determined that the asset group was to be fully impaired. As such, an impairment charge of $25.4 million was recognized during the year ended December 31, 2023, $21.2 million related to the right-of-use asset and $4.2 million related to the long-lived leasehold improvements, all of which were held for use.

In August 2019, we entered into an agreement to rent approximately 100,000 square feet in what was a to-be-constructed, new headquarters building in Seattle, Washington. In connection with the lease, we entered into a $2.1 million letter of credit with one of our existing financial institutions. The lease commenced in December 2020, when the landlord delivered the premises to us for construction of certain tenant improvements. We occupied the new building in 2021, cash payment for rent began in October 2021 and the lease term ends in August 2033, subject to our option to twice extend the lease for five years. In connection with this lease, the landlord agreed to fund $20.0 million in improvements, which was subsequently reduced to $14.8 million as a result of our change requests made during landlord construction of the building, net of an administration fee. As of December 31, 2022, we incurred $14.9 million in certain tenant improvement costs, all of which had been reimbursed by the landlord. As of December 31, 2021, we incurred $14.9 million in certain tenant improvement costs, of which $10.9 million had been reimbursed by the landlord. The remaining $4.0 million is presented as a reduction in the cash flows used to measure our ROU asset and lease liabilities on the consolidated balance sheet as of December 31, 2021. The lease also requires us to pay additional amounts for operating and maintenance expenses.

In April 2018, we entered into a lease agreement to lease approximately 13,400 square feet in South San Francisco, California. The lease term is through March 2026 and provides for one five-year extension option. We are responsible for our share of allocable operating expenses, tax expenses and utilities costs during the duration of the lease term. In connection with the lease, the landlord funded agreed-upon improvements. The landlord was solely responsible for the $2.4 million cost of such improvements. The lease agreement was amended in February 2020 to lease approximately 19,900 additional square feet and provides for a $0.6 million tenant improvement allowance.

In March 2021, we executed a lease to rent approximately 27,000 square feet of a warehouse in Bothell, Washington, which we classified as an operating lease upon commencement during the year ended December 31, 2021. Rent obligations commenced in October 2021 and the lease expires October 2031, subject to an early termination option after the seventh year and an option to twice extend the lease for five years. The lease requires us to pay certain operating expenses. Furthermore, the landlord agreed to fund $1.2 million in improvements in connection with this lease.

As of December 31, 2023, we were not party to any finance leases. Our leases have remaining terms ranging from 2.2 years to 9.7 years and include options to extend certain of the leases up to 10.0 years and terminate certain of the leases after 7.0 years of leasing. We adjust lease terms for these options only when it is reasonably certain we will exercise these options.

Other information related to our operating leases as of December 31, 2023 and 2022 was as follows:

	December 31,	
	2023	2022
Weighted-average remaining lease term (in years)	8.91	9.75
Weighted-average discount rate	4.6%	4.6%

The following table reconciles our undiscounted operating lease cash flows to our operating lease liabilities, less current portion balance on the consolidated balance sheet as of December 31, 2023 (in thousands):

2024	$ 13,692
2025	14,098
2026	12,330
2027	11,944
2028	12,282
Thereafter	56,962
Total undiscounted lease payments	121,308
Less: Imputed interest rate	(22,536)
Total operating lease liabilities	98,772
Less: Current portion	(9,384)
Operating lease liabilities, less current portion	$ 89,388

Operating lease expense was $11.4 million, $12.4 million and $12.4 million for the year ended December 31, 2023, 2022 and 2021, respectively. Variable lease expense for operating leases was $7.1 million, $7.2 million and $3.5 million for the year ended December 31, 2023, 2022 and 2021, respectively.

Cash paid for amounts included in the measurement of lease liabilities for the year ended December 31, 2023 was $13.4 million. Cash paid for amounts included in the measurement of lease liabilities for the year ended December 31, 2022 was $9.2 million, net of $5.2 million of cash received for tenant improvement allowances. Cash paid for amounts included in the measurement of lease liabilities was $8.3 million and cash received for tenant improvement allowances was $11.5 million during the year ended December 31, 2021. For the year ended December 31, 2021, ROU assets obtained in exchange for operating lease liabilities was $5.4 million.

11. Revenue Interest Purchase Agreement

Revenue Interest Purchase Agreement

In September 2022, we entered into the Purchase Agreement with OrbiMed Royalty & Credit Opportunities IV, LP ("OrbiMed"), an affiliate of OrbiMed Advisors LLC, as collateral agent and administrative agent for the purchasers party thereto (the "Purchasers"). Pursuant to the Purchase Agreement, we received $125.0 million from the Purchasers at closing (the "First Payment"), less certain transaction expenses. We are also entitled to receive up to $125.0 million in subsequent installments as follows: (i) $75.0 million upon our request occurring no later than September 12, 2025 (the "Second Payment") and (ii) $50.0 million upon our request in connection with certain permitted acquisitions occurring no later than September 12, 2025 (the "Third Payment"), in each case subject to certain funding conditions. To secure our obligations under the Purchase Agreement, we and our subsidiaries have granted OrbiMed a security interest in our core platform technology assets, subject to certain customary exclusions, as defined in the Purchase Agreement.

Revenue Interest Payments

As consideration for such payments, the Purchasers have a right to receive certain revenue interests (the "Revenue Interests") from us based on a percentage (the "Applicable Payment Percentage") of all GAAP revenue (the "Revenue Base"). If only the First Payment has been made, the Applicable Payment Percentage shall be five percent of the quarterly Revenue Base. If both the First Payment and Second Payment have been made, the Applicable Payment Percentage shall be eight percent of the quarterly Revenue Base. If each of the First Payment, Second Payment and Third Payment have been made, the applicable payment percentage applied to the Revenue Interest shall be ten percent of the quarterly Revenue Base.

Payments in respect of the Revenue Interests shall be made quarterly within 45 days following the end of each fiscal quarter (each, a "Revenue Interest Payment"). If OrbiMed has not received Revenue Interest Payments in the aggregate equal to or greater than the sum of its invested capital (the "Cumulative Purchaser Payments") on or prior to September 12, 2028, the revenue interest rate shall be increased to a rate which, if applied retroactively to our cumulative Revenue Base, would have resulted in Revenue Interest Payments equal to the sum of all Cumulative Purchaser Payments.

Return Cap

OrbiMed will be entitled to 100% of the Revenue Interest Payments until it has received a total cumulative value of 165% of the Cumulative Purchaser Payments (the "Return Cap"), unless full repayment of the amount of the Return Cap has not been made by September 12, 2032, in which case the Return Cap shall be increased to 175% of the Cumulative Purchaser Payments.

Put/Call Options

Upon the occurrence of a Put Option Event (as defined in the Purchase Agreement), including material divestitures by us, a change in control, material judgments, or bankruptcy events, Purchasers representing at least a majority of the purchase commitments under the Purchase Agreement shall have the right but not the obligation ("the Put Option") to require us to repurchase all of the outstanding Revenue Interests at the applicable price (the "Put/Call Price"). Additionally, at any time following receipt of the First Payment, we may exercise a call option to repurchase all Revenue Interests at the applicable Put/Call Price.

For all Put Option Events other than a change of control or a material divestiture, the Put/Call Price shall be an amount equal to the applicable Return Cap. For a change of control or a material divestiture, prior to March 12, 2024, the Put/Call Price shall be an amount equal to 120% of the Cumulative Purchaser Payments less the sum of all Revenue Interest Payments made by us to the Purchasers prior to such date, between March 12, 2024 and September 12, 2024, the Put/Call Price shall be an amount equal to 125% of the Cumulative Purchaser Payments less the sum of all Revenue Interest Payments made by us to the Purchasers prior to such date, and after September 12, 2024, the Put/Call Price shall be equal to the applicable Return Cap.

Accounting Treatment

We evaluated the terms of the Purchase Agreement and concluded that the features of the Cumulative Purchaser Payments are similar to those of a debt instrument. Accordingly, we accounted for the transaction as debt recorded at amortized cost using the effective interest rate method. We further evaluated the terms of the debt and determined that the Put Option that is exercisable by the Purchasers upon certain contingent events requires bifurcation as a derivative. However, the value of the Put Option was determined to be immaterial due to the remote possibility of exercise. We assess the value of the Put Option periodically.

To determine the amortization of the Purchase Agreement obligation, we are required to estimate the amount and timing of future Revenue Interest Payments based on our estimate of the timing and amount of future revenues and calculate an effective interest rate which will amortize the obligation to zero over the amortization period. The calculated effective interest rate as of December 31, 2023 was 9.2%.

In connection with the Purchase Agreement, we incurred debt issuance costs of $0.6 million. Debt issuance costs have been recorded to debt and are being amortized over the estimated term of the debt using the effective interest method, adjusted on a prospective basis for changes in the underlying assumptions and inputs.

The assumptions used in determining the expected repayment term of the obligation and amortization period of the issuance costs requires that we make estimates that could impact the short- and long-term classification of these costs, as well as the period over which these costs will be amortized. We periodically assess the amount and timing of expected Revenue Interest Payments based on internal forecasts.

To the extent such payments are greater or less than our initial estimates or the timing of such payments is materially different than our original estimates, we will prospectively adjust the amortization of the revenue interest liability and the effective interest rate.

The following table sets forth the revenue interest liability, net activity during the years ended December 31, 2023 and 2022 (in thousands):

Revenue interest liability at inception	$	125,000
Capitalized issuance costs		(625)
Interest expense		4,238
Revenue interest paid		(493)
Revenue interest payable		(2,760)
Revenue interest liability, net at December 31, 2022		125,360
Interest expense		13,800
Revenue interest paid		(6,225)
Revenue interest payable		(2,275)
Revenue interest liability, net at December 31, 2023	$	130,660

Revenue interest payable of $2.3 million and $2.8 million was included within the accounts payable balance on the consolidated balance sheet as of December 31, 2023 and 2022, respectively.

12. Commitments and Contingencies

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 were not party to any material legal proceedings as of December 31, 2023.

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.

13. Shareholders' Equity

Common Stock

Our common stock has 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, 2023, we had reserved shares of common stock for the following:

Shares issuable upon the exercise of outstanding stock options granted	12,875,045
Shares issuable upon the vesting of outstanding restricted stock units granted and the maximum outstanding market-based restricted stock units eligible to be earned	11,582,134
Shares available for future grant under the 2019 Equity Incentive Plan	15,299,763
Shares available for future grant under the Employee Stock Purchase Plan	4,235,348
Total shares of common stock reserved for future issuance	43,992,290

Our 2019 Equity Incentive Plan (the "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 (the "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% 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.

Effective January 1, 2023, our 2019 Plan and ESPP reserves increased by 7,155,250 shares and 1,431,050 shares, respectively. Effective January 1, 2024, our 2019 Plan and ESPP reserves increased by 7,254,113 shares and 1,450,822 shares, respectively.

14. Equity Incentive Plans

2009 Equity Incentive Plan

We adopted an equity incentive plan in 2009 (the "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 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. Stock 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 stock 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 grant under the 2009 Plan, it continues to govern outstanding equity awards granted thereunder.

2019 Equity Incentive Plan

The 2019 Plan became effective immediately prior to the closing of our initial public offering in July 2019. The 2019 Plan provides for the issuance of awards in the form of stock options and other share-based awards for employees, directors and consultants. Under the 2019 Plan, the stock option exercise price per share shall not be less than the fair market value of a share of stock on the effective date of grant, 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, stock 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 stock option and restricted stock unit grants made to non-employee directors, stock options and restricted stock units 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, 2023, we had 34,853,581 shares of common stock authorized for issuance under the 2019 Plan.

Changes in shares available for grant during the year ended December 31, 2023 were as follows:

	Shares Available for Grant
Shares available for grant at December 31, 2022	14,581,975
2019 Equity Incentive Plan reserve increase effective January 1, 2023	7,155,250
Stock options and restricted stock units granted and the maximum market-based restricted stock units granted eligible to be earned	(9,980,059)
Stock options and restricted stock units forfeited or expired	3,542,597
Shares available for grant at December 31, 2023	15,299,763

Stock Options

Stock option activity under the 2009 Plan and 2019 Plan during the year ended December 31, 2023 was as follows:

	Shares Subject to Outstanding Stock Options	Weighted-Average Exercise Price per Share	Aggregate Intrinsic Value (in thousands)
Stock options outstanding at December 31, 2022	13,520,997	$ 16.88	
Stock options granted	1,612,032	8.46	
Stock options forfeited	(1,030,388)	17.07	
Stock options expired	(757,191)	22.92	
Stock options exercised	(470,405)	4.77	
Stock options outstanding at December 31, 2023	12,875,045	$ 15.90	$ 506
Stock options vested and exercisable at December 31, 2023	9,071,627	$ 16.20	$ 506

The weighted-average remaining contractual life for stock options outstanding as of December 31, 2023 was 6.2 years. The weighted-average remaining contractual life for vested and exercisable stock options as of December 31, 2023 was 5.3 years.

The total intrinsic value of stock options exercised during the year ended December 31, 2023, 2022 and 2021 was $1.4 million, $7.6 million and $156.5 million, respectively.

Of the $26.7 million proceeds from exercise of stock options included on the consolidated statements of cash flows for the year ended December 31, 2021, $0.3 million related to stock options exercised during the year ended December 31, 2020 but settled during the year ended December 31, 2021.

Restricted Stock Units

Restricted stock unit activity under the 2019 Plan during the year ended December 31, 2023 was as follows:

	Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value per Share
Nonvested restricted stock units outstanding at December 31, 2022	5,981,755	$ 14.11
Restricted stock units granted	6,949,587	8.29
Restricted stock units forfeited	(1,755,018)	11.24
Restricted stock units vested	(1,506,864)	14.95
Nonvested restricted stock units outstanding at December 31, 2023	9,669,460	$ 10.32

The total fair value of restricted stock units vested during the year ended December 31, 2023, 2022 and 2021 was $12.0 million, $3.5 million and $0.8 million, respectively.

Market-Based Restricted Stock Units

In addition to the restricted stock units described above, our board of directors approved awards of market-based restricted stock units to our chief executive officer and chief scientific officer in March 2023. The shares of common stock that may be earned under the awards, each ranging from zero shares to 709,220 shares, are calculated based upon our total shareholder return during a three-year performance period as measured against that of the group of companies comprising the S&P Biotechnology Select Industry Index as of the grant date, subject to certain adjustments to such index group. Except as expressly provided in the terms of each award's agreement, vesting is subject to the respective grantee's continuous service through the end of the three-year performance period. These market-based restricted stock units, along with those granted to our chief executive officer in March 2022, under which zero shares to 494,234 shares may be earned, remained outstanding as of December 31, 2023.

Grant Date Fair Value of Stock Options, Restricted Stock Units and Market-Based Restricted Stock Units Granted

The estimated grant date fair values of stock options granted during the years ended December 31, 2023, 2022 and 2021 were estimated using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2023	2022	2021
Fair value of common stock	$8.46	$7.30 - $14.95	$30.86 - $66.50
Expected term (in years)	5.27 - 6.08	5.27 - 6.08	5.27 - 6.08
Risk-free interest rate	4.2% - 4.3%	1.7% - 3.9%	0.5% - 1.4%
Expected volatility	71.2% - 71.6%	68.2% - 71.0%	67.1% - 70.0%
Expected dividend yield	—	—	—

The determination of the grant date fair value of stock options granted using a Black-Scholes option-pricing model is affected by the fair value of our common stock, as well as assumptions regarding a number of variables that are subjective and generally require judgment to determine. The valuation assumptions were determined as follows:

Fair value of common stock—The fair value of each share of common stock is 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 stock 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 stock 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 terms of the stock options.

Expected volatility—As we do not have sufficient trading history for our common stock, expected volatility is based on the historical volatility of our publicly traded industry peers utilizing a period of time consistent with our estimate of 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.

The weighted-average grant date fair value per share of stock options granted during the year ended December 31, 2023, 2022 and 2021 was $5.61, $7.36 and $24.22, respectively.

The grant date fair value of restricted stock units granted is 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. The weighted-average grant date fair value per share of restricted stock units granted during the year ended December 31, 2023, 2022 and 2021 was $8.29, $11.43 and $37.98, respectively.

The weighted-average grant date fair value per share of the market-based restricted stock units granted during the year ended December 31, 2023 and 2022 was $13.82 and $18.89, respectively, and was determined using a Monte Carlo valuation model, which uses assumptions such as volatility, risk-free interest rate and dividend estimated for the respective performance periods. The weighted-average grant date fair value per share of the target payout level of the market-based restricted stock units outstanding as of December 31, 2023, 956,337 shares, was $15.13. The aggregate share-based compensation expense of the market-based restricted stock units granted during the year ended December 31, 2023 and 2022 was $9.8 million and $4.7 million, respectively, and is recognized on a straight-line basis over the respective grants' three-year performance periods, which are also the requisite service periods. Attainment of each grant's respective market condition and the number of shares earned and vested does not impact the related share-based compensation expense recognized. Share-based compensation expense will be reversed only if the respective grantee does not provide continuous service through the respective performance period for reasons other than those expressly provided in the terms of the respective award.

The compensation cost related to stock options, restricted stock units and market-based restricted stock units for the years ended December 31, 2023, 2022 and 2021 are included on the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Cost of revenue	$ 4,186	$ 3,910	$ 2,100
Research and development	20,465	17,689	14,061
Sales and marketing	14,553	13,597	12,312
General and administrative	23,704	20,281	14,778
Total share-based compensation expense	$ 62,908	$ 55,477	$ 43,251

As of December 31, 2023, unrecognized share-based compensation expense and the remaining weighted-average recognition period were as follows:

	Unrecognized Share-Based Compensation Expense (in thousands)	Remaining Weighted-Average Recognition Period (in years)
Nonvested stock options	$ 33,892	1.94
Nonvested restricted stock units	76,944	2.67
Nonvested market-based restricted stock units	8,941	1.97

15. Microsoft Collaboration Agreement

Summary of Agreement

In December 2017, we entered into a collaboration agreement with Microsoft Corporation ("Microsoft") (the “Microsoft Agreement”) to computationally derive a comprehensive T cell receptor 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 purchase requirement of $12.0 million over the seven-year term of the Microsoft Agreement, which has been met.

In addition, contemporaneously with entering into the Microsoft Agreement, Microsoft made a preferred stock investment of $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 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 purchase Microsoft’s Azure cloud services was at market terms and we expected to meet the commitment in the ordinary course of business during the seven-year term, we recorded the expenses in the period in which the services were consumed. These costs are recorded in the consolidated statements 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.

16. Restructuring

In March 2022, we implemented a restructuring plan to reduce operating costs and reduced our workforce by approximately 100 employees. We incurred aggregate restructuring costs of $2.0 million, all of which was recognized during the year ended December 31, 2022. These costs primarily related to one-time termination benefits and ongoing benefit arrangements, both of which included severance payments and extended benefits coverage support and were contingent upon the impacted employees’ execution and non-revocation of separation agreements. Our aggregate restructuring costs also included certain contract termination costs. The activities related to our reduction in workforce were primarily completed in March 2022 and the $2.0 million aggregate restructuring costs were paid as of December 31, 2022.

17. Income Taxes

The components of loss before provision for income taxes for the periods presented were as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Domestic	$ (225,335)	$ (200,427)	$ (207,314)
Foreign	31	59	16
Total loss before provision for income taxes	$ (225,304)	$ (200,368)	$ (207,298)

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 as of the dates presented were as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets		
Net operating losses	$ 251,724	$ 210,609
Tax credit carryforward	43,528	36,848
Nonqualifying stock options	29,166	23,885
Operating lease liabilities	25,357	27,199
Deferred revenue	18,874	26,170
Capitalized research and development	42,134	40,957
Other	6,146	5,859
Total deferred tax assets	416,929	371,527
Less: Valuation allowance	(402,424)	(346,578)
Deferred tax assets, net of valuation allowance	14,505	24,949
Deferred tax liabilities		
Tangible and intangible assets	(1,281)	(4,897)
Right-of-use assets	(13,224)	(20,052)
Net deferred taxes	$ —	$ —

ASC Topic 740, *Income Taxes*, requires that the tax benefit of net operating losses ("NOLs"), 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 $55.8 million and $49.6 million during the year ended December 31, 2023 and 2022, respectively.

Federal tax laws impose substantial restrictions on the utilization of NOL and credit carryforwards in the event of an ownership change, as defined in Section 382 of the Internal Revenue Code of 1986. Accordingly, our ability to utilize these carryforwards may be limited due to such ownership changes. We have completed a Section 382 analysis for changes in ownership through June 30, 2023 and continue to monitor for changes that could trigger a limitation. Based on this analysis, we do not expect to have any permanent limitations on the utilization of our federal NOLs. Under the Tax Cuts and Jobs Act of 2017 federal income tax law, federal NOLs incurred in 2018 and future years may be carried forward indefinitely, but the deductibility of such federal NOLs is subject to an annual limitation. NOLs generated prior to 2018 are eligible to be carried forward up to 20 years. As of December 31, 2023, we had U.S. federal NOLs of $192.5 million and U.S. federal tax credits of $47.2 million that will begin to expire in 2028. We also had $768.2 million of NOLs as of December 31, 2023 that do not expire.

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,		
	2023	2022	2021
Statutory rate	21.0%	21.0%	21.0%
State tax, net of federal tax benefit	4.0	3.8	8.3
Share-based compensation	(2.9)	(2.0)	14.1
Permanent items	(0.1)	(0.2)	(0.1)
Credits	2.3	3.0	4.7
Other	1.0	(1.2)	(0.3)
Change in valuation allowance	(25.3)	(24.4)	(47.7)
Total	0.0%	0.0%	0.0%

We account for global intangible low-taxed income as period costs when incurred.

We recognize, in the consolidated 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 $9.3 million as of December 31, 2023.

A reconciliation of the beginning and ending amounts of unrecognized tax benefits for the dates presented are as follows (in thousands):

Balance at December 31, 2020	$ 3,489
Additions in 2021	3,426
Balance at December 31, 2021	6,915
Additions in 2022	1,202
Balance at December 31, 2022	8,117
Additions in 2023	1,186
Balance at December 31, 2023	$ 9,303

During the year ended December 31, 2023, 2022 and 2021, we recognized uncertain tax positions of $1.2 million, $1.2 million and $3.4 million, respectively, related to a reduction of the research and development credit deferred tax asset. Unrecognized tax benefits may change during the next twelve months for items that arise in the ordinary course of business. We do not expect 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, 2023 and 2022.

We file federal and certain state income tax returns, which provide varying statutes of limitations on assessments. However, because of NOL carryforwards, substantially all tax years since inception remain open to federal and state tax examination.

18. Net Loss Per Share Attributable to Adaptive Biotechnologies Corporation Common Shareholders

The following table sets forth the computation of basic and diluted net loss per share attributable to our common shareholders for the years ended December 31, 2023, 2022 and 2021 (in thousands, except share and per share amounts):

	Year Ended December 31,		
	2023	2022	2021
Net loss attributable to Adaptive Biotechnologies Corporation	$ (225,250)	$ (200,191)	$ (207,279)
Weighted-average shares used in computing net loss per share attributable to Adaptive Biotechnologies Corporation common shareholders, basic and diluted	144,383,294	142,515,917	140,354,915
Net loss per share attributable to Adaptive Biotechnologies Corporation common shareholders, basic and diluted	$ (1.56)	$ (1.40)	$ (1.48)

Given the loss position for all periods presented, basic net loss per share attributable to our common shareholders is the same as diluted net loss per share attributable to our 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 our common shareholders for the years ended December 31, 2023, 2022 and 2021, as they had an anti-dilutive effect:

	Year Ended December 31,		
	2023	2022	2021
Stock options outstanding	13,839,067	13,892,287	13,097,374
Nonvested restricted stock units outstanding	9,630,579	4,799,850	693,173
Maximum nonvested market-based restricted stock units outstanding eligible to be earned	1,663,961	410,282	—
Common stock warrant outstanding	—	—	8,570
Total	25,133,607	19,102,419	13,799,117

19. 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 made $2.3 million, $2.8 million and $2.5 million in discretionary contributions during the year ended December 31, 2023, 2022 and 2021, respectively, which are fully vested after one year of employee service.

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, 2023. 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, 2023.

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, 2023 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with GAAP.

The effectiveness of our internal control over financial reporting as of December 31, 2023 has been audited by an independent registered public accounting firm, as stated in their report, which is included below.

Changes in Internal Control

There was not any change in our internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act, during the three months ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control Over Financial Reporting

We have audited Adaptive Biotechnologies Corporation's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Adaptive Biotechnologies Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes and our report dated February 29, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ Ernst & Young LLP

Seattle, Washington
February 29, 2024

Item 9B. Other Information

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 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 2024 Annual Meeting of Shareholders ("2024 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 2024 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 our equity compensation plans, will be included in our 2024 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 2024 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 2024 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) Financial Statements

See Index to Consolidated 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 consolidated 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

			Incorporated by Reference			
Exhibit Number	Exhibit Title	Filed/Furnished With This Report	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	Description of Securities		10-K	001-38957	4.3	2/26/2020
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
10.6*	Form of Amended and Restated Employment Agreement between the Registrant 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*	Form of Executive Severance Agreement between the Registrant and certain of its executive officers		10-Q	001-38957	10.1	8/10/2020

Exhibit Number	Exhibit Title	Filed/Furnished With This Report	Incorporated by Reference			
			Form	File No.	Exhibit	Filing Date
10.9*	Form of Indemnification Agreement between the Registrant and its directors and executive officers		S-1	333-231838	10.13	5/30/2019
10.10*	Adaptive Biotechnologies Corporation Non-Employee Director Compensation Policy		10-K	001-38957	10.10	2/14/2023
10.11*	Adaptive Biotechnologies Corporation 2009 Equity Incentive Plan and form of award agreement thereunder		S-1	333-231838	10.15	5/30/2019
10.12*	Adaptive Biotechnologies Corporation 2019 Equity Incentive Plan and form of award agreement thereunder		10-Q	001-38957	10.12	8/13/2019
10.13*	Form of Stock Option Agreement for Non-U.S. Participants		10-K	001-38957	10.16	2/24/2021
10.14*	Form of Restricted Stock Unit Agreement for Non-U.S. Participants		10-K	001-38957	10.17	2/24/2021
10.15*	Form of Performance Units Agreement and Notice of Grant of Performance Units		10-Q	001-38957	10.1	5/4/2022
10.16*	Adaptive Biotechnologies Corporation 2019 Employee Stock Purchase Plan		S-1/A	333-231838	10.17	6/17/2019
10.17	Revenue Interest Purchase Agreement, made and entered into as of September 12, 2022, by and among Adaptive Biotechnologies Corporation, the Purchasers from time to time party hereto, and OrbiMed Royalty & Credit Opportunities IV, LP		8-K	001-38957	10.1	9/12/2022
10.18	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
10.19†	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
10.20†	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
21.1	List of Subsidiaries		10-K	001-38957	21.1	2/14/2023
23.1	Consent of Independent Registered Public Accounting Firm	X				
24.1	Power of Attorney (included on the signature page)	X				
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				

Exhibit Number	Exhibit Title	Filed/Furnished With This Report	Incorporated by Reference			
			Form	File No.	Exhibit	Filing Date
31.2	Certification of Principal Financial 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 Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
97.1*	Adaptive Biotechnologies Corporation Policy for the Recovery of Erroneously Awarded Compensation	X				
101.INS	Inline 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 With Embedded Linkbase Documents	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 29, 2024.

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 29, 2024
/s/ Tycho Peterson Tycho Peterson	Chief Financial Officer *(Principal Financial Officer)*	February 29, 2024
/s/ Kyle Piskel Kyle Piskel	VP, Principal Accounting Officer *(Principal Accounting Officer)*	February 29, 2024
/s/ Michelle Griffin Michelle Griffin	Director	February 29, 2024
/s/ Robert Hershberg Robert Hershberg, PhD, MD	Director	February 29, 2024
/s/ Peter Neupert Peter Neupert	Director	February 29, 2024
/s/ Katey Owen Katey Owen, PhD	Director	February 29, 2024
/s/ Michael Pellini Michael Pellini, MD	Director	February 29, 2024

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Corporate Information

BOARD OF DIRECTORS

Chad Robins
Chairman & Chief Executive Officer

Peter Neupert
Lead Independent Director

Michelle Griffin
Independent Director

Robert Hershberg, MD, PhD
Independent Director

Katey Owen, PhD
Independent Director

Michael Pellini, MD
Independent Director

LEADERSHIP

Chad Robins
Chairman & Chief Executive Officer

Harlan Robins, PhD
Chief Scientific Officer

Julie Rubinstein
President & Chief Operating Officer

Kyle Piskel
Chief Financial Officer

Francis Lo
Chief People Officer

Sharon Benzeno, PhD
Chief Commercial Officer, Immune Medicine

Susan Bobulsky
Chief Commercial Officer, MRD

Stacy Taylor
Senior Vice President, General Counsel

Mary Pat Lancelotta
Senior Vice President, MRD BioPharma

HEADQUARTERS

1165 Eastlake Ave. E
Seattle, WA 98109
United States

WEBSITE

adaptivebiotech.com

STOCK LISTING

The company's common stock is traded on the Nasdaq Global Select Market under the symbol ADPT.

SHAREHOLDER INQUIRIES

Karina Calzadilla
Vice President, Investor Relations
+1 650-825-1656
kcalzadilla@adaptivebiotech.com

Adaptive biotechnologies™

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