UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2021

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

For the transition period from to

Commission File No. 001-36847

Invitae Corporation

(Exact name of the registrant as specified in its charter)

Delaware	**27-1701898**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1400 16th Street, San Francisco, California 94103

(Address of principal executive offices, Zip Code)

(415) 374-7782

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, $0.0001 par value per share	NVTA	New York Stock Exchange

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 and post such files). Yes ☒ No ☐

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

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

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

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

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

As of June 30, 2021, the aggregate market value of common stock held by non-affiliates of the Registrant was approximately $6.8 billion, based on the closing price of the common stock as reported on The New York Stock Exchange for that date.

The number of shares of the registrant's Common Stock outstanding as of February 25, 2022 was 228,356,928.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10 (as to directors and Section 16(a) Beneficial Ownership Reporting Compliance), 11, 12, 13 and 14 of Part III incorporate by reference information from the registrant's proxy statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the registrant's 2022 Annual Meeting of Stockholders.

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Forward-Looking Statements

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this report other than statements of historical fact, including statements identified by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions, are forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our views regarding the future of genetic testing and its role in mainstream medical practice;
- the impact of the COVID-19 pandemic on our business and the actions we have taken or may take in response thereto;
- our mission and strategy for our business, products and technology;
- the implementation of our business model and our success entering new markets;
- the expected benefits from and our ability to integrate our acquisitions;
- our ability to obtain regulatory approvals for our tests;
- the rate and degree of market acceptance of our tests and genetic testing generally;
- our ability to scale our infrastructure and operations in a cost-effective manner;
- the timing of and our ability to introduce improvements to our genetic testing platform and to expand our assays to include additional genes;
- the timing and results of studies with respect to our tests;
- developments and projections relating to our competitors and our industry;
- our competitive strengths;
- the degree to which individuals will share genetic information generally, as well as share any related potential economic opportunities with us;
- our commercial plans, including our sales and marketing expectations as well as our ability to expand internationally;
- our ability to obtain and maintain adequate reimbursement for our tests;
- regulatory developments in the United States and foreign countries;
- our ability to attract and retain key scientific, sales, engineering or management personnel;
- our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- the effects of litigation or investigations on our business;
- our ability to obtain funding for our operations and the growth of our business, including potential acquisitions;
- our financial performance;
- our expectations regarding environmental, social and governance matters;
- the impact of accounting pronouncements and our critical accounting policies, judgments, estimates and assumptions on our financial results;
- our expectations regarding our future revenue, cost of revenue, operating expenses and capital expenditures, and our future capital requirements; and
- the impact of tax laws on our business.

Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed in Item 1A. of this report. Although we believe that the expectations and assumptions reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Any forward-looking statements in this report speak only as of the date of this report. We expressly disclaim any obligation or undertaking to update any forward-looking statements.

In this report, all references to "Invitae," "we," "us," "our," or "the Company" mean Invitae Corporation.

Invitae and the Invitae logo are trademarks of Invitae Corporation. AMP™, LiquidPlex™, VariantPlex® and FusionPlex®, are the property of ArcherDX, LLC, a wholly owned subsidiary of Invitae Corporation. We also refer to trademarks of other companies and organizations in this report.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties that could affect our ability to successfully implement our business strategy and affect our financial results. You should carefully consider all of the information in this report and, in particular, the following principal risks and all of the other specific factors described in Item 1A. of this report, “Risk Factors,” before deciding whether to invest in our company.

- We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.
- Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.
- We have acquired and may continue to acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders’ ownership, or cause us to incur debt or significant expense.
- We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.
- We need to scale our infrastructure in advance of demand for our tests and other products and services, and our failure to generate sufficient demand for our products and services would have a negative impact on our business and our ability to attain profitability.
- We face risks related to health epidemics, including the ongoing COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.
- If third-party payers, including managed care organizations, private health insurers and government health plans, do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.
- We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the markets in which we operate. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.
- We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.
- The market for patient data software is competitive, and our business will be adversely affected if we are unable to successfully compete.
- Security breaches, privacy issues, loss of data and other incidents could compromise sensitive or personal information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- If we are not able to continue to generate substantial demand of our tests, our commercial success will be negatively affected.
- If our therapy selection in vitro diagnostic ("IVD") and Personalized Cancer Monitoring ("PCM") products and related services do not perform as expected, we may not realize the expected benefits of our acquisition of ArcherDX.
- The future growth of our distributed products business is partially dependent upon regulatory approval and market acceptance of our IVD products.
- Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.
- If the Food and Drug Administration ("FDA") regulates the tests we currently offer as laboratory-developed tests ("LDTs") as medical devices, we could incur substantial costs and our business, financial condition and results of operations could be adversely affected.
- If we are unable to transition to the new European Union In Vitro Diagnostic Regulation ("IVDR") regulations, we could lose the ability to serve the European market.

- We may not be able to obtain regulatory clearance or approval of our IVD products, or even if approved, such products may not be approved for guideline inclusion, which could adversely affect our ability to realize the intended benefits of our acquisition of ArcherDX.
- One of our competitors has alleged that our Anchored Multiplex PCR, or AMP, chemistry and products using AMP are infringing on its intellectual property, and we may be required to redesign the technology, obtain a license, cease using the AMP chemistry altogether and/or pay significant damages, among other consequences, any of which would have a material adverse effect on our business as well as our financial condition and results of operations, and the intended benefits of our acquisition of ArcherDX.
- We have a large amount of debt, servicing our debt requires a significant amount of cash, and our debt service obligations may prevent us from taking actions that we would otherwise consider to be in our best interests.

PART I

ITEM 1. Business

Overview

Invitae is in the business of delivering genetic testing services, digital health solutions and health data services that support a lifetime of patient care and improved outcomes – from inherited disease diagnoses, to family planning, to proactive health screening to personalized diagnosis, treatment and monitoring of cancer. Testing and other services are delivered via a unique, rapidly expanding platform that serves patients, healthcare providers, biopharma companies and other partners, thereby capturing the broad potential of genetics and helping to expand its use across the healthcare continuum. Invitae applies proprietary design, process automation, robotics and bioinformatics software solutions to expand the use and impact of genetic information and achieve efficiencies in sample processing and complex variant interpretation, allowing medical interpretation at scale. The result is a new and simplified process for obtaining and using affordable, high-quality genetic information to inform critical healthcare decisions. That access and scale also enable genomic information to speed the discovery and development of new personalized medical therapies — all while making clinical genetic testing available to billions of people.

By pioneering new ways of sharing, understanding and applying genetic information, Invitae is transforming the field of genetics and the application of healthcare data from a series of one-time, one-dimensional queries to a lifelong clinical dialogue with our genes using complex analyses and information management to improve medical decisions, optimize health interventions and improve the delivery of healthcare across a lifetime.

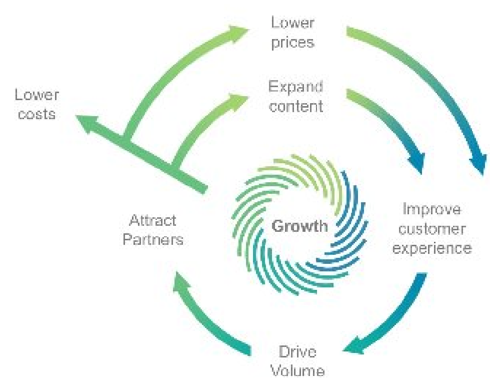
Mission and strategy

Invitae's mission is to bring comprehensive genetic information into mainstream medical practice to improve the quality of healthcare for billions of people. Our goal is to aggregate a majority of the world's genetic information into a comprehensive network that enables sharing of data among network participants to improve healthcare and clinical outcomes.

We were founded on four core principles:

- Patients should own and control their own genetic information;
- Healthcare professionals are fundamental in ordering and interpreting genetic information;
- Driving down the price of genetic information will increase its clinical and personal utility; and
- Genetic information is more valuable when shared.

Our strategy for long-term growth centers on five key drivers of our business, which we believe work in conjunction to create a flywheel effect extending our leadership position in the new market we are building:



- **Expanding our content offering.** We intend to continue steadily adding additional testing and analysis content to the Invitae platform, ultimately leading to affordable and ongoing access to the molecular information that enables personalized medicine. The breadth and depth of our offering is a core and central contribution to an improved user experience.
- **Creating a unique user experience.** A state-of-the-art interactive platform will enhance our service offering, leverage the uniquely empowering characteristics of online sharing of genetic information and, we believe, enable a superior economic offering to clients. We intend to continue to expend substantial efforts developing, acquiring and implementing technology-driven improvements to our customers' experience. We believe that an enhanced user experience and the resulting benefits to our brand and reputation will help draw customers to us over and above our direct efforts to do so.
- **Driving volume.** We intend to increase our brand equity and visibility through a commitment to precision testing results, excellent service and a variety of marketing and promotional techniques, including scientific publications and presentations, sales, marketing, public relations, social media and web technology vehicles. We believe that rapidly increasing the number of customers using our platform helps us to attract partners.
- **Attracting partners.** As we add more customers to our platform, we believe our business becomes particularly attractive to potential partners that can help the patients in our network further benefit from their genetic information or that provide us access to new customers who may wish to join our network. We believe the cumulative effect of the increased volume brought by these strategic components will allow us to lower the cost of our service and expand patient access globally.
- **Lowering the cost and price of genetic information.** Our goal is to provide customers with a broad menu of genetic content at a reasonable price and rapid turn-around times in order to grow volume and, in turn, achieve greater economies of scale. As our customers and our business benefit from further cost savings, we expect that those cost savings will allow us to deliver still more comprehensive information at decreasing prices and further improve the customer experience, allowing us to reap the cumulative benefits from all of the efforts outlined above.

We seek to differentiate our service in the market by establishing an exceptional experience for our customers. To that end, we believe that elevating the needs of the customer over those of our other stakeholders is essential to our success. Thus, in our decision-making processes, we strive to prioritize, in order:

- The needs of our customers;
- Motivating our employees to serve our customers; and
- Our long-term stockholder value.

We are certain that focusing on customers as our top priority rather than short-term financial goals is the best way to build and operate an organization for maximum long-term value creation.

Business overview

We are focused on making comprehensive, high-quality genetic information more accessible by lowering the cost of genetic testing, by utilizing a testing delivery platform that is accessible to patients throughout their lives, by enabling a growing network of partners to increase the utility of genetic information across the healthcare continuum, and, ultimately, by managing that information on behalf of our customers, enabling improved health and the advancement of molecular medicine around the globe.

As our market share grows, we expect that our business will grow in three stages:

1) **Genetic testing:** making genetic testing more affordable and more accessible with fast turnaround time. We believe that there is a significant market opportunity for high-volume, low-cost genetic testing that allows us to serve a large number of customers. We launched our first commercial offering in November 2013 with an offering of approximately 200 genes, growing the test menu over time to include more than 20,000 genes to help diagnose disease, inform family planning, and serve healthy individuals. In 2021, we processed billable volume of approximately 1,169,000 units and generated revenue of $460.4 million reflecting an approximate 77% and 65% increase over 2020 billable volume and revenue, respectively.

2) **Genome network:** sharing genetic information on a global scale to advance science and medicine. We are focusing our efforts on partnering with patients, family members, healthcare professionals, payers, industry professionals, researchers, and clinical trial sponsors to advance the development of our genome network. Our goal is to enable and build a network through which individuals and organizations can access, aggregate, and customize genetic information in order to participate in research, clinical trials, treatment planning, or other related purposes that may benefit the individual and/or their clinician. Individuals can also share information if they feel it will benefit them or will contribute more broadly to furthering knowledge about their conditions.

   In addition to investing in informatics solutions and infrastructure to support network development, we have been expanding our partnerships, which now number more than 100 of the world's leading biopharmaceutical companies supporting improved patient diagnosis, clinical trial recruitment and other research-related initiatives. Our biopharmaceutical industry partnerships are complemented by partnerships with leading health systems, executive health programs and leading research institutions, including The Christ Hospital Health Network, the Cleveland Clinic, the Geisinger Health System, the Mayo Clinic, Memorial Sloan Kettering Cancer Center, MedCan, and Stanford Health Care, among others.

   We partner with global biopharmaceutical companies such as AstraZeneca AB (Publ), Illumina and Merck KGaA, Darmstadt, Germany, through collaboration agreements to bring new treatment options for patients to market faster by enabling clinical research and trials.

3) **Genome management:** building a secure and trusted genome management infrastructure. By generating and storing large amounts of individualized genetic information for every patient sample and enabling the analysis of that cumulative data for broad health research applications, we believe we can create value for all the constituents of our testing platform and partner network. Broad access to centralized, standardized genomic data can benefit patients and their families with information that will improve therapy and outcomes, while it is also expected to aid in the compression of drug development timelines and the greater application of fact-based healthcare decisions throughout life.

Competition

Our competitors include companies that offer molecular genetic testing and consulting services, including specialty and reference laboratories that offer traditional single- and multi-gene tests and biopharmaceutical companies. Principal competitors include companies such as Ambry Genetics, a subsidiary of Konica Minolta Inc.; Athena Diagnostics and Blueprint Genetics, subsidiaries of Quest Diagnostics Incorporated; Baylor-Miraca Genetics Laboratories; Caris Life Sciences, Inc.; Centogene AG; Color Genomics, Inc.; Connective Tissue Gene Test LLC, a subsidiary of Health Network Laboratories, L.P.; Cooper Surgical, Inc.; Emory Genetics Laboratory, a subsidiary of Eurofins Scientific; Foundation Medicine, a subsidiary of Roche Holding AG; Fulgent Genetics, Inc.; Guardant Health, Inc.; Integrated Genetics, Sequenom Inc., Correlagen Diagnostics, Inc., and MNG Laboratories, subsidiaries of Laboratory Corporation of America Holdings; Myriad Genetics, Inc.; Natera, Inc.; Perkin Elmer, Inc.; and Sema4 Genomics; as well as other commercial and academic labs.

In addition, there are a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness, including Illumina, Inc. which is also one of our suppliers. In addition to the companies that currently offer traditional genetic testing services and research centers, other established and emerging healthcare, information technology and service companies may commercialize competitive products including informatics, analysis, integrated genetic tools and services for health and wellness.

We believe the principal competitive factors in our market are:

- breadth and depth of content;
- quality;
- reliability;
- accessibility of results;
- turnaround time of testing results;
- price and quality of tests;
- coverage and reimbursement arrangements with third-party payers;

- convenience of testing;
- brand recognition of test provider;
- additional value-added services and informatics tools;
- client service; and
- quality of website content.

We believe that we compare favorably with our competitors on the basis of these factors. However, certain competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration in certain testing categories, substantially greater financial, technological and research and development resources, selling and marketing capabilities, and/or more experience dealing with third-party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests, or sell their tests at prices designed to win significant levels of market share. We may compete less effectively against these organizations in some areas of testing.

Regulation

Reimbursement

Under the Protecting Access to Medicare Act of 2014 (as amended), or PAMA, and its implementing regulations, laboratories that realize at least $12,500 in Medicare Clinical Laboratory Fee Schedule, or CLFS, revenues during the six month reporting period and that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule must report, beginning in 2017, and then in 2023 and every three years thereafter (or annually for “advanced diagnostic laboratory tests”), private payer payment rates and volumes for their tests. We have not sought advanced diagnostic laboratory test status for our tests and therefore believe we are required to report private payer rates for our tests on an every three years basis starting next in 2023. Centers for Medicare & Medicaid Services, or CMS, uses the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payer payment rates for the tests. Laboratories that fail to report the required payment information may be subject to substantial civil money penalties.

Since January 1, 2018, Medicare payments for clinical diagnostic laboratory tests have been paid based upon these reported private payer rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests will be assigned by the cross-walk or gap-fill methodology, as under prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test.

Where applicable, reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2018 through 2020. Rates were held at 2020 levels during 2021 and will continue to be held at such levels in 2022, and then, where applicable based upon median private payer rates reported in 2017 or 2023, reduced by up to 15% per test per year in each of 2023 through 2025 (with a second round of private payer rate reporting in 2023 to establish rates for 2024 through 2026).

PAMA codified Medicare coverage rules for laboratory tests by requiring any local coverage determination to be made following the local coverage determination process. PAMA also authorizes CMS to consolidate coverage policies for clinical laboratory tests among one to four laboratory-specific Medicare Administrative Contractors, or MACs. These same contractors may also be designated to process claims if CMS determines that such a model is appropriate. It is unclear whether CMS will proceed with contractor consolidation under this authorization.

PAMA also authorized the adoption of new, temporary billing codes and/or unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The American Medical Association has created a new section of billing codes, Proprietary Laboratory Analyses, or PLAs, to facilitate implementation of this section of PAMA. These codes may apply to one or more of our tests if we apply for PLA coding.

CMS maintains a national coverage determination, or NCD, for next generation sequencing, or NGS, tests for somatic (acquired) and germline (inherited) cancer testing. For somatic cancer testing, the NCD establishes full coverage for FDA-approved or FDA-cleared NGS-based companion diagnostic assays that report results using report templates that specify treatment options when offered for their FDA-approved or FDA-cleared use(s), ordered by the patient’s treating physician for Medicare beneficiaries with advanced cancer (recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer) who have not have previously been tested with the same test using

NGS for the same cancer genetic content, and have decided to seek further cancer treatment (e.g., therapeutic chemotherapy.) The NCD also gives MACs the authority to establish local coverage for NGS-based somatic cancer assays that are not FDA-approved or FDA-cleared companion diagnostics when offered to patients meeting the above-referenced criteria. It appears that NGS-based somatic cancer tests provided for patients with cancer that do not meet the above-referenced criteria - e.g., patients with earlier stage cancers - are currently nationally non-covered under the NCD.

The NCD also establishes full coverage for FDA-approved or FDA-cleared NGS-based germline tests that report results using report templates that specify treatment options when ordered by the patient's treating physician for patients with ovarian or breast cancer, a clinical indication for germline testing for hereditary breast or ovarian cancer, and a risk factor for germline breast or ovarian cancer, provided the patient has not previously been tested with the same germline test using NGS for the same germline genetic content. The NCD also gives MACs the authority to establish local coverage for NGS-based germline tests for ovarian or breast cancer that are not FDA-approved or FDA-cleared, as well as for NGS-based tests for any other cancer diagnosis (regardless of the test's FDA regulatory status) when offered to patients meeting the above-referenced criteria for germline testing. Since we already have local coverage for our germline tests for ovarian and breast cancer, we believe that the NCD will not have a material impact on which of our tests will be reimbursable by CMS for Medicare patients.

Clinical Laboratory Improvement Amendments of 1988, or CLIA

Our clinical reference laboratories in California, Colorado and New Jersey are required to hold certain federal certificates to conduct our business. Under CLIA, we are required to hold certificates applicable to the type of laboratory examinations we perform and to comply with standards covering personnel, facilities administration, inspections, quality control, quality assurance and proficiency testing.

We have current certifications under CLIA to perform testing at our laboratory locations in San Francisco and Irvine, California, Golden, Colorado, and Iselin, New Jersey. To renew our CLIA certifications, we are subject to survey and inspection every two years to assess compliance with program standards. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

If our clinical reference laboratories are out of compliance with CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificates, as well as directed plan of correction, state on-site monitoring, significant civil money penalties, civil injunctive suit or criminal penalties. We must maintain CLIA compliance and certifications to be eligible to bill for diagnostic services provided to Medicare and Medicaid beneficiaries. If we were to be found out of compliance with CLIA requirements and subjected to sanction, our business could be harmed.

State laboratory licensure requirements

We are required to maintain in-state licenses to conduct testing in California, New Jersey and Washington. California, New Jersey and Washington laws establish standards for day-to-day operations of our laboratories in San Francisco and Irvine, Iselin and Seattle, respectively. Such laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratories. If our clinical reference laboratories are out of compliance with applicable standards, the appropriate state agency may suspend, restrict or revoke our licenses to operate our clinical reference laboratories, assess substantial civil money penalties, or impose specific corrective action plans. Any such actions could materially affect our business. We maintain current licenses in good standing. However, we cannot provide assurance that state regulators will at all times in the future find us to be in compliance with all such laws.

Several states require the licensure of out-of-state laboratories that accept specimens from those states. Our California laboratories hold the required out-of-state laboratory licenses for Maryland, New York, Pennsylvania, and Rhode Island. Our Seattle and Iselin laboratories hold the required out-of-state laboratory licenses in California, Maryland, New York, Pennsylvania, and Rhode Island. Our laboratory in Golden, Colorado holds the required out-of-state laboratory licenses for California, Maryland, Pennsylvania and Rhode Island (but not New York).

In addition to having laboratory licenses in New York, our clinical reference laboratories are also required to obtain approval on a test-specific basis for the tests they run as LDTs by the New York State Department of Health, or NYDOH, before specific testing is performed on samples from New York.

Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays. 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.

We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of human blood or saliva necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States.

Federal oversight of laboratory developed tests

We provide many of our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by CLIA and state law, respectively).

Historically, the U.S. Food and Drug Administration, or FDA, has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality system regulations, premarket clearance or premarket approval, and post- market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. For example, in 2014, the FDA issued two draft guidance documents that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. These documents have not been finalized to date.

Subsequently, in August 2020, the U.S. Department of Health and Human Services – the parent agency for FDA – announced that the FDA "will not require premarket review of LDTs absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances." In November 2021, the Biden Administration rescinded this policy.

At this time, it is unclear when, or if, the FDA will finalize its plans to end enforcement discretion (e.g., via notice and comment rulemaking or otherwise), and even then, the new regulatory requirements are expected to be phased-in over time. Nevertheless, the FDA may attempt to regulate certain LDTs on a case-by-case basis at any time.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced in the current and previous Congresses, and we expect that new legislative proposals will be introduced from time-to-time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate certain LDTs as medical devices is difficult to predict at this time.

If the FDA ultimately regulates certain LDTs, whether via final guidance, final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements can be expensive, time-consuming, and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's requirements to our tests could materially and adversely affect our business, financial condition, and results of operations.

Notwithstanding the FDA's current position with respect to oversight of our LDTs, we may voluntarily decide to pursue FDA pre-market review for our current LDTs and/or LDTs we may offer in the future if we determine that doing so would be appropriate from a strategic perspective – e.g., if CMS indicated that it no longer intended to cover tests offered as LDTs.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

In addition, in November 2013, the FDA issued final guidance regarding the distribution of products labeled for research use only. Certain of the reagents and other products we use in our tests are labeled as research use only products. Certain of our suppliers may cease selling research use only products to us and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

Medical device regulatory framework

Pursuant to its authority under the Federal Food, Drug, and Cosmetic Act, or FDCA, the FDA has jurisdiction over medical devices, which are defined to include, among other things, in vitro diagnostics, or IVDs. The FDA regulates the research, design, development, pre-clinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. Specifically, for the test we offer that FDA currently regulates as a device, and if the FDA begins to actively regulate LDTs, then for those tests as well, each new or significantly modified test we seek to commercially distribute in the United States could require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a premarket approval, or PMA, application, unless an exemption applies. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees.

Device classification

Under the FDCA, medical devices are classified into one of three classes (Class I, Class II or Class III) depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to General Controls for Medical Devices, which require compliance with the applicable portions of the FDA's Quality System Regulation, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. While some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below, most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These Special Controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review by the FDA. Premarket review by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk, such as life-supporting, life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent to a legally-marketed predicate device. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA process, which is generally more costly and time-consuming than the 510(k) process. Through the PMA process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The 510(k) clearance process

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to a PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics, but the information submitted demonstrates that the device is as safe and effective and does not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) premarket notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including data from samples collected in a clinical setting, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III because there is no available predicate device, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the De Novo classification process. The De Novo classification process is an alternate pathway to classify medical devices that are automatically classified into Class III but which are low to moderate risk. A manufacturer can submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents moderate or low risk. De Novo classification may also be available after receipt of a "not substantially equivalent" letter following submission of a 510(k) to FDA.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to determine whether the proposed change requires a new submission in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by an internal letter-to-file in which the manufacturer documents its reasoning for why a change does not require premarket submission to the FDA. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing 510(k)-cleared device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite application(s).

The PMA approval process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA.

Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA clearance or approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facility is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post- approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. New PMA applications or PMA supplements may also be required for modifications to any approved diagnostic tests, including modifications to manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

The investigational device process

In the United States, absent certain exceptions, human clinical trials intended to support medical device clearance or approval require an investigational device exemption, or IDE, application. Investigations that meet certain requirements – i.e., involve tests that are labeled investigational use only (IUO), are noninvasive, do not require an invasive sampling procedure that presents significant risk, do not by design or intention introduce energy into a subject, and are not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established product or procedure — are exempt from the IDE requirement. Some types of studies deemed to present “non-significant risk” are deemed to have an approved IDE — without affirmative submission of an IDE application to the FDA — once certain requirements are addressed and Institutional Review Board, or IRB, approval is obtained. If the device presents a “significant risk” to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials.

Where applicable, the IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. Submission of an IDE will not necessarily result in the ability to commence clinical trials, and although the FDA’s approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product’s safety and efficacy, even if the trial meets its intended success criteria.

Such clinical trials must be conducted in accordance with the FDA’s IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA for any clinical trials subject to FDA oversight. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a 510(k) premarket notification, for numerous reasons.

The Breakthrough Devices Program is a voluntary program intended to expedite the review, development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, provided the device also represents breakthrough technology, is one for which no approved or cleared treatment exists, offers significant advantages over existing approved or cleared alternatives, or is one whose availability is in the best interest of patients. All submissions for devices designated as Breakthrough Devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as needed. Although Breakthrough Device designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory clearance or approval for such product.

Research use only, or RUO

In the United States, products labeled and sold for research use only, and not for the diagnosis or treatment of disease, are sold to a variety of parties, including biopharmaceutical companies, academic institutions and molecular labs. Because such products are not intended for use in clinical practice in diagnostics, and the products cannot include clinical or diagnostic claims, they are exempt from many regulatory requirements otherwise applicable to medical devices. In particular, while the FDA regulations require that RUO products be labeled, "For Research Use Only. Not for use in diagnostic procedures," the regulations do not otherwise subject such products to the FDA's pre- and post-market controls for medical devices.

A significant change in the laws governing RUO products or how they are enforced may require a change to our RUO products business model in order to maintain compliance. For instance, in November 2013 the FDA issued a guidance document entitled "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only", or the RUO Guidance, which highlights the FDA's interpretation that distribution of RUO products with any labeling, advertising or promotion that suggests that clinical laboratories can validate the test through their own procedures and subsequently offer it for clinical diagnostic use as a laboratory developed test is in conflict with RUO status. The RUO Guidance further articulates the FDA's position that any assistance offered in performing clinical validation or verification, or similar specialized technical support, to clinical laboratories, conflicts with RUO status. If we engage in any activities that the FDA deems to be in conflict with the RUO labeling on the products that we sell, we may be subject to immediate, severe and broad FDA enforcement action that would adversely affect our ability to continue operations selling these products. Accordingly, if the FDA finds that we are distributing RUO products in a manner that is inconsistent with its regulations or guidance, we may be forced to stop distribution of our RUO products until we are in compliance, which would reduce our revenues, increase our costs and adversely affect our business, prospects, results of operations and financial condition. In addition, if the FDA ends enforcement discretion for LDTs, it may negatively impact the LDT market and thereby reduce demand for RUO products. If the FDA requires marketing authorization of our RUO products in the future, there can be no assurance that the FDA will ultimately grant any clearance or approval we request in a timely manner, or at all.

Post-market regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- Quality System Requirements ("QSR"), which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;

- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Device manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or approval or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, including the following:

- issuance of warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- requesting or requiring recalls, withdrawals, or administrative detention or seizure of our products;
- imposing operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

HIPAA and state privacy, security and breach notification laws

Under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, the U.S. Department of Health and Human Services issued regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and requirements for protecting the privacy and security of protected health information, or PHI, used or disclosed by covered entities, including most health care providers and their respective business associates, as well as the business associates' subcontractors. We are required to comply with the provisions of HIPAA and HITECH and the regulations implemented thereunder setting forth standards for the privacy of PHI; security standards for the protection of electronic PHI; breach notification requirements; and standards for electronic transactions, which establish standards for common healthcare transactions.

The HIPAA privacy regulations establish requirements and restrictions for the use and disclosure of PHI by covered entities as well as business associates, which are persons or entities that perform certain functions for or on behalf of a covered entity that involve the creation, receipt, maintenance, or transmittal of PHI. Business associates are defined to include a subcontractor to whom a business associate delegates a function, activity, or service, other than in the capacity of the business associate's workforce. As a general rule, a covered entity or business associate may not use or disclose PHI except as permitted or required under the privacy regulations. The privacy regulations also set forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity or business associate, including the right to access and amend certain records containing his or her PHI, request restrictions on the use or disclosure of his or her PHI, and request an accounting of disclosures of his or her PHI.

Covered entities and business associates also must comply with the HIPAA security regulations, which establish requirements for safeguarding the confidentiality, integrity, and availability of PHI that is electronically transmitted or electronically stored. The HIPAA security regulations give covered entities and business associates flexibility in complying with certain of the standards and implementation specifications under the regulations.

However, the requirements are extensive and include implementing workforce training, implementing policies and procedures to comply with the HIPAA security regulations, and conducting an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic PHI maintained by the covered entity or business associate.

In addition, covered entities and business associates must comply with certain breach notification requirements. In particular, a covered entity must notify any individual whose unsecured PHI is breached according to the specifications set forth in the HITECH breach notification rule. A covered entity must also notify the Secretary of the U.S. Department of Health and Human Services and, under certain circumstances, the media of a breach of unsecured PHI. A business associate must notify the relevant covered entity of any breach of unsecured PHI.

There are significant civil and criminal penalties that may be imposed on us as a covered entity or business associate for violating HIPAA. A covered entity or business associate may also be liable for civil money penalties for a violation that is based on an act or omission of any of its agents as determined according to the federal common law of agency, which may include a business associate or subcontractor business associates. Complying with HIPAA and HITECH requires significant resources, and we may be restricted in our ability to perform certain activities that involve the collection, use, or disclosure of PHI due to the limitations set forth in the HIPAA privacy regulations. 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.

The HIPAA and HITECH privacy, security, and breach notification regulations establish a uniform federal “floor” and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI or insofar as such state laws apply to personal information that is broader in scope than PHI as defined under HIPAA. Massachusetts, for example, has a state law that protects the privacy and security of personal information of Massachusetts residents. In addition, every U.S. state has a data breach notification law that requires entities to report certain security breaches to affected consumers and, in some instances, state regulators and consumer reporting agencies. Many states also have laws or regulations that specifically apply to genetic testing and genetic information and are more stringent than the standards under HIPAA. These state genetic information privacy laws include specific informed consent requirements for the conduct of genetic testing and restrict the collection, use, disclosure, or retention of genetic information. A number of states, including California and Florida, have recently enacted new or amended genetic privacy laws. While many of these new genetic privacy laws include exceptions for PHI and for covered entities and business associates to the extent they process genetic information in the same manner as PHI, not all such laws are limited in this manner, and the enactment of these laws may generally bring enhanced scrutiny of companies like us that generate and maintain genetic information. Failure to comply with applicable state laws that impose privacy, security, or breach notification requirements for genetic or other personal information could result in significant civil or criminal penalties, administrative actions, or private causes of action by patients, and adversely affect our business, results of operations and reputation.

Federal and state consumer protection laws

The Federal Trade Commission, or FTC, is an independent U.S. law enforcement agency charged with protecting consumers and enhancing competition across broad sectors of the economy. The FTC has indicated that, in 2022, it will be considering new data privacy regulations, which, if adopted, could impact our operations if they impose substantial new obligations or restrictions with respect to our data collection and processing activities. The FTC’s primary legal authority with respect to data privacy and security comes from Section 5 of the FTC Act, which prohibits unfair or deceptive acts or practices in the marketplace. The FTC uses this broad authority to police data privacy and security, using its powers to investigate and bring lawsuits. Where appropriate, the FTC can seek a variety of remedies, such as but not limited to requiring the implementation of comprehensive privacy and security programs, biennial assessments by independent experts, monetary redress to consumers, and provision of robust notice and choice mechanisms to consumers. In addition to its enforcement mechanisms, the FTC uses a variety of tools to protect consumers’ privacy and personal information, including pursuing enforcement actions to stop violations of law, conducting studies and issuing reports, hosting public workshops, developing educational materials, and testifying before the U.S. Congress on issues that affect consumer privacy.

The vast majority of data privacy cases brought by the FTC fall under the “deceptive” acts prong of Section 5. These cases often involve a failure on the part of a company to adhere to its own privacy and data protection principles set forth in its policies. To avoid Section 5 violations, the FTC encourages companies to build privacy protections and safeguards into relevant portions of their business, and to consider privacy and data protection as the company grows and evolves. In addition, privacy notices should clearly and accurately disclose the type(s) of personal information the company collects, how the company uses and shares that information, and the security measures used by the company to protect that information.

In recent years, the FTC's enforcement under Section 5 related to data security has included alleged violations of the "unfairness" prong. Many of these cases have alleged that companies were unfair to consumers because they failed to take reasonable and necessary measures to protect consumer data. The FTC has not provided bright line rules defining what constitutes "reasonable and necessary measures" for implementing a cybersecurity program, but it has provided guidance, tips and advice for companies. The FTC has also published past complaints and consent orders, which it urges companies use as guidance to help avoid an FTC enforcement action, even if a data breach or loss occurs.

In addition to the FTC Act, most U.S. states have unfair and deceptive acts and practices statutes, known as UDAP statutes, that substantially mirror the FTC Act and have been applied in the privacy and data security context. These UDAP statutes vary in substance and strength from state to state. Many have broad prohibitions against unfair and deceptive acts and practices. These statutes generally allow for private rights of action and are enforced by the states' Attorneys General.

California Consumer Privacy Act and Copy Cat Legislation

The California Consumer Privacy Act, or CCPA, is a comprehensive consumer privacy law that took effect on January 1, 2020, and regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of consumers who reside in California. Among other things, the CCPA confers to California consumers the right to: receive notice information collection and use practices; access, delete, or transfer personal information; and opt out of the "sale" of their personal information, which the CCPA defines broadly as any disclosure of personal information to a third party in exchange for monetary or other valuable consideration. The CCPA also requires a business to implement reasonable security procedures to safeguard personal information against unauthorized access, use, or disclosure. The CCPA provides partial exemptions for employee and business-to-business information that are set to expire on January 1, 2023.

The CCPA does not apply to personal information that is PHI under HIPAA. The CCPA also does not apply to a HIPAA-regulated entity to the extent that the entity maintains patient information in the same manner as PHI. In addition, de-identified data as defined under HIPAA is also exempt from the CCPA. Accordingly, we do not have CCPA compliance obligations with respect to most genetic testing and patient information we collect and process. However, we are required to comply with the CCPA insofar as we collect other categories of California consumers' personal information.

The California Attorney General has authority to enforce the CCPA and its implementing regulations against covered businesses. The CCPA provides for civil penalties for violations, as well as private right of action for certain data breaches.

On November 3, 2020, California passed the California Privacy Rights Act, or CPRA, through a ballot initiative. Under the CPRA, a new California Privacy Protection Agency has been created to enforce the CPRA. Among other things, the CPRA will create a new category of "sensitive personal information" and offer consumers the right to limit processing of such information, impose purpose limitation, data minimization, data retention, and security compliance obligations on regulated businesses, and add or modify the rights available to consumers, including by providing a right to correct the information a business holds about them. The CPRA's amendments to the CCPA will take effect on January 1, 2023, and will generally apply to personal information collected by businesses on or after January 1, 2022. CPRA enforcement will begin on July 1, 2023.

On March 2, 2021, Virginia's Governor signed into law the Virginia Consumer Data Protection Act (VCDPA), which will take effect on January 1, 2023. On July 7, 2021, Colorado's Governor signed into law Colorado's Consumer Privacy Act (CPA), which will take effect on July 1, 2023. Like the CPRA, both the VCDPA and the CPA regulate how certain businesses collect, use and disclose the personal information of consumers in either Virginia or Colorado. Both the VCDPA and the CPA provide for substantially the same rights to Virginia and Colorado residents, respectively, as the CPRA does for California residents. Unlike the CPRA, however, both the VCDPA and the CPA permanently exclude information collected from employees or business-to-business contacts. In addition, the VCDPA and CPA will require that companies obtain consent from consumers in Virginia and Colorado before their "sensitive personal information" is collected or processed. The VCDPA and the CPA also allow consumers to opt-out of the use of their information for specific purposes, such as targeted marketing. Both the VCDPA and the CPA do not apply to PHI under HIPAA and both laws also generally exempt HIPAA-regulated entities from their reach. Both the VCDPA and the CPA are enforced by their respective state's Attorney Generals, and neither includes a private right of action.

Dozens of other states in the United States are currently considering similar consumer data privacy laws, which could impact our operations if enacted.

Privacy and data protection laws

There are a growing number of jurisdictions around the globe that have privacy and data protection laws that may apply to Invitae as it enters or expands its business in jurisdictions outside of the United States. These laws are typically triggered by a company's establishment or physical location in the jurisdiction, data processing activities that take place in the jurisdiction, and/or the processing of personal information about individuals located in that jurisdiction. Certain international privacy and data protection laws, such as those in the European Union (EU), are more restrictive and prescriptive than those in the U.S., while other jurisdictions may have laws less restrictive or prescriptive than those in the U.S. Enforcement of these laws varies from jurisdiction to jurisdiction, with a variety of consequences, including civil or criminal penalties, litigation, private rights of action or damage to our reputation.

Europe

The EU's General Data Protection Regulation, or GDPR, took effect on May 25, 2018. The GDPR applies to any entity established in the EU as well as extraterritorially to any entity outside the EU that offers goods or services to, or monitors the behavior of, individuals who are located in the EU. The GDPR imposes strict requirements on controllers and processors of personal data, including enhanced protections for "special categories" of personal data, which includes sensitive information such as health and genetic information of data subjects. The GDPR also grants individuals various rights in relation to their personal data, including the rights of access, rectification, objection to certain processing and deletion. The GDPR provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR or the related national data protection laws of the member states of the EU, which may deviate from or be more restrictive than the GDPR, may result in significant administrative fines issued by EU regulators. Maximum penalties for violations of the EU GDPR are capped at 20 million euros or 4% of an organization's annual global revenue, whichever is greater.

Australia

Australia's federal Privacy Act 1988, or the Privacy Act, and the 13 Australian Privacy Principles, or the APPs, contained in the Privacy Act, apply to government agencies and private sector organizations with annual turnover exceeding AU $3 million. The Privacy Act extends to all of Australia's external territories, but also applies to an act done, or practice engaged in, or outside Australia (and Australia's external territories) by an organization, or small business operator, that has a link to Australia, such as a continued presence, partnership, incorporation, central management and control, or citizenship in Australia. An organization may also have a link to Australia if the organization conducts business in Australia and collects or stores personal information in Australia. The Privacy Act applies to any collection, holding, use or disclosure of personal information by a regulated entity, with enhanced protections for sensitive information such as genetic information. The Privacy Act prescribes certain rights for individuals, including rights to know why the information is collected, how it is used, and to whom it is disclosed, the right of the individual not to identify themself in certain circumstances, the right of access, the right to stop receiving unwanted direct marketing, the right to correct information, and the right to make a complaint. Australia's Privacy Commissioner enforces the Privacy Act and any acts that may violate an individual's privacy. The Privacy Commissioner can levy significant fines on individuals and corporations that violate the Privacy Act.

Canada

Canada has several federal, provincial and territorial privacy statutes that govern the protection of personal information. The Personal Information Protection and Electronic Documents Act 2000, or PIPEDA, applies to the collection, use, and disclosure of personal information in the course of commercial activities in Canada. Although PIPEDA is silent with respect to its extraterritorial application, the Federal Court of Canada has concluded that PIPEDA applies to businesses established in other jurisdictions if there is a "real and substantial connection" between the organization's activities and Canada. PIPEDA and provincial data protection laws require specific notices regarding openness and transparency and require regulated organizations to obtain consent in order to process such information. Canadian individuals enjoy rights or access and to correct inaccuracies. Violations of Canadian data protection laws can result in significant fines. Canada is evaluating replacing or substantially amending PIPEDA so as to make it similar to the GDPR. Such changes to PIPEDA could impact our operations if enacted.

India

The Indian Constitution has been interpreted by India's highest court to include a fundamental right to privacy. In addition, the Information Technology Act 2000, as amended, or the IT Act, is the primary national law regulating the collection and use of personal information that is sensitive. The IT Act applies to corporations and other “body corporates” that possess, maintain, or otherwise process personal information, including body corporates that act on behalf of other body corporates. Certain provisions of the IT Act provide liability for negligent handling of personal information. For example, the IT Act provides that any corporation or other body corporate that handles sensitive personal data is liable to pay damages for any loss caused by its negligence in implementing and maintaining reasonable security practices and procedures.

In addition, the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules 2011, or the Data Privacy Rules, issued under the IT Act regulate the use of personal information and sensitive personal data. The Data Privacy Rules mandate that businesses have a privacy policy, obtain consent when collecting or transferring personal information, and inform the data subject about any recipients of that data. The IT Act includes a private right of action for individuals, and authorizes criminal punishment (with a fine, three years in prison, or both) for disclosing personal information without the consent of the data subject or in breach of any relevant contract.

India’s parliament is currently evaluating a new data privacy bill that would bear many similarities with GDPR, but that would also contain certain additional requirements including, for example, possible data localization requirements. If enacted, India’s new law could impact our operations.

Israel

Israel’s data protection regime is governed primarily by the Protection of Privacy Law and the regulations promulgated under it, or the PPL, and the guidelines of the Israeli regulator, the Privacy Protection Authority, or the PPA. The PPL applies to: (1) database owners, database holders, and database managers based in Israel; and (2) data processing operations that take place in Israel, regardless of whether the individuals about whom the data relates are residents or citizens of Israel. The PPL could also be interpreted to apply to non-Israeli database owners, database holders, or database managers that process personal information about Israeli residents or citizens when such processing takes place outside of Israel. Various regulations promulgated under the PPL by the PPA set out rules and procedures for data security, data retention, data subject rights, and cross border transfers of data. These regulations also do not clearly state their jurisdictional scope, such that there is a risk they could be interpreted as applying to foreign-based entities that process data about Israeli citizens.

The PPA is required to maintain a registry of databases and is empowered to supervise compliance with and investigate alleged violations of the PPL and related regulations. The PPA may impose administrative fines for violations of the PPL and related regulations, and willful violations may result in criminal liability and up to five years in prison. A breach of privacy is also actionable, and an individual claimant may obtain monetary compensation or injunctive relief. A court may award statutory damages without proof of damages for breach of privacy rights. If the breach was intentional, the damages may be doubled. The PPL also specifies that an act or omission in breach of certain of its provisions, such as failure to ensure data security, may give rise to a tort claim.

Japan

Japan’s primary data protection law, the Act on the Protection of Personal Information was amended in 2020 to include GDPR-like requirements, including additional transparency requirements, data transfer obligations, enhanced data breach notification requirements, additional data subject rights and stronger penalties for violations, including significant fines. The amendment clarifies that its provisions, obligations and penalties apply to entities outside of Japan that supply goods or services in Japan and handle personal information from an individual in Japan. These amendments will go into effect on April 1, 2022.

Information blocking prohibition

On May 1, 2020, the Office of the National Coordinator for Health Information Technology promulgated final regulations under the authority of the 21st Century Cures Act to impose new conditions to obtain and maintain certification of certified health information technology and prohibit certain covered actors, including developers of certified health information technology, health information networks / health information exchanges, and health care providers (including laboratories), from engaging in activities that are likely to interfere with the access, exchange, or use of electronic health information (information blocking). The final regulations further defined exceptions for activities that are permissible, even though they may have the effect of interfering with the access, exchange, or use of electronic health information. The information blocking regulation effective date was April 5, 2021. Under the 21st Century Cures Act, health care providers that violate the information blocking prohibition will be subject to appropriate disincentives, which the U.S. Department of Health and Human services has yet to establish through required rulemaking. Developers of certified information technology and health information networks / health information exchanges, however, may be subject to civil monetary penalties of up to just over $1 million (as adjusted for inflation) per violation. If the government were to conclude that we met the definition of a health information network or health information exchange, we could be potentially subject to such penalties. However, the U.S. Department of Health and Human Services Office of Inspector General has the authority to impose such penalties and on April 24, 2020 published a proposed rule to codify new authority in regulation, which the agency proposed would be effective 60 days after it issues a final rule, but in no event before November 2, 2020. The U.S. Department of Health and Human Services Office of Inspector General has not yet issued a final rule.

Federal, state and foreign fraud and abuse laws

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

In the United States, the federal Anti-Kickback Statute prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering of any good, facility, service or item for which payment may be made in whole or in part by a federal healthcare program. Many courts have held that the Anti-Kickback Statute may be violated if any one purpose of the remuneration is to induce or reward 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, credit arrangements, payments of cash, consulting fees, waivers of co-payments, ownership interests, and providing anything at less than its fair market value. The Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry. The Anti-Kickback Statute includes several statutory exceptions, and the U.S. Department of Health and Human Services has issued a series of regulatory “safe harbors.” These exceptions and safe harbor regulations set forth certain requirements for various types of arrangements, which, if met, will protect the arrangement from potential liability under the Anti-Kickback Statute. Although full compliance with the statutory exceptions or regulatory safe harbors ensures against liability under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific statutory exception or regulatory safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. Penalties for violations of the Anti-Kickback Statute are severe, and include imprisonment, criminal fines, civil money penalties, and exclusion from participation in federal healthcare programs. Many states also have anti- kickback statutes, some of which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

There are also federal laws related to healthcare fraud and false statements, among others, that apply to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payer programs such as the Medicare and Medicaid programs. The false statements statute prohibits, among other things, 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 benefits, items, or services. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payer programs.

Another development affecting the healthcare industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act’s “whistleblower” or “qui tam” provisions. 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 payer 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 presenting or causing to be presented 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. 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. For penalties assessed after December 13, 2021, whose associated violations occurred after November 2, 2015, the penalties range from $11,803 to $23,607 for each false claim. The minimum and maximum per claim penalty amounts are subject to annual increases for inflation.

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

Additionally, the civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have knowingly presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or for a claim that is false or fraudulent. This law also prohibits the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier for items or services reimbursable by Medicare or a state healthcare program. There are several exceptions to the prohibition on beneficiary inducement.

The Eliminating Kickbacks in Recovery Act of 2018, or EKRA, prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA’s reach extends beyond federal health care programs, to include private insurance (i.e., it is an “all payer” statute). For purposes of EKRA, the term “laboratory” is defined broadly and without reference to any connection to substance use disorder treatment. EKRA is a criminal statute and violations can result in fines of up to $200,000, up to 10 years in prison, or both, per violation. The law includes a limited number of exceptions, some of which closely align with corresponding federal Anti-Kickback Statute exceptions and safe harbors and others that materially differ.

We are also subject to the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. In Europe various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/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 went into effect in July 2011, a bribery 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 the new regime, an individual found in violation of the Bribery Act 2010, faces imprisonment of up to ten years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

The Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, also imposed annual reporting requirements on entities including manufacturers of certain devices, medical supplies, drugs and biologics for certain payments and transfers of value that the manufacturer provides, directly or indirectly, to or on behalf of physicians (defined to include various healthcare professionals such as doctors, physician assistants, and nurse practitioners) and teaching hospitals. The Physician Payments Sunshine Act also requires entities including applicable manufacturers to report certain ownership and investment interests held by physicians and their immediate family members in such manufacturers. In addition, certain states, such as Vermont and Massachusetts, have enacted laws that impose certain reporting requirements for payments and transfers of value provided to covered healthcare providers. These state laws are not preempted by the federal Physician Payments Sunshine Act to the extent the state law requires the reporting of information that is not required to be reported under the federal Physician Payments Sunshine Act. Finally, certain states such as Massachusetts, Nevada, and Vermont have enacted laws that limit or prohibit the provision of payments or other transfers of value to covered recipients, such as certain health care providers, hospitals, and health benefit plan administrators.

Physician referral prohibitions

A federal law directed at “self-referrals,” commonly known as the “Stark Law,” prohibits a physician from referring a patient to an entity for certain Medicare-covered designated health services, including laboratory services, if the physician, or an immediate family member, has a financial relationship with the entity, unless an exception applies. The Stark Law also prohibits an entity from billing for services furnished pursuant to a prohibited referral. A physician or entity that engages in a scheme to circumvent the Stark Law’s referral prohibition may be fined up to $174,172 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare program in violation of the Stark Law is subject to civil monetary penalties of up to $26,125 per service, an assessment of up to three times the amount claimed and possible exclusion from participation in federal healthcare programs. Bills submitted in violation of the Stark Law may not be paid by

Medicare, 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 apply to services covered by other third-party payers. The Stark Law also prohibits state receipt of federal Medicaid matching funds for services furnished pursuant to a prohibited referral. This provision of the Stark Law has not been implemented by regulations, but some courts have held that the submission of claims to Medicaid that would be prohibited as self-referrals under the Stark Law for Medicare could implicate the False Claims Act.

Corporate practice of medicine

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging clinicians 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 and/or the professional through licensure proceedings.

Intellectual property

We rely on a combination of intellectual property rights, including trade secrets, copyrights, trademarks, customary contractual protections and, to a lesser extent, patents, to protect our core technology and intellectual property. With respect to patents, we believe that the practice of patenting individual genes, along with patenting tools and methods specific to individual genes, has impeded the progress of the genetic testing industry beyond single gene tests and is antithetical to our core principle that patients should own and control their own genomic information. The U.S. Supreme Court has issued a series of unanimous (9-0) decisions setting forth limits on the patentability of natural phenomena, natural laws, abstract ideas and their applications — *i.e.*, *Mayo Collaborative v. Prometheus Laboratories (2012)*, or *Mayo*, *Association for Molecular Pathology v. Myriad Genetics (2013)*, or *Myriad*, and *Alice Corporation v. CLS Bank (2014)*, or *Alice.* As discussed below, we believe the *Mayo*, *Myriad* and *Alice* decisions bring clarity to the limits to which patents may cover specific genes, mutations of such genes, or gene-specific technology for determining a patient's genomic information.

Patents

U.S. Supreme Court cases have clarified that naturally occurring DNA sequences are natural phenomena, which should not be patentable. On June 13, 2013, the U.S. Supreme Court decided *Myriad*, a case challenging the validity of patent claims held by Myriad relating to the cancer genes BRCA1 and BRCA2. The *Myriad* Court held that genomic DNAs that have been isolated from, or have the same sequence as, naturally occurring samples, such as the DNA constituting the BRCA1 and BRCA2 genes or fragments thereof, are not eligible for patent protection. Instead, the *Myriad* Court held that only those complementary DNAs (cDNAs) which have a sequence that differs from a naturally occurring fragment of genomic DNA may be patent eligible. Because it will be applied by other courts to all gene patents, the holding in *Myriad* also invalidates patent claims to other genes and gene variants. Prior to *Myriad*, on August 16, 2012, the U.S. Court of Appeals for the Federal Circuit had held that certain patent claims of Myriad directed to methods of comparing or analyzing BRCA1 and BRCA2 sequences to determine whether or not a person has a variant or mutation are unpatentable abstract processes, and Myriad did not appeal such ruling.

We do not currently have any patents or patent applications directed to the sequences of specific genes or variants of such genes, nor do we rely on any such in-licensed patent rights of any third party. We believe that correlations between specific gene variants and a person's susceptibility to certain conditions or diseases are natural laws that are not patentable under the U.S. Supreme Court's decision in *Mayo*. The *Mayo* case involved patent claims directed to optimizing, on a patient-specific basis, the dosage of a certain drug by measuring its metabolites in a patient. The *Mayo* Court determined that patent claims directed at detection of natural correlations, such as the correlation between drug metabolite levels in a patient and that drug's optimal dosage for such patient, are not eligible for patent protection. The *Mayo* Court held that claims based on this type of comparison between an observed fact and an understanding of that fact's implications represent attempts to patent a natural law and, moreover, when the processes for making the comparison are not themselves sufficiently inventive, claims to such processes are similarly patent-ineligible. On June 19, 2014, the U.S. Supreme Court decided *Alice*, where it amplified its *Mayo* and *Myriad* decisions and clarified the analytical framework for distinguishing between patents that claim laws of nature, natural phenomena and abstract ideas and those that claim patent-eligible applications of such concepts. According to the *Alice* Court, the analysis depends on whether a patent claim directed to a law of nature, a natural phenomenon or an abstract idea contains additional elements, an “inventive concept,” that “is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself;” (citing *Mayo*).

We believe that *Mayo*, *Myriad* and *Alice* not only render as unpatentable genes, gene fragments and the detection of a person’s sequence for a gene, but also have the same effect on generic applications of conventional technology to specific gene sequences. For example, we believe that generic claims to primers or probes directed to specific gene sequences and uses of such primers and probes in determining a person’s genetic information are not patentable. We do not currently have any patents or patent applications directed to such subject matter nor have we in-licensed such patents rights of any third party.

Unlike patents directed to specific genes, we do rely upon, in part, patent protection to protect technology that is not gene-specific and that provides us with a potential competitive advantage as we focus on making comprehensive genetic information less expensive and more broadly available to our customers. In this regard, we have issued U.S. patents, pending U.S. patent applications and corresponding non-U.S. patents and patent applications directed to various aspects of our laboratory, analytic and business practices. We intend to pursue further patent protection where appropriate.

For information regarding legal actions that pertain to intellectual property rights, see Note 8, “Commitments and contingencies” in Notes to Consolidated Financial Statements in Part II, Item 8 of this report.

Trade secrets

In addition to seeking patent protection for some of our laboratory, analytic and business practices, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain and develop our competitive position. We have developed proprietary procedures for both the laboratory processing of patient samples and the analysis of the resulting data to generate clinical reports. For example, we have automated aspects of our processes for curating information about known variants, identifying variants in an individual’s sequence information, associating those variants with known information about their potential effects on disease, and presenting that information for review by personnel responsible for its interpretation and for the delivery of test reports to clinicians and patients. We try to protect these trade secrets, in part, by taking reasonable steps to keep them confidential. This includes entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees and certain third parties. We also enter into invention or patent assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. However, we may not enter into such agreements with all relevant parties, and these parties may not abide by the terms of their agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy or independently develop and commercially exploit aspects of our technology or obtain and use information that we regard as proprietary.

Trademarks

We work hard to achieve a high level of quality in our operations and to provide our customers with a superior experience when interacting with us. As a consequence, our brand is very important to us, as it is a symbol of our reputation and representative of the goodwill we seek to generate with our customers. As a consequence, we have invested significant resources in protection of our trademarks.

Environmental matters

We are committed to maintaining compliance with all environmental laws applicable to our operations and products, and also realize that we need to begin to take steps to address our environmental footprint. We take our responsibility for environmental stewardship seriously and believe that we must do our part in addressing global climate change challenges. While we are early on this journey, we are committed to reducing our environmental impact. We aim to integrate sustainable business practices, energy-efficient technologies and eco-friendly products that advance our progress in reducing our carbon footprint, water consumption and waste.

We realize that our effectiveness in executing upon our environmental objectives first begins with understanding our environmental impact and carbon footprint. We engaged a third-party to complete an in-depth analysis of our 2020 and 2021 emissions, water and waste data. With this insight, we established a baseline from which to facilitate ongoing internal measuring, managing and reporting of these factors. We believe this foundation now better positions us to improve internal tracking systems, launch eco-friendly initiatives, normalize our metrics and establish science-based targets to reduce our environmental footprint over time.

Our operations require the use of hazardous materials (including biological materials) that subject us to a variety of federal, state and local environmental and safety laws and regulations. Some of these regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', business operations should contamination of the environment or individual exposure to hazardous substances occur. We cannot predict how changes in laws or new regulations will affect our business, operations or the cost of compliance.

Raw materials and suppliers

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Agena Bioscience, Inc., Illumina, Inc., Integrated DNA Technologies Incorporated, Roche Holdings Ltd., QIAGEN, Inc. and Twist Bioscience Corporation for certain laboratory reagents, as well as sequencers and other equipment and materials which we use in our laboratory operations. We are in active litigation with affiliates of QIAGEN, Inc. as described in Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this report. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers and QIAGEN, Inc. to provide the enzymes that we use in our products. Our operations could be interrupted if we encounter delays or difficulties in securing these reagents and enzymes, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our operations, including sequencers and various associated reagents and enzymes. The use of equipment or materials provided by these replacement suppliers would require us to alter our operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot be certain that we will be able to secure alternative equipment, reagents and other materials, or bring such equipment, reagents and materials on line and revalidate them without experiencing interruptions in our workflow. If we encounter delays or difficulties in securing, reconfiguring or revalidating equipment and materials, our business and reputation could be adversely affected.

Customer concentration and seasonality

We receive payment for our products and services from patients, biopharmaceutical partners, third-party payers and other business-to-business customers. As of December 31, 2021, our revenue has been primarily derived from test reports generated from our assays. See information regarding our customer concentration in Note 2, "Summary of significant accounting policies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

We have historically experienced higher revenue in our fourth quarter compared to other quarters in our fiscal year due in part to seasonal demand of our tests from patients who have met their annual insurance deductible. However, changes in our product and payer mix might cause these historical seasonal patterns to be different than future patterns of revenue or financial performance.

Human capital resources

Our people

The strength of our team and the culture in which we work is essential to our ability to achieve our broader mission. Attracting, developing and retaining exceptional employees is vitally important to us, but we also invest in creating a differentiated culture for our team that is designed to enable continuous innovation at scale. We want Invitae to be a force for good, a team that is helping make genetics and healthcare equally accessible to all.

We had approximately 3,000 employees as of December 31, 2021, of which approximately 55% are women and 45% men. Our management team is 25% women and 75% men, and our Board is 50% women and 50% men.

Our culture and mission

Our team is driven to make a difference for the patients we serve. We aim to be a highly functioning and collaborative team, well equipped to attract, acquire, onboard, develop and retain diverse talent and teams while leading culture and change management in support of business objectives. Our People & Culture business partners are embedded within leadership teams to help support our talent strategy throughout our organization.

Our total rewards philosophy

We aim to create a culture where our employees thrive and innovate at scale. We encourage an environment where employees are empowered to speak up, try new things and make decisions that push us forward. We provide employees with opportunities to grow and advance, supported by flexible work hours, flexible paid time off (uncapped, non-accrual), the ability to work remotely for many roles and the satisfaction of doing meaningful work.

We offer a competitive total rewards package, which includes base compensation, incentive compensation, equity, healthcare and insurance coverage, 401(k) (with a partial match), and a broad range of other benefits.

Our generous parental leave benefits are offered to new parents. This past year, we introduced a new health vendor to provide fertility and adoption benefits for our U.S. population as well as most of our global employees. Additionally, we have an employer-sponsored testing program, which provides employees and their covered dependents access to all of our genetic testing at no cost.

Diversity, Equity and Inclusion, or DEI

Our DEI mission is to engage, develop and retain talent from diverse backgrounds by fostering community, providing education and support, and advancing inclusive research and health equity globally. Our vision is to cultivate a place where we all belong. Today, 20% of employees are members of one or more of our nine active employee resource groups. And in attracting new employees, our hiring process has been designed to provide an equitable candidate experience, facilitate the inclusion of new perspectives, foster innovation and creativity, and leverage technology and data analytics to address gaps in representation. As of December 31, 2021, approximately 63% of our workforce was White, 18% Asian, 8% Hispanic, 5% Black or African American, 4% two or more races (not Hispanic or Latino) and 2% not self-identified based on our payroll system and individual self-identification. On our management team, 37% are people who identify as non-White and on our Board 33% so identify.

People development

We empower our employees to own their career path and seek out training programs to take them to the next level. We have invested in our training and development programs and infrastructure for our employees. Our Leadership Principles were introduced in January 2021. The ten principles capture what we have found to be critical skills and observable behaviors that best help our team deliver results. The Leadership Principles link all talent processes including hiring, talent development, differentiating performance, assessing potential, building a leadership pipeline, maintaining a strong leadership bench and succession planning.

People engagement

As part of our commitment to data-driven decision making, we conduct a monthly “Morale Survey” that asks our teammates three questions: how they feel about the company’s direction, what’s going well, and what’s not going well. We’ve been asking these questions consistently for several years so we can quickly identify trends as they emerge and inform management decision-making. We also initiated quarterly team surveys to gauge how employees feel about the effectiveness of their teams and the identification of “helpers” and “blockers” to cross functional success. Our leadership teams get feedback from these surveys regarding manager effectiveness, as well as annual updates about the health of our culture to support continuous improvement. Our surveys have the option for employees to escalate their comments to People & Culture to address and follow-up.

Health and safety

We are committed to maintaining and improving the health and safety of our employees. All employees are responsible for maintaining a safe workplace. We promote, train and ensure employees are following our protocols, rules, policies and practices and are reporting accidents, injuries and unsafe equipment, practices or conditions, in accordance with our Code of Business Conduct and Ethics and health and safety policies. In addition, we established an Enterprise Crisis Management Team that, along with the Employee Health and Safety Administrator, comprise the Steering Committee for pandemic response responsible for ensuring our COVID-19 policies and practices meet all necessary standards and regulations. Our response has evolved as the situation has evolved.

Information about our executive officers

The names of our executive officers and other corporate officers, and their ages as of March 1, 2022, are as follows:

Name	Age	Position
Sean E. George, Ph.D.	48	President, Chief Executive Officer, Director and Co-Founder
Thomas R. Brida	51	General Counsel and Secretary
Kenneth D. Knight	61	Chief Operating Officer
Robert L. Nussbaum, M.D.	72	Chief Medical Officer
Yafei (Roxi) Wen	49	Chief Financial Officer
Robert F. Werner	48	Chief Accounting Officer

Sean E. George, Ph.D. is one of our co-founders and has been our President and Chief Executive Officer since January 2017, a position he also held from January 2010 through August 2012. Dr. George also served as our President since August 2012 and he served as our Chief Operating Officer from August 2012 until January 2017. He has also served as a director since January 2010. Prior to co-founding Invitae, Dr. George served as Chief Operating Officer from 2007 to November 2009 at Navigenics, Inc., a personalized medicine company. Previously, he served as Senior Vice President of Marketing and Senior Vice President, Life Science Business at Affymetrix, Inc., a provider of life science and molecular diagnostic products, as well as Vice President, Labeling and Detection Business at Invitrogen Corporation, a provider of tools to the life sciences industry, during his tenure there from 2002 to 2007. Dr. George currently serves as a director of CM Life Sciences, Inc., a publicly traded special purpose acquisition company. Dr. George holds a B.S. in Microbiology and Molecular Genetics from the University of California Los Angeles, an M.S. in Molecular and Cellular Biology from the University of California Santa Barbara, and a Ph.D. in Molecular Genetics from the University of California Santa Cruz.

Thomas R. Brida has served as our General Counsel since January 2017. Mr. Brida also served as our Deputy General Counsel from January 2016 to January 2017. Prior to joining Invitae, he was Associate General Counsel at Bio-Rad Laboratories, a life science research and clinical diagnostics manufacturer, from January 2004 to January 2016. He holds a B.A. from Stanford University and a J.D. from the U.C. Berkeley School of Law.

Kenneth D. Knight has served as our Chief Operating Officer since June 2020. Prior to that, he most recently served as Vice President of transportation services at Amazon.com, Inc., a multinational and diversified technology company, from December 2019 to June 2020, and as Vice President of Amazon's global delivery services, fulfillment operations and human resources from April 2016 to December 2019. Prior to his time at Amazon, from 2012 to March 2016, Mr. Knight served as general manager of material handling and underground business division at Caterpillar Inc., a manufacturer of machinery and equipment. Prior to that, Mr. Knight served in various capacities at General Motors Company, a vehicle manufacturer, for 27 years, including as executive director of global manufacturing engineering and as manufacturing general manager. Mr. Knight holds a B.S. in Electrical Engineering from the Georgia Institute of Technology and a Master of Business Administration from the Massachusetts Institute of Technology.

Robert L. Nussbaum, M.D. has served as our Chief Medical Officer since August 2015. From April 2006 to August 2015, he was chief of the Division of Genomic Medicine at UCSF Health where he also held leadership roles in the Cancer Genetics and Prevention Program beginning in January 2009 and the Program in Cardiovascular Genetics beginning in July 2007. From April 2006 to August 2015, he served as a member of the UCSF Institute for Human Genetics. Prior to joining UCSF Health, Dr. Nussbaum was chief of the Genetic Disease Research Branch of the National Human Genome Research Institute, one of the National Institutes of Health, from 1994 to 2006. He is a member of the National Academy of Medicine and a fellow at the American Academy of Arts and Sciences. Dr. Nussbaum is a board-certified internist and medical geneticist who holds a B.S. in Applied Mathematics from Harvard College and an M.D. from Harvard Medical School in the Harvard-MIT joint program in Health Sciences and Technology. He completed his residency in internal medicine at Barnes-Jewish Hospital and a fellowship in medical genetics at the Baylor College of Medicine.

Yafei (Roxi) Wen has served as our Chief Financial officer since June 2021. Prior to Invitae, she served as the Chief Financial Officer at Mozilla Corporation, overseeing finance and accounting, mergers and acquisitions, business development, data and analytics, information technology and engineering operations, workplace resources and sustainability. Prior to Mozilla, Roxi served as the Chief Financial Officer at Elo Touch Solutions and General Electric Critical Power following experience driving capital market and business finance efforts at Medtronic, a leading medical technology company. Roxi is a CFA charterholder and has a Master of Business Administration from the University of Minnesota.

Robert F. Werner has served as our Chief Accounting and Principal Accounting Officer since May 2020. Prior to that, Mr. Werner served as our Corporate Controller from September 2017. Prior to joining Invitae, from February 2015 to September 2017, Mr. Werner served as Vice President of Finance and Corporate Controller of Proteus Digital Health, Inc., a digital medicine pharmaceuticals company. Prior to that, Mr. Werner served as Corporate Controller and Principal Accounting Officer of CardioDx, Inc., a molecular diagnostics company, from March 2012 to February 2015. Mr. Werner is a Certified Public Accountant in California and started his career at Ernst & Young LLP. Mr. Werner holds a Bachelor of Science in Accounting and a Master of Accountancy in Professional Accounting from Brigham Young University's Marriott School of Management.

General Information

We were incorporated in the State of Delaware on January 13, 2010 under the name Locus Development, Inc. and changed our name to Invitae Corporation in 2012.

Our principal executive offices are located at 1400 16th Street, San Francisco, California 94103, and our telephone number is (415) 374-7782. Our website address is www.invitae.com. The information contained on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K.

We make available free of charge on our website our Annual Reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission, or SEC. You may obtain a free copy of these reports in the Investor Relations section of our website, www.invitae.com. All reports that we file are also available at www.sec.gov.

ITEM 1A. Risk Factors

Risks related to our business and strategy

We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.

We have incurred substantial losses since our inception. For the years ended December 31, 2021, 2020 and 2019, our net losses were $379.0 million, $602.2 million and $242.0 million, respectively. At December 31, 2021, our accumulated deficit was $1.7 billion. We expect to continue to incur significant losses as we invest in our business. We incurred research and development expenses of $416.1 million, $240.6 million and $141.5 million and selling and marketing expenses of $225.9 million, $168.3 million and $122.2 million in 2021, 2020 and 2019, respectively. We expect these losses may increase driven by increased investments in research and development and selling and marketing as we focus on scaling our business and operations and expanding our testing capabilities. We have also experienced and may continue to experience decreases in test volume due to the impact of COVID-19. Additionally, in 2021, widespread inflationary pressures were experienced across global economies, resulting in higher costs for our raw materials, non-material costs, labor and other business costs, and significant increases in the future could adversely affect our results of operations. In addition, as a result of the integration of acquired businesses, we may be subject to unforeseen or additional expenditures, costs or liabilities, including costs and potential liabilities associated with litigation. Our prior losses and expected future losses have had and may continue to have an adverse effect on our stockholders' equity, working capital and stock price. Our failure to achieve and sustain profitability in the future would negatively affect our business, financial condition, results of operations and cash flows, and could cause the market price of our common stock to decline.

We began operations in January 2010 and commercially launched our initial assay in late November 2013. Our prospects must be considered in light of the risks and difficulties frequently encountered by companies in a similar stage of development, particularly companies in new and rapidly evolving markets such as ours. These risks include an evolving and unpredictable business model and the management of growth. To address these risks, we must, among other things, increase our customer base; continue to implement and successfully execute our business and marketing strategy; identify, acquire and successfully integrate companies, assets or technologies in areas that are complementary to our business strategy; successfully enter into other strategic collaborations or relationships; obtain access to capital on acceptable terms and effectively utilize that capital; identify, attract, hire, retain, motivate and successfully integrate additional employees; continue to expand, automate and upgrade our laboratory, technology and data systems; obtain, maintain and expand coverage and reimbursement by healthcare payers; obtain and maintain sufficient payment by partners, institutions and individuals; provide rapid test turnaround times with accurate results at low prices; provide superior customer service; and respond to competitive developments. We cannot assure you that we will be successful in addressing these risks, and the failure to do so could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.

We expect capital expenditures and operating expenses to increase over the next several years as we expand our infrastructure, commercial operations, research and development and selling and marketing activities and pursue acquisitions and integrate acquired businesses. We expect we will need to raise additional capital to finance operations prior to achieving profitability, or should we make additional acquisitions. We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. In addition, the terms of our credit agreement restrict our ability to incur certain indebtedness and issue certain equity securities. If we raise funds by issuing equity securities, dilution to our stockholders would result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings, if available, could impose significant restrictions on our operations.

The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire companies or acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to tests we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, selling and marketing initiatives, or potential acquisitions. In addition, we may have to work with a partner on one or more aspects of our tests or market development programs, which could lower the economic value of those tests or programs to our company.

We have acquired and may continue to acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, or cause us to incur debt or significant expense.

As part of our business strategy, we have pursued and expect to continue to pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. Since 2017, we have acquired numerous companies, including companies in family health genetic information services, the patient data collection and platform industry, the non-invasive prenatal screen offering industry, the genetic information industry and the use of artificial intelligence in such industry, the pharmacogenetic testing industry, the oncology industry and the infectious disease industry.

With respect to our acquired businesses and any acquisitions we may make in the future, we may not be able to integrate these businesses successfully into our existing business, and we could assume unknown or contingent liabilities. For example, if we are unable to integrate ArcherDX's technology, people and distributed products business model into our existing business, we will not realize the expected benefits of that acquisition. Any acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Furthermore, as we experienced in the past, the loss of customers, payers, partners, suppliers or key management following the completion of any acquisitions by us could harm our business. Changes in services, sources of revenue, and branding or rebranding initiatives may involve substantial costs and may not be favorably received by customers, resulting in an adverse impact on our financial results, financial condition and stock price. Integration of an acquired company or business also may require management's time and resources that otherwise would be available for ongoing development of our existing business. We may also need to divert cash from other uses to fund these integration activities and these new businesses. Ultimately, we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment, or these benefits may take longer to realize than we expected.

In connection with certain of our completed acquisitions, we have agreed to pay cash and/or stock consideration that is contingent upon the achievement of specified objectives, such as development objectives, regulatory submissions, regulatory approvals and revenue related to certain products. As of the date of the applicable acquisition, we record a contingent liability representing the estimated fair value of the contingent consideration we expect to pay. On a quarterly basis, we reassess these obligations and, in the event our estimate of the fair value of the contingent consideration changes, we record increases or decreases in the fair value as an adjustment to operating expense, which could have a material impact on our results of operations. As of December 31, 2021, we accrued $1.9 million of contingent consideration, which is related to our acquisition of Genelex.

To finance any acquisitions or investments, we may raise additional funds, which could adversely affect our existing stockholders and our business. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. In addition, our stockholders may experience substantial dilution as a result of additional securities we may issue for acquisitions. Open market sales of substantial amounts of our common stock issued to stockholders of companies we acquire could also depress our stock price. Additional funds may not be available on terms that are favorable to us, or at all.

We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.

Our performance, including our research and development programs and laboratory operations, largely depend on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization, including software developers, geneticists, biostatisticians, certified laboratory scientists and other scientific and technical personnel to process and interpret our genetic tests. In addition, we may need to continue to expand our sales force with qualified and experienced personnel. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future due to the competition for qualified personnel among life science and technology businesses as well as universities and public and private research institutions, particularly in the San Francisco Bay Area. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees. If the value of our common stock declines significantly, as it has in the recent past, and remains depressed, or if we do not have enough shares authorized to grant equity awards to new and existing employees, it may prevent us from recruiting and retaining qualified employees. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to scale our business and support our research and development efforts and our clinical laboratory. We believe that our corporate culture fosters innovation, creativity and teamwork. However, as our organization grows, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

We need to scale our infrastructure in advance of demand for our tests and other products and services, and our failure to generate sufficient demand for our products and services would have a negative impact on our business and our ability to attain profitability.

Our success depends in large part on our ability to extend our market position, to develop new products and services, to provide customers with high-quality test reports quickly and at a lower price than our competitors, and to achieve sufficient test volume to realize economies of scale. In order to execute our business model, we intend to continue to invest heavily in order to significantly scale our infrastructure, including our testing capacity and information systems, expand our commercial operations, customer service, billing and systems processes and enhance our internal quality assurance program. We expect that much of this growth will be in advance of demand for our tests and other products and services. Our current and future expense levels are to a large extent fixed and are largely based on our investment plans and our estimates of future revenue. Because the timing and amount of revenue from our products and services is difficult to forecast, when revenue does not meet our expectations, we may not be able to adjust our spending promptly or reduce our spending to levels commensurate with our revenue. Even if we are able to successfully scale our infrastructure and operations, we cannot assure you that demand for our products and services will increase at levels consistent with the growth of our infrastructure. If we fail to generate demand commensurate with this growth or if we fail to scale our infrastructure sufficiently in advance of demand to successfully meet such demand, our business, prospects, financial condition and results of operations could be adversely affected.

We face risks related to health epidemics, including the ongoing COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

Our business has been and could continue to be adversely affected by a widespread outbreak of contagious disease, including the pandemic of respiratory illness caused by a novel coronavirus known as COVID-19. Global health concerns relating to COVID-19 have negatively affected the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty.

The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. For example, some of our personnel located at our headquarters and other offices in California, elsewhere in the United States and in other countries, have been subject to shelter-in-place or stay-at-home orders from state and local governments. These measures have adversely impacted and may further impact our employees and operations and the operations of our customers, suppliers and business partners, and may continue to negatively impact spending patterns, payment cycles and insurance coverage levels. These measures have adversely affected and may continue to adversely affect demand for our tests. In 2020, many of our customers, including hospitals and clinics, suspended non-emergency appointments and services, which resulted in a significant decrease in our test volume. Travel bans, restrictions and border closures have also impacted our ability to ship tests to and receive samples from our customers. While some of these measures have been lifted, they may be implemented again if COVID-19 is not contained or a new surge occurs. These measures have adversely affected and may continue to adversely affect our test volume, sales activities and results of operations.

The spread of COVID-19 caused us to modify our business practices (including employee travel, mandating that all non-essential personnel work from home, temporary closures of our offices, cancellation of physical participation in sales activities, meetings, events and conferences and increasing inventories of certain supplies because we have experienced supply delays and disruptions as a result of the COVID-19 pandemic and have also had to obtain supplies from new suppliers). We may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, customers and business partners. Such actions have impacted our ability to fully integrate businesses we have acquired and may impact those we may acquire in the future. There is no certainty that such actions will be sufficient to mitigate the risks posed by the virus or otherwise be satisfactory to government authorities. If significant portions of our workforce are unable to work effectively, including due to illness, quarantines, social distancing, government actions or other restrictions in connection with COVID-19, our operations will be impacted.

The extent to which COVID-19 continues to impact our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration and spread of the pandemic, the actions to contain the virus and treat its impact, and how quickly and to what extent normal economic and operating activities can resume. COVID-19 could limit the ability of our customers, suppliers and business partners to perform, including third-party payers' ability to make timely payments to us during and following the pandemic. Some of our biopharmaceutical partners have been impacted by COVID-19, which has delayed certain programs and impacted the timing of our revenue. We have also experienced and may continue to experience a shortage of, or delays in, laboratory supplies and equipment, or a suspension of services from other laboratories or third parties. Even after COVID-19 has subsided, we may continue to experience an adverse impact to our business as a result of its global economic impact, including any recession that has occurred or may occur in the future, and loss of health insurance coverage resulting from pandemic-related job losses.

Specifically, difficult macroeconomic conditions, such as cost inflation, decreases in per capita income and level of disposable income, increased and prolonged unemployment or a decline in consumer confidence as a result of COVID-19, as well as limited or significantly reduced points of access of our tests, could have a material adverse effect on the demand for our tests. Under difficult economic conditions, consumers may seek to reduce discretionary spending by forgoing our tests. Decreased demand for our tests, particularly in the United States, has negatively affected and could continue to negatively affect our overall financial performance.

There are no comparable recent events which may provide guidance as to the effect of the spread of COVID-19, and, as a result, the ultimate impact of COVID-19 or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of COVID-19's impact on our business, our operations, or the global economy as a whole. However, the effects could have a material impact on our results of operations, and we continue to monitor the situation closely.

To the extent the COVID-19 pandemic continues to adversely affect our business and financial results, it may also have the effect of heightening many of the other risks described in this section.

If third-party payers, including managed care organizations, private health insurers and government health plans, do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.

Our ability to increase the number of billable tests and our revenue will depend on our success achieving reimbursement for our tests from third-party payers. Reimbursement by a payer may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary, cost-effective and has received prior authorization. The commercial success of our distributed products, including our therapy selection in vitro diagnostic, or IVD, products and our Personalized Cancer Monitoring product, or PCM, if approved, will depend on the extent to which our customers receive coverage and adequate reimbursement from third-party payers, including managed care organizations and government payers (e.g., Medicare and Medicaid).

Since each payer makes its own decision as to whether to establish a policy or enter into a contract to cover our tests, as well as the amount it will reimburse for a test, seeking these approvals is a time-consuming and costly process. In addition, the determination by a payer to cover and the amount it will reimburse for our tests will likely be made on an indication-by-indication basis. To date, we have obtained policy-level reimbursement approval or contractual reimbursement for some indications for our germline tests from most of the large commercial third-party payers in the United States, and the Centers for Medicare & Medicaid Services, or CMS, provides reimbursement for our multi-gene tests for hereditary breast and ovarian cancer-related disorders as well as colon cancer. We believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from third-party payers may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive and may not result in payment. In cases where there is not a contracted rate for reimbursement, there is typically a greater coinsurance or co-payment requirement from the patient, which may result in further delay or decreased likelihood of collection.

In cases where we have established reimbursement rates with third-party payers, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements often vary from payer to payer, and we have needed additional time and resources to comply with them. We have also experienced, and may continue to experience, delays in or denials of coverage if we do not adequately comply with these requirements. Our third-party payers have also requested, and in the future may request, audits of the amounts paid to us. We have been required to repay certain amounts to payers as a result of such audits, and we could be adversely affected if we are required to repay other payers for alleged overpayments due to lack of compliance with their reimbursement policies. In addition, we have experienced, and may continue to experience, delays in reimbursement when we transition to being an in-network provider with a payer.

We expect to continue to focus our resources on increasing adoption of, and expanding coverage and reimbursement for, our current tests and any future tests we may develop or acquire. If we fail to expand and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the markets in which we operate. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.

With the development of next generation sequencing, the clinical genetics market is becoming increasingly competitive, and we expect this competition to intensify in the future. We face competition from a variety of sources, including:

- dozens of relatively specialized competitors focused on genetics applied to healthcare, such as Ambry Genetics, a subsidiary of Konica Minolta Inc.; Athena Diagnostics and Blueprint Genetics, subsidiaries of Quest Diagnostics Incorporated; Baylor-Miraca Genetics Laboratories; Caris Life Sciences, Inc.; Centogene AG; Color Genomics, Inc.; Connective Tissue Gene Test LLC, a subsidiary of Health Network Laboratories, L.P.; Cooper Surgical, Inc.; Emory Genetics Laboratory, a subsidiary of Eurofins Scientific; Foundation Medicine, a subsidiary of Roche Holding AG; Fulgent Genetics, Inc.; Guardant Health, Inc.; Integrated Genetics, Sequenom Inc., Correlagen Diagnostics, Inc., and MNG Laboratories, subsidiaries of Laboratory Corporation of America Holdings; Myriad Genetics, Inc.; Natera, Inc.; Perkin Elmer, Inc.; and Sema4 Genomics; as well as other commercial and academic labs;
- a few large, established general testing companies with large market share and significant channel power, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated;
- a large number of clinical laboratories in an academic or healthcare provider setting that perform clinical genetic testing on behalf of their affiliated institutions and often sell and market more broadly; and
- a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness including Illumina, Inc., which is also one of our suppliers.

Hospitals, academic medical centers and eventually physician practice groups and individual clinicians may also seek to perform at their own facilities the type of genetic testing we would otherwise perform for them. In this regard, continued development of equipment, reagents, and other materials as well as databases and interpretation services may enable broader direct participation in genetic testing and analysis.

Participants in closely related markets such as clinical trial or companion diagnostic testing could converge on offerings that are competitive with the type of tests we perform. Instances where potential competitors are aligned with key suppliers or are themselves suppliers could provide such potential competitors with significant advantages.

In addition, the biotechnology and genetic testing fields are intensely competitive both in terms of service and price, and continue to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition.

We also face competition as a result of our 2020 acquisition of ArcherDX and our 2021 acquisition of Ciitizen. In particular, ArcherDX competes with numerous companies in the life sciences research, clinical diagnostics and drug development spaces, including, among others, Natera, QIAGEN N.V., Guardant Health, Inc., Thermo Fisher, Inc., Foundation Medicine, Caris Life Sciences, Inc., Tempus, Laboratory Corporation of America, Quest Diagnostics, Inc., NeoGenomics, Inc., BioReference Laboratories, Inc. and Illumina, Inc. Ciitizen competes with companies in the patient data platform business, including, among others, Picnic Health, All Stripes, Seqster, Apple, Flatiron Health, and Tempus.

We believe the principal competitive factors in our market are:

- breadth and depth of content;
- quality;
- reliability;

- accessibility of results;
- turnaround time of testing results;
- price and quality of tests;
- coverage and reimbursement arrangements with third-party payers;
- convenience of testing;
- brand recognition of test provider;
- additional value-added services and informatics tools;
- client service; and
- quality of website content.

Many of our competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration, higher margins on their tests, substantially greater financial, technological and research and development resources, selling and marketing capabilities, lobbying efforts, and more experience dealing with third-party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests than we do, sell their tests at prices designed to win significant levels of market share, or obtain reimbursement from more third-party payers and at higher prices than we do. We may not be able to compete effectively against these organizations. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payers are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies as use of next generation sequencing for clinical diagnosis and preventative care increases. Certain of our competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing policies and devote substantially more resources to website and systems development than we can. In the past, our competitors have been successful in recruiting our employees and may continue to recruit qualified employees from us. In addition, companies or governments that control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. Some of our competitors have obtained approval or clearance for certain of their tests from the U.S. Food and Drug Administration, or FDA. If payers decide to reimburse only for tests that are FDA-approved or FDA-cleared, or if they are more likely to reimburse for such tests, we may not be able to compete effectively unless we obtain similar approval or clearance for our tests. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.

Our expected future growth could create a strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, technology services, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand as it grows. We may need to continue expanding our sales force to facilitate our growth, and we may have difficulties locating, recruiting, training and retaining sales personnel. Our ability to manage our growth effectively will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. As we grow, any failure of our controls or interruption of our production facilities or systems could have a negative impact on our business and financial operations. We plan to implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain, and failure to complete these activities in a timely and efficient manner could adversely affect our operations. Future growth in our business could also make it difficult for us to maintain our corporate culture. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

The market for patient data software is competitive, and our business will be adversely affected if we are unable to successfully compete.

The market for patient data software is competitive. Other than product innovation and access to healthcare data, there are no substantial barriers to entry in this market, and established or new entities may enter this market in the future. While software internally developed by enterprises represents indirect competition, we also compete directly with packaged application software vendors. In addition, we face actual or potential competition from larger companies such as Apple, and similar companies that may attempt to sell customer engagement software to their installed base.

We believe competition will continue to be substantial as current competitors increase the sophistication of their offerings and as new participants enter the market. Many of our current and potential competitors have longer operating histories, larger customer bases, broader brand recognition, and significantly greater financial, marketing and other resources. With more established and better-financed competitors, these companies may be able to undertake more extensive marketing campaigns, adopt more aggressive pricing policies, and make more attractive offers to businesses to induce them to use their products or services. If we are unable to compete successfully, our business will be adversely affected.

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

In the ordinary course of our business, we collect and store sensitive data, including protected health information, or PHI, personally identifiable information, genetic information, credit card information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payers and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based systems. We also communicate PHI and other sensitive patient data through our various customer tools and platforms. In addition to storing and transmitting sensitive data that is subject to multiple legal protections, these applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure, inappropriate modification, and the risk of our being unable to adequately monitor and modify our controls over our critical information. Any technical problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions to our business and operations or exposure to security vulnerabilities. These types of problems may be caused by a variety of factors, including infrastructure changes, intentional or accidental human actions or omissions, software errors, malware, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. In addition, there has recently been a significant increase in ransomware attacks, which could result in substantial harm to internal systems necessary for running our critical operations and revenue generating services.

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 what we believe to be reasonable and appropriate measures, including a formal, dedicated enterprise security program, to protect sensitive information from various compromises (including unauthorized access, disclosure, or modification or lack of availability), our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. For example, we have been subject to phishing incidents in the past, and we may experience additional incidents in the future. Any such breach or interruption could compromise our networks, and the information stored therein could be accessed by unauthorized parties, altered, publicly disclosed, lost or stolen. Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business) and damage our reputation, any of which could adversely affect our business.

In addition to data security risks, we also face privacy risks. Should we actually violate, or be perceived to have violated, any privacy promises we make to patients or consumers, we could be subject to a complaint from an affected individual or interested privacy regulator, such as the FTC, a state Attorney General, an EU Member State Data Protection Authority, or a data protection authority in another international jurisdiction. This risk is heightened given the sensitivity of the data we collect.

Any security compromise that causes an apparent privacy violation could also result in legal claims or proceedings; liability under federal, state, foreign, or multinational laws that regulate the privacy, security, or breach of personal information, such as but not limited to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, state data security and data breach notification laws, the European Union's General Data Protection Regulation, or

GDPR, and the UK Data Protection Act of 2018; and related regulatory penalties. Penalties for failure to comply with a requirement of HIPAA or HITECH vary significantly, and, depending on the knowledge and culpability of the HIPAA-regulated entity, may include civil monetary penalties of up to $1.5 million per calendar year for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $50,000 and up to one-year 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. Penalties for unfair or deceptive acts or practices under the FTC Act or state Unfair and Deceptive Acts and Practices, or UDAP, statutes may also vary significantly.

There has been unprecedented activity in the development of data protection regulation around the world. As a result, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. The GDPR took effect on May 25, 2018. The GDPR applies to any entity established in the EU as well as extraterritorially to any entity outside the EU that offers goods or services to, or monitors the behavior of, individuals who are located in the EU. The GDPR imposes strict requirements on controllers and processors of personal data, including enhanced protections for "special categories" of personal data, which includes sensitive information such as health and genetic information of data subjects. The GDPR also grants individuals various rights in relation to their personal data, including the rights of access, rectification, objection to certain processing and deletion. The GDPR provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR or the related national data protection laws of the member states of the EU, which may deviate from or be more restrictive than the GDPR, may result in significant administrative fines issued by EU regulators. Maximum penalties for violations of the GDPR are capped at 20M euros or 4% of an organization's annual global revenue, whichever is greater.

Additionally, the implementation of GDPR has led other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, on June 28, 2018, California adopted the California Consumer Privacy Act of 2018, or the CCPA. The CCPA regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of consumers who reside in California. Among other things, the CCPA confers to California consumers the right to receive notice of the categories of personal information that will be collected by a business, how the business will use and share the personal information, and the third parties who will receive the personal information; the CCPA also confers rights to access, delete, or transfer personal information; and the right to receive equal service and pricing from a business after exercising a consumer right granted by the CCPA. In addition, the CCPA allows California consumers the right to opt out of the "sale" of their personal information, which the CCPA defines broadly as any disclosure of personal information to a third party in exchange for monetary or other valuable consideration. The CCPA also requires a business to implement reasonable security procedures to safeguard personal information against unauthorized access, use, or disclosure. California amended the law in September 2018 to exempt all PHI collected by certain parties subject to HIPAA, and further amended the law in September 2020 to clarify that de-identified data as defined under HIPAA will also be exempt from the CCPA. The California Attorney General's final regulations implementing the CCPA took effect on August 14, 2020. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches resulting from a business's failure to implement and maintain reasonable data security procedures that is expected to increase data breach litigation.

In addition, California voters recently approved the California Privacy Rights Act of 2020, or CPRA, that is scheduled to go into effect on January 1, 2023. The CPRA would, among other things, amend the CCPA to give California residents the ability to limit the use of their sensitive information, provide for penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the law. Virginia and Colorado have recently enacted similar privacy acts, and other jurisdictions in the United States are beginning to propose laws similar to the CCPA. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business, results of operations, and financial condition.

It is possible the GDPR, CCPA and other emerging United States and international data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy laws and regulations may differ from country to country and state to state, and our obligations under these laws and regulations vary based on the nature of our activities in the particular jurisdiction, such as whether we collect samples from individuals in the local jurisdiction, perform testing in the local jurisdiction, or process personal information regarding employees or other individuals in the local jurisdiction. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. We can provide no assurance that we are or will remain in compliance with diverse privacy and data security requirements in all of the jurisdictions in which we do business. Failure to comply with privacy and data security requirements could result in a variety of consequences, including civil or criminal penalties, litigation, or damage to our reputation, any of which could have a material adverse effect on our business.

If we are not able to continue to generate substantial demand of our tests, our commercial success will be negatively affected.

Our business model assumes that we will be able to generate significant test volume, and we may not succeed in continuing to drive adoption of our tests to achieve sufficient volumes. Inasmuch as detailed genetic data from broad-based testing panels such as our tests have only recently become available at relatively affordable prices, the continued pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic testing that is specific to one or a few genes. Given the substantial amount of additional information available from a broad-based testing panel such as ours, there may be distrust as to the reliability of such information when compared with more limited and focused genetic tests. To generate further demand for our tests, we will need to continue to make clinicians aware of the benefits of our tests, including the price, the breadth of our testing options, and the benefits of having additional genetic data available from which to make treatment decisions. A lack of or delay in clinical acceptance of broad-based panels such as our tests would negatively impact sales and market acceptance of our tests and limit our revenue growth and potential profitability. Genetic testing can be expensive and many potential customers may be sensitive to pricing. In addition, potential customers may not adopt our tests if adequate reimbursement is not available, or if we are not able to maintain low prices relative to our competitors. Also, we may not be successful in increasing demand for our tests through our direct channel, in which we facilitate the ordering of our genetic tests by consumers through an online network of physicians.

If we are not able to generate demand for our tests at sufficient volume, or if it takes significantly more time to generate this demand than we anticipate, our business, prospects, financial condition and results of operations could be materially harmed.

We have devoted a portion of our resources to the development and commercialization of our therapy selection IVDs and to research and development activities related to our PCM product for cancer monitoring, including clinical and regulatory initiatives to obtain diagnostic clearance and marketing approval. The demand for these regulated products is unproven, and we may not be successful in achieving market awareness and demand for these products through our sales and marketing operations.

If our therapy selection IVDs and PCM products and related services do not perform as expected, we may not realize the expected benefits of our acquisition of ArcherDX.

The success of our therapy selection IVDs and PCM products depends on the market’s confidence that we can provide reliable products that enable high quality diagnostic testing with high sensitivity and specificity and short turnaround times. There is no guarantee that the accuracy and reproducibility we demonstrated in the research use only, or RUO, market will continue as we launch commercial IVD products and our product deliveries increase and product portfolio expands.

Our RUO products, therapy selection IVDs and PCM products and related services use a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. An operational, technological or other failure in one of these complex processes or fluctuations in external variables may result in sensitivity or specificity rates that are lower than we anticipate or result in longer than expected turnaround times. In addition, laboratories are required to validate their processes before using these products for clinical purposes. These validations are outside of our control. If our products do not perform, or are perceived to not have performed, as expected or favorably to competitive products, our consolidated operating results, reputation, and business will suffer, and we may also be subject to legal claims arising from product limitations, errors, or inaccuracies.

In addition, we plan to match our test reports for therapy selection IVDs to identified mutations with FDA-approved targeted therapies or relevant clinical trials of targeted therapies. If a patient or physician who orders a test using one of our products is unable to obtain, or be reimbursed for the use of, targeted therapies because they are not indicated in the FDA-approved label for treatment, the patient is unable to enroll in an identified clinical trial due to the enrollment criteria of the trial, or some other reason, the ordering physician may conclude the test report does not contain actionable information. If physicians do not believe our products consistently generate actionable information about their patients' disease or condition, they may be less likely to use our products. Any of the foregoing could have a material adverse effect on our ability to realize the intended benefits of our acquisition of ArcherDX.

Furthermore, we cannot provide assurance that customers will always use these products in the manner in which intended. Any intentional or unintentional misuse of these products by customers could lead to substantial civil and criminal monetary and non-monetary penalties, and could result in significant legal and investigatory fees.

The future growth of our distributed products business is partially dependent upon regulatory approval and market acceptance of our IVD products.

We anticipate that the future success of our distributed products business will depend in large part on our ability to effectively introduce enhanced or new offerings of IVD products. The development and launch of enhanced or new products and services, whether RUO or IVD, require the completion of certain clinical development and commercialization activities that are complex, costly, time-intensive and uncertain, and require us to accurately anticipate patients', providers' and, if applicable, payers' attitudes and needs and emerging technology and industry trends. This process is conducted in various stages, and each stage presents the risk that we will not achieve its goals on a timely basis, or at all.

We have limited experience commercializing IVD products. We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new products or new services and result in increased costs and the diversion of management's attention and resources from other business matters.

An important factor in our ability to commercialize our distributed products is collecting data that supports their value proposition. The data collected from any studies we complete may not be favorable or consistent with its existing data or may not be statistically significant or compelling to the medical community or to third-party payers seeking such data for purposes of determining coverage for these products. This is particularly true with respect to service defects and errors. Any of the foregoing could have a negative impact on our ability to commercialize our future products, which could have a material adverse effect on the growth of our business and our results of operations.

Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.

Our success depends on our ability to provide reliable, high-quality tests that incorporate rapidly evolving information about the role of genes and gene variants in disease and clinically relevant outcomes associated with those variants. Errors, such as failure to detect genomic variants with high accuracy, or mistakes, such as failure to identify, or incompletely or incorrectly identifying, gene variants or their significance, could have a significant adverse impact on our business.

Hundreds of genes can be implicated in some disorders, and overlapping networks of genes and symptoms can be implicated in multiple conditions. As a result, a substantial amount of judgment is required in order to interpret testing results for an individual patient and to develop an appropriate patient report. We classify variants in accordance with published guidelines as benign, likely benign, variants of uncertain significance, likely pathogenic or pathogenic, and these guidelines are subject to change. In addition, it is our practice to offer support to clinicians and geneticists ordering our tests regarding which genes or panels to order as well as interpretation of genetic variants. We also rely on clinicians to interpret what we report and to incorporate specific information about an individual patient into the physician's treatment decision.

The marketing, sale and use of our genetic tests could subject us to liability for errors in, misunderstandings of, or inappropriate reliance on, information we provide to clinicians, geneticists or patients, and lead to claims against us if someone were to allege that a test failed to perform as it was designed, if we failed to correctly interpret the test results, if we failed to update the test results due to a reclassification of the variants according to new published guidelines, or if the ordering physician were to misinterpret test results or improperly rely on them when making a clinical decision. In addition, our entry into the reproductive health and pharmacogenetic testing markets expose us to increased liability. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain liability insurance, including for errors and omissions, we cannot assure you that such insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any liability claim, including an errors and omissions 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 liability lawsuit could cause injury to our reputation or cause us to suspend sales of our tests. The occurrence of any of these events could have an adverse effect on our reputation and results of operations.

Our industry is subject to rapidly changing technology and new and increasing amounts of scientific data related to genes and genetic variants and their role in disease. Our failure to develop tests to keep pace with these changes could make us obsolete.

In recent years, there have been numerous advances in methods used to analyze very large amounts of genomic information and the role of genetics and gene variants in disease and treatment therapies. Our industry has and will continue to be characterized by rapid technological change, increasingly larger amounts of data, frequent new testing service introductions and evolving industry standards, all of which could make our tests obsolete. Our future success will also depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. Our tests could become obsolete and our business adversely affected unless we continually update our offerings to reflect new scientific knowledge about genes and genetic variations and their role in diseases and treatment therapies.

Our success will depend in part on our ability to generate sales using our internal sales team and through alternative marketing strategies.

We may not be able to market or sell our current tests and any future tests we may develop or acquire effectively enough to drive demand sufficient to support our planned growth. We currently sell our tests primarily through our internal sales force. Historically, our sales efforts have been focused primarily on hereditary cancer and more recently on reproductive health. Our efforts to sell our tests to clinicians and patients outside of oncology may not be successful, or may be difficult to do successfully without significant additional selling and marketing efforts and expense. In addition, following the acquisition of ArcherDX, our sales efforts have expanded to include distributed products sold to laboratories. In the past, we have increased our sales force each year in order to drive our growth. In addition to the efforts of our sales force, future sales will depend in large part on our ability to develop and substantially expand awareness of our company and our tests through alternative strategies including through education of key opinion leaders, through social media-related and online outreach, education and marketing efforts, and through focused channel partner strategies designed to drive demand for our tests. We also plan to continue to spend on consumer advertising in connection with our direct channel to consumers, which could be costly. We have limited experience implementing these types of marketing efforts. We may not be able to drive sufficient levels of revenue using these sales and marketing methods and strategies necessary to support our planned growth, and our failure to do so could limit our revenue and potential profitability.

We also use a limited number of distributors to assist internationally with sales, logistics, education and customer support. Sales practices utilized by our distributors that are locally acceptable may not comply with sales practices standards required under U.S. laws that apply to us, which could create additional compliance risk. If our sales and marketing efforts are not successful outside the United States, we may not achieve significant market acceptance for our tests outside the United States, which could adversely impact our business.

Impairment in the value of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition.

We record goodwill and intangible assets at fair value upon the acquisition of a business. Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired. Goodwill and indefinite-lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors that impact the fair value of our reporting unit could result in an impairment of goodwill or intangible assets and, in turn, a charge to net income. Any such charges could have a material adverse effect on our results of operations or financial condition.

We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our laboratory instruments, materials and services, and we may not be able to find replacements or immediately transition to alternative suppliers.

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Illumina, Inc., Integrated DNA Technologies Incorporated, Qiagen N.V., Roche Holdings Ltd. and Twist Bioscience Corporation for certain laboratory substances used in the chemical reactions incorporated into our processes, which we refer to as reagents, as well as sequencers and other equipment and materials which we use in our laboratory operations. We do not have short- or long-term agreements with most of our suppliers, and our suppliers could cease supplying these materials and equipment at any time, or fail to provide us with sufficient quantities of materials or materials that meet our specifications. Our laboratory operations could be interrupted if we encounter delays or difficulties in securing these reagents, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers. Any disruption in Illumina’s operations could impact our supply chain and laboratory operations as well as our ability to conduct our tests, and it could take a substantial amount of time to integrate replacement equipment into our laboratory operations.

We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier 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 our tests. We cannot assure you that we will be able to secure alternative equipment, reagents and other materials, and bring such equipment, reagents and materials online and revalidate them without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, we cannot assure you that replacement sequencers and associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations. If we encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and reagents we require for our tests, our business, financial condition, results of operations and reputation could be adversely affected.

Our planned therapy selection IVDs and PCM products are currently being developed to use only Illumina’s sequencing platform. Without access to these sequencers, we would be unable commercialize these products. In addition, any efforts to validate these distributed products on additional sequencing platforms would require significant resources, expenditures and time and attention of our management, and there is no guarantee that we would be successful in implementing any such sequencing platforms in a commercially sustainable way.

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 for significant elements of our operations, including our laboratory information management system, our bioinformatics analytical software systems, our database of information relating to genetic variations and their role in disease process and drug metabolism, our patient data platform, our clinical report optimization systems, our customer-facing web-based software, our customer reporting, and our various customer tools and platforms. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including for example, systems handling human resources, financial controls and reporting, customer relationship management, regulatory compliance and other infrastructure operations. In addition, we 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, including financial reporting.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from conducting tests, preparing and providing reports to clinicians, billing payers, processing reimbursement appeals, handling physician or patient inquiries, conducting research and development activities, and managing the administrative and financial aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and results of operations.

Technical problems have arisen, and may arise in the future, in connection with our data and systems, including those that are hosted by third-party providers, which have in the past and may in the future result in interruptions in our business and operations. These types of problems may be caused by a variety of factors, including infrastructure changes, human or software errors, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

If our laboratories or other facilities become inoperable due to disasters, health epidemics or for any other reasons, we will be unable to perform our tests and our business will be harmed.

We perform all of our tests at our production facilities in San Francisco and Irvine, California, in Golden, Colorado, in Iselin, New Jersey, and in Seattle, Washington. We also plan to open a new laboratory and production facility in Morrisville, North Carolina. Our laboratories and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use. Our laboratories may be harmed or rendered inoperable or inaccessible due to natural or man-made disasters, including earthquakes, hurricanes, flooding, fire and power outages, or by health epidemics, such as the COVID-19 pandemic, which may render it difficult or impossible for us to perform our tests for some period of time. This risk of natural disaster is especially high for us since we perform the majority of our tests at our San Francisco laboratory, which is located in an active seismic region, and we do not have a redundant facility to perform the same tests in the event our San Francisco laboratory is inoperable. The inability to perform our tests or the backlog that could develop if our laboratories are inoperable for even a short period of time may result in the loss of customers or harm our reputation. If a natural disaster were to damage one of our facilities significantly or if other events were to cause our operations to fail or be significantly curtailed, we may be unable to manufacture our products, provide our services, or develop new products. For example, we temporarily closed our office in Boulder, Colorado and our warehouse in Louisville, Colorado following the December 2021 wildfire in Boulder County, Colorado. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all. The inability to open the planned facility in North Carolina, delays in opening such facility or failure to obtain required permits, licenses, or certifications could result in increased costs and prevent us from realizing the intended benefits of the new facility.

The loss of any member or change in structure of our senior management team could adversely affect our business.

Our success depends in large part upon the skills, experience and performance of members of our executive management team and others in key leadership positions. The efforts of these persons are critical to us as we continue to develop our technologies and test processes and focus on scaling our business. If we were to lose one or more key executives, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy. All of our executives and employees are at-will, which means that either we or the executive or employee may terminate their employment at any time. We do not carry key person insurance for any of our executives or employees. In addition, we do not have a long-term retention agreement in place with our president and chief executive officer.

Development of new tests is a complex process, and we may be unable to commercialize new tests on a timely basis, or at all.

We cannot assure you that we will be able to develop and commercialize new tests on a timely basis. Before we can commercialize any new tests, we will need to expend significant funds in order to:

- conduct research and development;
- further develop and scale our laboratory processes; and
- further develop and scale our infrastructure to be able to analyze increasingly larger and more diverse amounts of data.

Our testing service development process involves risk, and development efforts may fail for many reasons, including:

- failure of any test to perform as expected;
- lack of validation or reference data; or
- failure to demonstrate utility of a test.

As we develop tests, we will have to make significant investments in development, marketing and selling resources. In addition, competitors may develop and commercialize competing tests faster than we are able to do so.

Our research and development efforts to add additional indications to our IVD products, if approved, will be hindered if we are not able to contract with third parties for access to tissue samples.

Under standard clinical practice, tumor biopsies removed from patients are preserved and stored in formalin-fixed paraffin embedded, or FFPE, format, and liquid biopsies are taken with a blood draw and stored in blood collection tubes. In order to add additional indications to our IVD products, if approved, we will need to secure access to these FFPE tumor biopsy and liquid biopsy samples, as well as information pertaining to the clinical outcomes of the patients from which they were derived for IVD development activities. Others compete with us for access to these samples. Additionally, the process of negotiating access to samples is lengthy because it typically involves numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters. We have in the past and may in the future be unable to negotiate access to tissue samples on a timely basis or on commercially reasonable terms, or at all. If we are unable to obtain access to these samples, or if other laboratories or competitors secure access to these samples before us, our ability to research, develop and commercialize future IVD products will be limited or delayed.

Ethical, legal and social concerns related to the use of genetic information could reduce demand for our tests.

Genetic testing has raised ethical, legal and social issues regarding privacy rights and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, genomic tests even if permissible. These and other ethical, legal and social concerns may limit market acceptance of our tests or reduce the potential markets for our tests, either of which could have an adverse effect on our business, financial condition or results of operations.

We rely on third-party laboratories to perform portions of our biopharmaceutical testing services.

A portion of our biopharmaceutical testing services is performed by third-party laboratories. These third-party laboratories are subject to contractual obligations to perform these services for us, but are not otherwise under our control. We therefore do not control the capacity and quality control efforts of these third-party laboratories other than through our ability to enforce contractual obligations on volume and quality systems, and have no control over such laboratories' compliance with applicable legal and regulatory requirements. We also have no control over the timeliness of such laboratories' performance of their obligations to us, and the third-party laboratories that we have contracted with have in the past had, and occasionally continue to have, issues with delivering results to us or resolving issues with us within the time frames we expected or established in our contracts with them, which sometimes results in longer than expected turnaround times for, or negatively impacts the performance of, these tests and services. In the event of any adverse developments with these third-party laboratories or their ability to perform their obligations in a timely manner and in accordance with the standards that we and our customers expect, our ability to service customers may be delayed, interrupted or otherwise adversely affected, which could result in a loss of customers and harm to our reputation. Furthermore, when these issues arise, we have had to expend time, management's attention and other resources to address and remedy such issues.

We may not have sufficient alternative backup if one or more of the third-party laboratories that we contract with are unable to satisfy their obligations to us with sufficient performance, quality and timeliness. Any natural or other disaster, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at one or more of these third-party laboratories' facilities that causes a loss of capacity would heighten the risks that we face. Changes to or termination of agreements or inability to renew agreements with these third-party laboratories or enter into new agreements with other laboratories that are able to perform such portions of our service offerings could impair, delay or suspend our efforts to market and sell these services.

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

Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the use of our tests in various countries;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- logistics and regulations associated with shipping samples, including infrastructure conditions, customs and transportation delays;
- limits on our ability to penetrate international markets if we do not to conduct our tests locally;
- natural disasters and outbreaks of disease, including the ongoing COVID-19 pandemic;
- political and economic instability, including wars such as the current conflict in Ukraine, terrorism and political unrest, boycotts, curtailment of trade, government sanctions and other business restrictions;
- inflationary pressures, such as those the global market is currently experiencing, which have and may increase costs for materials, supplies, and services; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

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

In addition, applicable export or import laws and regulations such as prohibitions on the export of samples imposed by countries outside of the United States, or international privacy or data restrictions that are different or more stringent than those of the United States, may require that we build additional laboratories or engage in joint ventures or other business partnerships in order to offer our tests internationally in the future. Any such restrictions would impair our ability to offer our tests in such countries and could have an adverse effect on our business, financial condition and results of operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

At December 31, 2021, our total gross deferred tax assets were $640.5 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, our net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets are primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Furthermore, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Some of our prior acquisitions have resulted in an ownership change, and we may experience ownership changes in the future. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with completed acquisitions, or other future transactions in our stock, our ability to utilize NOLs and tax credit carryovers could be further limited by Section 382 of the Internal Revenue Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss and tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. In addition, the Tax Cuts and Jobs Act limits the deduction for NOLs to 80% of current year taxable income and eliminates NOL carrybacks. Also, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks related to government regulation

If the FDA regulates the tests we currently offer as LDTs as medical devices, we could incur substantial costs and our business, financial condition and results of operations could be adversely affected.

We provide many of our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by CLIA, and state law, respectively).

Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality system regulations, premarket clearance or premarket approval, and post-market controls). See Part I, Item 1. under the heading "Federal oversight of laboratory developed tests" for a description of applicable federal regulations, which is incorporated by reference herein.

If the FDA ultimately regulates certain LDTs, whether via final guidance, final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements can be expensive, time-consuming and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's requirements to our tests could materially and adversely affect our business, financial condition and results of operations.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

In addition, in November 2013, the FDA issued final guidance regarding the distribution of products labeled for research use only. Certain of the reagents and other products we use in our tests are labeled as research use only products. Certain of our suppliers may cease selling research use only products to us and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

If we are unable to transition to the new European Union IVDR regulations, we could lose the ability to serve the European market.

The European Union transitions to a new regulation for in vitro diagnostic devices in May 2022, the In Vitro Diagnostic Regulation, or IVDR, which changes the regulatory status of a substantial number of IVDs. The percentage of devices requiring approval from a notified body is estimated to be shifting from 15% of devices under the current directive to between 70% and 90% of devices under the new regulation. Notified bodies must themselves be certified to the new regulation, and few have as of 2022. Consequently, notified bodies may have little or no capacity for new clients. LDTs are newly considered IVDs and subject to the IVDR, requiring approval from a notified body to be marketed. An amendment to the IVDR was adopted in December 2021, coming into force January 28, 2022, that extends the transition period for some provisions of the IVDR between one and six years. However, if we are unable to obtain a Conformitè Europëenne ("CE") Mark on our products under the European Directive 98/79/EC, or IVDD, before May 2022 or implement the provisions of the IVDR that have not been delayed, we will not be able to take advantage of the extension. Moreover, any significant changes to one of our tests after May 2022 may cause it to be subject to the new regulations. If we are unable to secure a notified body or complete registration in time for implementation of the new regulation, our existing tests cannot be marketed in Europe.

If we fail to comply with federal, state and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers, for our tests. We have current CLIA certifications to conduct our tests at our laboratories in California, Colorado, New Jersey, and Washington. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories.

We are also required to maintain in-state licenses to conduct testing in California, New Jersey and Washington. California, New Jersey and Washington laws establish standards for day-to-day operation of our clinical reference laboratories in those states, which include the training and skills required of personnel and quality control. Our Colorado laboratory is not required to maintain a state clinical laboratory license.

Several states require the licensure of out-of-state laboratories that accept specimens from those states. All our laboratories hold the required state laboratory licenses for California, Maryland, Pennsylvania, and Rhode Island, and all our laboratories, with the exception of Colorado, hold a New York State permit.

In addition to having laboratory licenses in New York, our clinical reference laboratories are approved on test-specific bases for the tests they run as LDTs by the New York State Department of Health, or NYDOH, for tests offered to patients in New York. Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of samples necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays.

In order to eventually market certain 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. For example, the performance characteristics of certain of our products and services may need to be validated separately in specific ethnic and genetic populations. 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 certain 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. 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.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, cancellation of the laboratory’s approval to receive Medicare and Medicaid payment for its services, exclusion from some healthcare systems' programs, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certifications, a state or foreign license, or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

The College of American Pathologists, or CAP, maintains a clinical laboratory accreditation program. CAP asserts that its program is “designed to go well beyond regulatory compliance” and helps laboratories achieve the highest standards of excellence to positively impact patient care. While not required to operate a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. We have CAP accreditations for our laboratories. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

We may not be able to obtain regulatory clearance or approval of our IVD products, or even if approved, such products may not be approved for guideline inclusion, which could adversely affect our ability to realize the intended benefits of our acquisition of ArcherDX.

A significant portion of our therapy selection and personalized cancer monitoring commercial strategy, including for PCM, relies on receiving regulatory approvals with guideline inclusion to strengthen our position in establishing coverage and reimbursement of our IVD products with both public and private payers. If we do not receive such regulatory approvals in a timely manner or at all, or we are not successful in obtaining such guideline inclusion, we may not be able to commercialize our IVD products. Additionally, third-party payers may be unwilling to provide sufficient coverage and reimbursement for these products necessary for hospitals and other healthcare providers to adopt our solutions as part of their oncological treatment strategy. We have also focused our efforts on the development of PCM for FDA clearance and approval as a prognostic device for predicting recurrence of a primary cancer after initial treatment, which can include surgery alone or surgery plus adjuvant therapy.

Moreover, development of the data necessary to obtain regulatory clearance and/or approval of an IVD is time-consuming and carries with it the risk of not yielding the desired results. The performance achieved in published studies may not be repeated in later studies that may be required to obtain FDA clearance and/or approval or regulatory approvals in foreign jurisdictions. Limited results from earlier-stage verification studies may not predict results from studies in larger numbers of subjects drawn from more diverse populations over longer periods of time. Unfavorable results from ongoing preclinical and clinical studies could result in delays, modifications or abandonment of ongoing analytical or future clinical studies, or abandonment of a product development program, or may delay, limit or prevent regulatory approvals or clearances or commercialization of our product candidates, any of which may materially impact our ability to realize the expected benefits of our acquisition of ArcherDX.

Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Our operations are subject to other extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among others:

- HIPAA, which establishes comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions;
- amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators and expand vicarious liability, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- the GDPR, which imposes strict privacy and security requirements on controllers and processors of personal data, including enhanced protections for “special categories” of personal data, including sensitive information such as health and genetic information of data subjects;
- the CCPA, which, among other things, regulates how subject businesses may collect, use, and disclose the personal information of consumers who reside in California, affords rights to consumers that they may exercise against businesses that collect their information, and requires implementation of reasonable security measures to safeguard personal information of California consumers;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual, for the furnishing of or arrangement for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering, arranging for, or recommend purchasing, leasing or ordering, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program;
- The Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and reaches beyond federal health care programs, to include private insurance;
- the federal physician self-referral law, known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity unless an exception applies, and prohibits an entity from billing for designated health services furnished pursuant to a prohibited referral;

- the federal false claims law, which 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 to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the HIPAA fraud and abuse provisions, which create new federal criminal statutes that prohibit, among other things, defrauding health care benefit programs, willfully obstructing a criminal investigation of a healthcare offense and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payer, including private insurers;
- the 21st Century Cures Act information blocking prohibition, which prohibits covered actors from engaging in certain practices that are likely to interfere with the access, exchange, or use of electronic health information;
- the Physician Payments Sunshine Act and similar state laws that require reporting of certain payments and other transfers of value made by applicable manufacturers, directly or indirectly, to or on behalf of covered recipients including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- state laws that limit or prohibit the provision of certain payments and other transfers of value to certain covered healthcare providers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing clinicians for testing that they order; waiving coinsurance, copayments, deductibles and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payers; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

We have adopted policies and procedures designed to comply with these laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance may also be subject to governmental review. The growth of our business and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. We recently received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting that we produce certain documents regarding our sponsored testing programs. We are in the process of responding to the subpoena and are cooperating fully with the investigation. Although we remain committed to compliance with all applicable laws and regulations, we cannot predict the outcome of this investigation or any other requests or investigations that may arise in the future regarding these or other subject matters. Any action brought against us for violation of the above-referenced or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from participation in Federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Healthcare policy changes, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition, results of operations and cash flows.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Policy changes or implementation of new health care legislation could result in significant changes to health care systems. In the United States, this could include potential modification or repeal of all or parts of the Affordable Care Act.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, as amended, and its implementing regulations, clinical laboratories must report to CMS private payer rates beginning in 2017, and then in 2023 and every three years thereafter for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests and every year for advanced diagnostic laboratory tests.

We have not sought "advanced diagnostic laboratory test" status for our tests, but in the event that we seek designation for one or more of our tests as an advanced diagnostic laboratory test and the tests are determined by CMS to meet these criteria or new criteria developed by CMS, we would be required to report private payer data for those tests annually. Otherwise, we will be required to report private payer rates for our tests on an every three years basis starting in 2023. Laboratories that fail to timely report the required payment information may be subject to substantial civil money penalties.

See Part I, Item 1. under the heading "Reimbursement" for a description of how public and private payors pay for our products and services, which is incorporated by reference herein. Changes in these payments and the methodologies used to determine payment amounts could have a significant impact on our financial condition, results of operations and cash flows.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. For instance, the payment reductions imposed by the Affordable Care Act and the expansion of the federal and state governments' role in the U.S. healthcare industry as well as changes to the reimbursement amounts paid by payers for our tests and future tests or our medical procedure volumes may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Notably, Congress enacted legislation in 2017 that eliminated the Affordable Care Act's “individual mandate” beginning in 2019, which may significantly impact the number of covered lives participating in exchange plans. Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the clinical laboratory fee schedule, which would increase our billing and collecting costs and decrease our revenue. Further, it is possible that additional governmental action be taken in response to the COVID-19 pandemic.

If we use hazardous materials in a manner that causes injury, we could be liable for resulting damages.

Our activities currently require the use of hazardous chemicals and biological material. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. In 2018, we decommissioned our laboratory in Massachusetts; however, we could be held liable for any damages resulting from our prior use of hazardous chemicals and biological materials at this facility. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

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

We are 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. We are increasing our direct sales and operations personnel outside the United States, in which we have limited experience. We use a limited number of independent distributors to sell our tests internationally, which requires a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

Risks related to our intellectual property

One of our competitors has alleged that our Anchored Multiplex PCR, or AMP, chemistry and products using AMP are infringing on its intellectual property, and we may be required to redesign the technology, obtain a license, cease using the AMP chemistry altogether and/or pay significant damages, among other consequences, any of which would have a material adverse effect on our business as well as our financial condition and results of operations, and the intended benefits of our acquisition of ArcherDX.

ArcherDX's AMP chemistry underlies all of its RUO products and is also the foundation of our therapy selection IVDs and PCM. One of ArcherDX's competitors, Natera, Inc., or Natera, has filed complaints against ArcherDX, Invitae and Genosity alleging that our products using AMP chemistry, and the manufacture, use, sale, and offer for sale of such products, infringe certain patents. A description of this ongoing litigation is provided in Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

If any of our products or our use of AMP chemistry is found to infringe any of Natera's patents, we could be required to redesign our technology or obtain a license from Natera to continue developing, manufacturing, marketing, selling and commercializing AMP and related products. However, we may not be successful in the redesign of its technology or able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving Natera and other third parties the right to use the same technologies licensed to us, and Natera could require us to make substantial licensing, royalty and other payments. We also could be forced, including by court order, to permanently cease developing, manufacturing, marketing and commercializing our products that are found to be infringing. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed Natera's asserted patents. Even if we were ultimately to prevail, litigation with Natera could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We cannot reasonably estimate the final outcome, including any potential liability or any range of potential future charges associated with these litigations. However, any finding of infringement by us of Natera's asserted patents could have a material adverse effect on our business and the benefits we expected to achieve through our acquisition of ArcherDX, as well as our financial condition and results of operations.

Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation will require us to spend significant time and money, and could in the future prevent us from selling our tests or impact our stock price.

Our commercial success will depend in part on our avoiding infringement of patents and proprietary rights of third parties, including for example the intellectual property rights of competitors. As we continue to commercialize our tests in their current or an updated form, launch different and expanded tests, and enter new markets, competitors might claim that our tests infringe or misappropriate their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. Our activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. For example, as discussed in the preceding risk factor, we are currently engaged in litigation with a competitor of ArcherDX alleging infringement. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. We may be unaware of patents that a third party, including for example a competitor in the genetic testing market, might assert are infringed by our business. There may also be patent applications that, if issued as patents, could be asserted against us. Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales of any tests or other activities that are the subject of such suit. Defense of these claims, regardless of merit, could cause us to incur substantial expenses and be a substantial diversion of our employee resources. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our business and stock price. In the event of a successful claim of infringement against us by a third party, we may have to (1) pay substantial damages, possibly including treble damages and attorneys' fees if we are found to have willfully infringed patents; (2) obtain one or more licenses, which may not be available on commercially reasonable terms (if at all); (3) pay royalties; and/or (4) redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure, all of which could have a material adverse impact on our cash position and business and financial condition.

If licenses to third-party intellectual property rights are or become required for us to engage in our business, we may be unable to obtain them at a reasonable cost, if at all. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Moreover, we could encounter delays in the introduction of tests while we attempt to develop alternatives. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing tests, which could materially affect our ability to grow and thus adversely affect our business and financial condition.

Developments in patent law could have a negative impact on our business.

Although we view current U.S. Supreme Court precedent to be aligned with our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts (such as patient genetic data) and an understanding of that fact's implications (such as a patient's risk of disease associated with certain genetic variations) should not be patentable, it is possible that subsequent determinations by the U.S. Supreme Court or other federal courts could limit, alter or potentially overrule current law. Moreover, from time to time the U.S. Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office, or USPTO, may change the standards of patentability, and any such changes could run contrary to, or otherwise be inconsistent with, our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts and an understanding of that fact's implications should not be patentable, which could result in third parties newly claiming that our business practices infringe patents drawn from categories of patents which we currently view to be invalid as directed to unpatentable subject matter. For example, the U.S. Senate Judiciary Committee, Subcommittee on Intellectual Property held hearings in 2019 regarding a legislative proposal that would overrule current U.S. Supreme Court precedent concerning the scope of patentable subject matter. Our President and Chief Executive Officer, Sean George, appeared before this subcommittee. If such proposal were to be formulated as a bill and enacted into law, there could be an increase in third-party claims to patent rights over correlations between patient genetic data and its interpretation and such third parties may assert that our business practices infringe some of those resulting patent rights.

Our inability to effectively protect our proprietary technologies, including the confidentiality of our trade secrets, could harm our competitive position.

We currently rely upon trade secret protection and copyright, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, and to a limited extent patent protection, to protect our confidential and proprietary information. Although our competitors have utilized and are expected to continue utilizing similar methods and have aggregated and are expected to continue to aggregate similar databases of genetic testing information, our success will depend upon our ability to develop proprietary methods and databases and to defend any advantages afforded to us by such methods and databases relative to our competitors. If we do not protect our intellectual property adequately, competitors may be able to use our methods and databases and thereby erode any competitive advantages we may have.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. In this regard, we have applied, and we intend to continue applying, for patents covering such aspects of our technologies as we deem appropriate. However, we expect that potential patent coverage we may obtain will not be sufficient to prevent substantial competition. In this regard, we believe it is probable that others will independently develop similar or alternative technologies or design around those technologies for which we may obtain patent protection. In addition, any patent applications we file may be challenged and may not result in issued patents or may be invalidated or narrowed in scope after they are issued. Questions as to inventorship or ownership may also arise. Any finding that our patents or applications are unenforceable could harm our ability to prevent others from practicing the related technology, and a finding that others have inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, which would be expensive, and, if we lose, we may lose some of our intellectual property rights. Furthermore, these lawsuits may divert the attention of our management and technical personnel.

We expect to rely primarily upon trade secrets and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how or other confidential information. Among other things, we seek to protect our trade secrets and confidential information by entering into confidentiality agreements with employees and consultants. There can be no assurance that any confidentiality agreements that we have with our employees and consultants will provide meaningful protection for our trade secrets and confidential information or will provide adequate remedies in the event of unauthorized use or disclosure of such information. Accordingly, there also can be no assurance that our trade secrets will not otherwise become known or be independently developed by competitors. 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.

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

The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. 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. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or genetic testing, diagnostic or other healthcare companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. 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.

Risks related to being a public company

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the Securities and Exchange Commission, or SEC, and the New York Stock Exchange, or NYSE, impose a number of requirements on public companies, including with respect to corporate governance practices. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In addition, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, enacted in 2010, includes significant corporate governance and executive-compensation-related provisions. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. If these requirements divert the attention of our management and personnel from other aspects of our business concerns, they could have a material adverse effect on our business, financial condition and results of operations. Moreover, these rules and regulations applicable to public companies substantially increase our legal, accounting and financial compliance costs, require that we hire additional personnel and make some activities more time consuming and costly. It may also be more expensive for us to obtain director and officer liability insurance.

If we are unable to maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

We are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We have compiled the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. As we acquire companies, we will need to establish adequate controls and integrate them into our internal control system. We need to maintain and enhance these processes and controls as we grow and we have required, and may continue to require, additional personnel and resources to do so.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal controls, our management will be unable to conclude that our internal control over financial reporting is effective. Our independent registered public accounting firm is required to issue an attestation report on the effectiveness of our internal control over financial reporting every fiscal year. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective, or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Internal control deficiencies could also result in the restatement of our financial results in the future.

Risks related to our indebtedness

The terms of our credit agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In October 2020, we entered into a credit agreement with Perceptive Credit Holdings II, LP, pursuant to which we borrowed an aggregate principal amount of $135.0 million, or the 2020 Term Loan. The 2020 Term Loan is secured by a first priority lien on all of our and our subsidiaries' assets (including our intellectual property) and is guaranteed by our subsidiaries, in each case, excluding certain excluded assets and immaterial subsidiaries. If the 2020 Term Loan is prepaid, we may be required to pay a prepayment fee of up to 6% and a make-whole fee, in each case depending on when the prepayment is made. Our 2020 Term Loan bears interest at an annual rate equal to three-month London Interbank Offered Rates, or LIBOR, subject to a 2.00% LIBOR floor, plus a margin of 8.75% and is therefore sensitive to changes in interest rates. If three-month LIBOR can no longer be determined or if the applicable governmental authority ceases to supervise or sanction such rates, then we will endeavor to agree with the administrative agent, an alternate rate of interest that gives due consideration to the then prevailing market convention for determining interest for comparable loans in the United States; provided that until such alternative rate of interest is agreed, the 2020 Term Loan shall bear interest at the Wall Street Journal Prime Rate. We cannot predict what the impact of any such alternative rate would be to our interest expense. However, the discontinuation, reform, or replacement of LIBOR or any other benchmark rates may result in fluctuating interest rates that may have a negative impact on our interest expense and cash flows. Furthermore, we cannot predict or quantify the time, effort and cost required to transition to the use of new benchmark rates, including with respect to negotiating and implementing any necessary changes to the 2020 Term Loan, and implementing changes to our systems and processes.

The credit agreement restricts our ability to pursue certain mergers, acquisitions, amalgamations or consolidations, other than permitted acquisitions, that we may believe to be in our best interest. In addition, the credit agreement contains financial covenants that require us to maintain a minimum cash balance and minimum quarterly revenue levels. If we default under the credit agreement, the lender will be able to declare all obligations immediately due and payable, including prepayment fees and other obligations. The lender could declare an event of default under the credit agreement upon the occurrence of any event that it interprets as a material adverse change or material adverse effect, each as defined under the credit agreement. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

We have a large amount of debt, servicing our debt requires a significant amount of cash, and our debt service obligations may prevent us from taking actions that we would otherwise consider to be in our best interests.

In September 2019, we issued $350.0 million aggregate principal amount of our convertible senior notes due 2024 in a private placement, in October 2020 we entered into our credit agreement and borrowed $135.0 million through the 2020 Term Loan and in April 2021 we issued $1,150.0 million on aggregate principal amount of our convertible senior notes due 2028 in a private placement.

Our substantial leverage could have significant negative consequences for our future operations, including:

- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our ability to obtain additional financial for working capital, acquisitions, research and development expenditures, and general corporate purposes;
- requiring the dedication of a substantial portion of our expected cash flow or our existing cash to service our indebtedness, thereby reducing the amount of our cash available for other purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; or
- placing us at a possible competitive disadvantage compared to less leveraged competitors and competitors that have better access to capital resources.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not have the ability to raise the funds necessary to settle conversions of our convertible senior notes in cash or to repurchase the notes upon a fundamental change, and our current credit agreement contains and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the notes.

Holders of our convertible senior notes have the right to require us to repurchase all or any portion of their notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. The repurchase price for our convertible senior notes due 2028 will also include unpaid interest on those notes to the maturity date. In addition, upon conversion of the notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the notes being converted. However, we only have limited ability to make those cash payments under our credit agreement and, even if the credit agreement limitations are no longer in effect, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of notes surrendered therefor or notes being converted. In addition, our ability to repurchase the notes or to pay cash upon conversions of the notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase notes at a time when the repurchase is required by the indentures governing the notes or to pay any cash payable on future conversions of the notes as required by the indentures would constitute a default under the relevant indenture. A default under an indenture or the occurrence of the fundamental change itself could also lead to a default under our credit agreement and any agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and to repay or repurchase our convertible senior notes.

The conditional conversion feature of our convertible senior notes due 2024, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of our convertible senior notes due 2024 is triggered, holders of such notes will be entitled to convert the notes at any time during specified periods at their option. If one or more holders elect to convert their notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

General risk factors

Our stock price is volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

The trading price of our common stock is volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated fluctuations in our operating results;
- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts or changed recommendations for our stock;
- our focus on long-term goals over short-term results;
- the level of short interest in our stock, and the effect of short sellers on the price of our stock;
- the timing and magnitude of our investments in the growth of our business;
- actual or anticipated changes in regulatory oversight of our business;
- additions or departures of key management or other personnel;
- disputes or other developments related to our intellectual property or other proprietary rights, including litigation;
- changes in reimbursement by current or potential payers;
- general economic and market conditions; and
- issuances of significant amounts of our common stock.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. The closing price of our common stock on NYSE ranged from $9.68 to $53.62 between February 1, 2021 through January 31, 2022. Broad market and industry factors, including the COVID-19 pandemic, as well as general economic, political and geopolitical, and market conditions such as recessions, wars, elections, interest rate changes, or cost inflation, may seriously affect the market price of our common stock, regardless of our actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

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

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock, change their price targets, issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, the terms of our credit agreement restrict our ability to pay dividends. Any determination to pay dividends in the future will be 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. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

Anti-takeover provisions in our charter documents and under Delaware law could discourage, delay or prevent a change in control and may affect the trading price of our common stock.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 20,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, our chair of the board or our chief executive officer;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may, except as otherwise required by law, be filled only by a majority of directors then in office, even if less than a quorum; and
- require a super-majority of votes to amend certain of the above-mentioned provisions as well as to amend our bylaws generally.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. Section 203 generally prohibits us from engaging in a business combination with an interested stockholder subject to certain exceptions.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;

- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders;
- any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law; or
- any action asserting a claim against us governed by the internal affairs doctrine.

Section 27 of the Securities Exchange Act of 1934, or Exchange Act, creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision in our certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Section 22 of the Securities Act of 1933, or Securities Act, creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision in our certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Securities Act or any other claim for which the federal and state courts have concurrent jurisdiction.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of December 31, 2021, we had outstanding 228.1 million shares of our common stock, options to purchase 3.0 million shares of our common stock (of which 2.6 million were exercisable as of that date) and outstanding restricted stock units, or RSUs, representing 16.2 million shares of our common stock (which includes an estimated number of RSUs, subject to certain employees' continued service with us, or time-based RSUs, and RSUs that are performance based RSUs, or PRSUs, granted in connection with an acquisition). The foregoing does not include 10.2 million shares of common stock that may be issuable in connection with indemnification hold-backs and contingent consideration related to our acquisitions, shares that may be issuable in the future in connection with the convertible senior notes, or shares issuable pursuant to our May 2021 sales agreement with Cowen and Company, LLC under which we may offer and sell from time to time at our sole discretion up to $400 million of shares of our common stock. In addition, as of December 31, 2021, 10.2 million and 2.1 million shares of common stock are available for future issuance under our 2015 Stock Incentive Plan and Employee Stock Purchase Plan, respectively, and as of January 1, 2022, 9.1 million and 2.3 million additional shares of common stock became available for future issuance under our 2015 Stock Incentive Plan and our Employee Stock Purchase Plan, respectively. The sale or the availability for sale of a large number of shares of our common stock in the public market could cause the price of our common stock to decline.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

Our headquarters and main production facility is located in San Francisco, California, where we currently lease and occupy approximately 103,000 square feet of laboratory and office space. The lease for this facility expires in July 2026 and we may renew the lease for an additional ten years.

We also lease approximately 585,000 square feet of additional office and laboratory space domestically in California, Colorado, Massachusetts, New Jersey, New York, North Carolina and Washington, and internationally in Australia, Belgium and Israel.

We believe that our facilities are adequate for our current needs and that additional space will be available on commercially reasonable terms if required.

ITEM 3. Legal Proceedings

For a discussion of legal matters as of December 31, 2021, see Note 8, “Commitments and contingencies” in Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report, which is incorporated into this item by reference.

ITEM 4. Mine Safety Disclosure

Not applicable.

PART II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

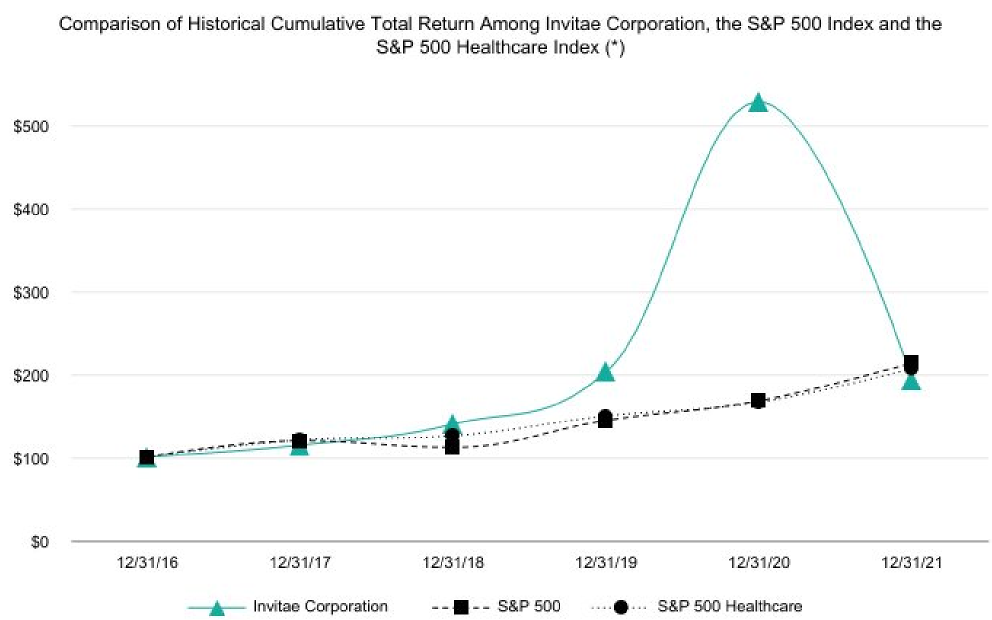
Our common stock has been publicly traded on the New York Stock Exchange under the symbol "NVTA" since February 12, 2015. Prior to that time, there was no public market for our common stock.

As of February 25, 2022, there were 297 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. In addition, the terms of the credit agreement restrict our ability to pay dividends. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements and general business conditions and other factors that our board of directors may deem relevant.

Stock performance graph

The following information shall not be deemed to be soliciting material or to be filed with the SEC, or subject to Regulations 14A or 14C under the Securities Exchange Act of 1934, or Exchange Act, or to the liabilities of Section 18 of the Exchange Act nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.



(*) The above graph shows the cumulative total stockholder return of an investment of $100 in cash on December 31, 2016 through December 31, 2021 for: (i) our common stock; (ii) the S&P 500 Index; and (iii) the S&P 500 Healthcare Index. All values assume reinvestment of the full amount of all dividends. The comparisons in the table are not intended to be forecasts or indicative of future stockholder returns.

	12/31/2016	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021
Invitae Corporation	$ 100.00	$ 114.36	$ 139.29	$ 203.15	$ 526.57	$ 192.32
S&P 500	$ 100.00	$ 119.42	$ 111.97	$ 144.31	$ 167.77	$ 212.89
S&P 500 Healthcare Index	$ 100.00	$ 120.00	$ 125.63	$ 149.10	$ 166.14	$ 206.29

ITEM 6. [Reserved]

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

The following discussion of our financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Historic results are not necessarily indicative of future results.

Business overview

We offer high-quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, cardiology, neurology, pediatrics, personalized oncology, metabolic conditions and rare diseases. To augment our offering and realize our mission, we have acquired multiple assets and businesses, which expanded our suite of genome management offerings and established a broader entry into key genomics markets. We are building a platform to harness genetics on a global scale to diagnose more patients correctly, earlier and bring therapies to market faster. Our genome management offerings will provide information services to the patient that are intended to enhance the customer experience through personalized insights, technology-enabled services and network connections that inform genetic healthcare throughout life.

In 2021, we completed the acquisitions of Reference Genomics, Inc. d/b/a One Codex, or One Codex, Genosity, Inc., or Genosity, Medneon LLC, or Medneon, Ciitizen Corporation, or Ciitizen, and Stratify Genomics Inc., or Stratify. One Codex is a data platform for applied microbial genomics. Its acquisition adds capabilities across microbiome and infectious disease testing capabilities and allows us to deliver a high-quality, low-cost, end-to-end metagenomics product (sequencing and results) and enables the development of future offerings in infectious disease, preterm birth and wellness.

Genosity is a genomics and laboratory services company offering software and laboratory solutions that enable the deployment of complex sequencing-based cancer testing. The acquisition brings Genosity's specialized capabilities onto the Invitae platform to accelerate the time to market and decentralization of Invitae's personalized oncology offerings, including somatic and germline offerings used in screening, therapy selection and personalized cancer monitoring.

The Medneon digital platform combines artificial intelligence and human insights with actionable information regarding an individual's cancer risk to inform precision prevention and management over time at the point-of-care or through telemedicine.

Ciitizen is a patient-centric consumer health tech company working to build a global platform to help patients collect, organize, store and share their medical records digitally.

Stratify is a cancer risk stratification company for the general population offering a prostate risk score product and is dedicated to advancing the knowledge of genetic predisposition to cancer and other diseases so that practitioners can screen more effectively and efficiently.

In October 2020, we completed the acquisition of ArcherDX, Inc., or ArcherDX, a genomics company democratizing precision oncology by offering a suite of products and services that are accurate, personal, actionable and easy to use in local settings, thereby empowering clinicians to control the sample, data, patient care and economics. As part of the acquisition, we agreed to pay contingent consideration based on the achievement of five post-closing development, regulatory and revenue milestones. The first milestone was achieved in November 2020, and in June 2021, three additional milestones were achieved or deemed to be achieved. The remaining milestone is based upon receiving FDA clearance or approval of a therapy selection IVD, which per the terms of the acquisition agreement, must be completed by March 31, 2022, subject to certain extensions. Based on the current development timeline, during the year ended December 31, 2021, we determined that this milestone will not be met by the required achievement date per the acquisition agreement, although we expect to receive FDA clearance or approval at a later date.

We have experienced rapid growth. For the years ended December 31, 2021, 2020 and 2019, our revenue was $460.4 million, $279.6 million and $216.8 million, respectively, and we incurred net losses of $379.0 million, $602.2 million and $242.0 million, respectively. At December 31, 2021, our accumulated deficit was $1.7 billion. To meet the demands of scaling our business, we increased our number of employees to approximately 3,000 at December 31, 2021 from approximately 2,100 at December 31, 2020. Our sales force grew to approximately 330 at December 31, 2021 from approximately 300 at December 31, 2020. We expect headcount will continue to increase as we add staff to support anticipated growth.

Sales of our tests have grown significantly. In 2021, 2020 and 2019, we generated 1,169,000, 659,000 and 469,000 billable units, respectively. We calculate volume using billable units, which are billable events that include individual test reports released and individual reactions shipped. We refer to the set of reagents needed to perform an

NGS test as a "reaction." Through December 31, 2021, approximately 57% of the billable volume generated were billable to patients, biopharmaceutical partners and other business-to-business customers (e.g., hospitals, clinics, medical centers), and the remainder were billable to government and private insurance payers. Many of the gene tests on our assays are reimbursable by health insurance companies. However, when we do not have reimbursement policies or contracts with private insurers, our claims for reimbursement may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. Even if we are successful in achieving reimbursement, we may be paid at lower rates than if we were under contract with the third-party payer. When there is not a contracted rate for reimbursement, there is typically a greater payment requirement from the patient that may result in further delay in payment for these tests.

We expect to incur operating losses for the near term as we continue to invest in our business to achieve our revenue growth objectives, including expansion of our platform to capture the broad potential of genetics across healthcare and expansion into new laboratory and production facilities, and expect we will need to raise additional capital in order to fund our operations. If we are unable to achieve these objectives and successfully manage our costs, we may not be able to achieve profitability in the near term or at all.

We believe that the keys to our future growth will be to increase billable volume, achieve broad reimbursement coverage for our tests from third-party payers and increase the amount we receive from other types of payers, advance digital health solutions and data services, drive down the price for genetic analysis and interpretation, reduce the costs associated with performing our genetic tests, steadily increase the amount of genetic content we offer, consistently improve the client experience, drive physician and patient utilization of our website for ordering and delivery of results and increase the number of strategic partners working with us to add value for our clients. We also believe that providing a unique genetic testing platform that is agnostic to stage of life or disease category will deliver unique benefits to customers, payers and other institutions that are seeking to make genetic information a standard element of healthcare decisions in the future.

Impact of COVID-19

Our daily test volumes have recovered from the low in March 2020, although the ongoing COVID-19 pandemic continues to impact our business operations and practices. While we expect it may continue to impact our business, we experienced limited disruption during 2021. We have reviewed and adjusted, when necessary, for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

In response to the pandemic, we have implemented measures to protect the health of all of our employees during this time with additional measures in place to better protect our on-site lab production and support teams. Our production facilities currently remain fully operational. While we have not experienced significant disruption in our supply chain, we have experienced supply delays as a result of the COVID-19 pandemic and have also had to obtain supplies from new suppliers. Although we do not yet know the ongoing impact COVID-19 will have on our supply chain, we have increased our inventory on hand to respond to potential future disruptions that may occur.

Many announced healthcare guidelines call for a shift of regular physician visits and healthcare delivery activities to remote/telehealth formats. This is particularly important for patients who, despite the fall-out from COVID-19, continue to be diagnosed with critical diseases, like cancer, and for women who are pregnant or are trying to conceive. We believe our investments in new access platforms and technologies has and will continue to position us well to provide a range of testing to clinicians and patients using a “clinical care from afar” model. An example is our rollout in April 2020 of our Gia telehealth platform, which expands access to remote interaction between patients and clinicians as well as direct ordering of genetic tests.

Given the unknown duration and extent of COVID-19’s impact on our business, and the healthcare system in general, we continue to monitor evolving market conditions and have pivoted our focus and investments on the commercial execution of workflows that support remote ordering, online support and telehealth. Approximately 8% of our workforce as of March 2020 was impacted by a reduction in force in April 2020 in an initiative to manage costs and cash burn, which resulted in one-time costs in the second quarter of 2020 of $3.8 million. In addition, effective May 2020, we reduced the salaries of our named executive officers by approximately 20%, which ceased as of January 2021.

In March 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was signed into law as a stimulus bill intended to bolster the economy, among other things, and provide assistance to qualifying businesses and individuals. The CARES Act included an infusion of funds into the healthcare system. In April 2020, we received $3.8 million as a part of this initiative, and in January 2021, we received an additional $2.3 million. These payments were recognized as other income, net in our consolidated statements of operations in the periods received. At this time, we are not certain of the availability, extent or impact of any future relief provided under the CARES Act.

Factors affecting our performance

Number of billable units

Our centralized test revenue is tied to the number of tests which we bill third-party payers, biopharmaceutical partners, other business-to-business customers (e.g., hospitals, clinics, medical centers), or patients. Our decentralized product revenue is based upon the number of individual reactions we ship biopharmaceutical partners and other business-to-business customers. We refer to the set of reagents needed to perform an NGS test as a "reaction," and we refer to billable events that include individual test reports released and individual reactions shipped as billable units. We typically bill for our services following delivery of the billable report derived from testing samples and interpreting the results. For units manufactured for use by customers in distributed facilities, we typically bill customers upon shipment of those units. Test orders are placed under signed requisitions or contractual agreements, as we often enter into contracts with biopharmaceutical partners, other business-to-business customers and insurance companies. We incur the expenses associated with a unit in the period in which the unit is processed regardless of when payment is received with respect to that unit. We believe the number of billable units in any period is an important indicator of the growth in our testing business, and with time, this will translate into the number of customers accessing our platform.

Number and size of research and commercial partnerships

Pharma development services revenue, which we recognize within other revenue in our consolidated statements of operations, is generated primarily from services provided to biopharmaceutical companies and other partners and is related to companion diagnostic development, clinical research, and clinical trial services across the research, development, and commercialization phases of collaborations. The result of these relationships may include the development of new targeted companion diagnostics, which underscore and expand the need for genetic testing and in some cases may lead to intellectual property and/or revenue sharing opportunities with third-party partners.

In addition to research partnerships, we also seek to grow the number of biopharmaceutical partners and other business-to-business customers for whom we provide testing technologies, analysis, supplies and expertise to institutions that provide independent testing services to customers in their respective regions.

Success obtaining and maintaining reimbursement

Our ability to increase volume and revenue will depend in part on our success achieving broad reimbursement coverage and laboratory service contracts for our tests from third-party payers and agreements with institutions and partners. Reimbursement may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary and cost-effective, as well as whether we are in contract, where we get paid more consistently and at higher rates. Because each payer makes its own decision as to whether to establish a policy or enter into a contract to reimburse for our testing services and specific tests, seeking these approvals is a time-consuming and costly process. In addition, clinicians and patients may decide not to order our tests if the cost of the test is not covered by insurance. Because we require an ordering physician to requisition a test, our revenue growth also depends on our ability to successfully promote the adoption of our testing services and expand our base of ordering clinicians. We believe that establishing coverage and obtaining contracts from third-party payers is an important factor in gaining adoption by ordering clinicians. Our arrangements for laboratory services with payers cover approximately 322 million lives, comprised of Medicare, national commercial health plans, and Medicaid in most states, including California (Medi-Cal), our home state.

Ability to lower the costs associated with performing our tests

Reducing the costs associated with performing our genetic tests is both a focus and a strategic objective of ours. Over the long term, we will need to reduce the cost of raw materials by improving the output efficiency of our assays and laboratory processes, modifying our platform-agnostic assays and laboratory processes to use materials and technologies that provide equal or greater quality at lower cost, improve how we manage our materials, port some tests onto a next generation sequencing platform and negotiate favorable terms for our materials purchases. We also intend to continue to design and implement hardware and software tools that are designed to reduce personnel-related costs for both laboratory and clinical operations/medical interpretation by increasing personnel efficiency and thus lowering labor costs per test. Finally, we plan to reduce the cost of providing test equipment and software to laboratories and other facilities in the United States and internationally. Those efforts are designed to enable more rapid expansion of genetic testing and patient access, enlarging our geographic footprint outside the United States while achieving lower costs.

Ability to expand our genetic content and create new pathways to test

We believe our focus on reducing the average cost per test will have a countervailing force — increasing the number of tests we offer, the content of each test and the means to connect our testing services with patients and physicians. We intend to continue to expand our test menus by steadily releasing additional genetic content for affordable prices, ultimately leading to affordable whole genome services. The breadth and flexibility of our offering will be a critical factor in our ability to address new markets, including internationally, for genetic testing services. Both of these, in conjunction with our continued focus on strategic partnerships, will be important to our ability to continue to grow the volume of billable tests we deliver. We have and will continue to identify new ways to connect our testing services and information to patients. These include direct patient outreach and ordering capacity, the use of automated assistants for physician customers to improve the ease of ordering and processing genetic tests and programs designed to reach underserved patient populations with genetic testing.

Investment in our business and timing of expenses

We plan to continue to invest in our genetic testing and information management business. We deploy state-of-the-art technologies in our genetic testing services, and we intend to continue to scale our infrastructure, including our testing capacity and capabilities as well as our information systems. We plan to do this through the acquisition of assets and businesses and expansion of our workforce and facilities, such as our new laboratory and production facility in North Carolina and the genomic laboratory space added through the acquisition of Genosity, which we expect to support our continued growth by significantly expanding our testing capacity. We also expect to incur software development costs as we seek to further automate our laboratory processes and our genetic interpretation and report sign-out procedures, scale our customer service capabilities to improve our customers' experience, and expand the functionality of our website. We also expect to incur costs as we seek to provide the testing equipment and software necessary to enable decentralized genetic and genomic testing in the United States and internationally. We will incur costs related to marketing and branding as we spread our initiatives beyond our current customer base and focus on providing access to customers through our website. We plan to hire additional personnel as necessary to support anticipated growth, including software engineers, sales and marketing personnel, billing personnel, research and development personnel, medical specialists, biostatisticians and geneticists. We will also incur additional costs related to the expansion of our production facilities to accommodate growth and as we expand domestically and internationally, including increased operating costs and capital expenditures related to the buildout of our new laboratory and production facility in North Carolina. In addition, we will incur ongoing expenses as a result of operating as a public company. The expenses we incur may vary significantly by quarter as we focus on building out different aspects of our business.

How we recognize revenue

We generally recognize revenue on an accrual basis, which is when a customer obtains control of the promised goods or services, typically a test report, or upon shipment of our precision oncology products. Accrual amounts recognized are based on estimates of the consideration that we expect to receive, and such estimates are adjusted and subsequently recorded until fully settled. Changes to such estimates may increase or decrease revenue recognized in future periods. Revenue from our tests may not be equal to billed amounts due to a number of factors, including differences in reimbursement rates, the amounts of patient payments, the existence of secondary payers and claim denials. Some test orders are placed under signed requisitions or contractual agreements, and we often enter into contracts with biopharmaceutical partners, other business-to-business customers and insurance companies that include pricing provisions under which such tests are billed.

Pharma development service revenues are generated primarily from custom assay design services, sample processing activities and consultative inputs, which is separate from revenue generated by any related or unrelated product component. Revenue is recognized as samples are processed or scope of work is completed based on contracted agreements with those biopharmaceutical customer companies.

Under these collaborations we also generate revenue from achievement of milestones, provision of on-going support, and related pass-through costs and fees. We generally have distinct performance obligations for development milestones related to our development of a companion diagnostic device. We use a cost plus a margin approach to estimate the standalone value of our companion diagnostic development service performance obligations. Revenue is recognized over time using input methods based on our assessments of performance completed to date toward each milestone.

Financial overview

Revenue

We primarily generate revenue from testing services and sales of distributed precision oncology products. Customers are typically billed upon delivery of test results or shipment of products. We also generate revenue from development agreements, access to data, data analytics and other related services provided for biopharmaceutical partners and other parties. Our ability to increase our revenue will depend on our ability to increase our market penetration, obtain FDA and other international regulatory authority approvals on future products and services offerings, obtain contracted reimbursement coverage from third-party payers, and grow our relationships with biopharmaceutical customers.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering our products and services and includes expenses for materials and supplies, personnel-related costs, freight, costs for lab services, genetic interpretation and clinical trial support, equipment and infrastructure expenses and allocated overhead including rent, information technology, equipment depreciation, amortization of acquired intangibles, and utilities. We expect cost of revenue to generally increase in line with the increase in billable volume, however, we expect a future increase in amortization of acquired intangible assets that is not dependent on billed volume. We anticipate our cost per unit for existing tests will generally decrease over time due to the efficiencies we expect to gain as volume increases and from automation and other cost reductions. These reductions in cost per unit will likely be offset by new offerings which often have a higher costs per unit during the introductory phases before we are able to gain efficiencies. The cost per unit may fluctuate significantly from quarter to quarter.

Operating expenses

Our operating expenses are classified into three categories: research and development, selling and marketing, and general and administrative. For each category, the largest component is generally personnel-related costs, which include salaries, employee benefit costs, bonuses, commissions, as applicable, and stock-based compensation expense.

Research and development

Research and development expenses represent costs incurred to develop our technology and future offerings. These costs are principally for process development associated with our efforts to expand the number of genes we can evaluate, our efforts to lower the costs per unit and our development of new products to expand our platform. We have and may continue to partner with other companies to develop new technologies and capabilities we expect to invest capital and incur significant operating costs to support these development efforts. In addition, we incur process development costs to further develop the software we use to operate our laboratories, analyze generated data, process customer orders, validate clinical activities, enable ease of customer ordering, deliver reports and automate our business processes. These costs consist of personnel-related costs, laboratory supplies and equipment expenses, consulting costs, amortization of acquired intangible assets, and allocated overhead including rent, information technology, equipment depreciation and utilities.

We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses to significantly increase as we continue our efforts to develop additional offerings, make investments to reduce costs, streamline our technology to provide patients access to testing, scale our business domestically and internationally and acquire and integrate new technologies. As a percentage of revenue, we expect research and development expenses to trend lower as we continue our efforts on scaling our business and operations and expanding our testing capabilities.

During October 2020 through our acquisition of ArcherDX, we recognized $512.4 million of in-process R&D technology for two assets representing a therapy selection IVD and PCM technologies, both using an income approach. We estimate these technologies to be developed in the next few years with significant development costs through completion.

Selling and marketing

Selling and marketing expenses consist of personnel-related costs, including commissions, client service expenses, advertising and marketing expenses, educational and promotional expenses, market research and analysis, and allocated overhead including rent, information technology, equipment depreciation, amortization of acquired intangibles, and utilities. We expect our selling and marketing expenses to increase as we continue to build our brand and focus on advertising our products and services. As a percentage of revenue, we expect our selling and marketing expenses to trend lower as we continue our efforts on scaling our business and operations and expanding our testing capabilities.

General and administrative

General and administrative expenses include executive, finance and accounting, billing and collections, legal and human resources functions as well as other administrative costs. These expenses include personnel-related costs; audit, accounting and legal expenses; consulting costs; allocated overhead including rent, information technology, equipment depreciation, and utilities; costs incurred in relation to our co-development agreements; and post-combination expenses incurred in relation to companies we acquire. We expect our general and administrative expenses to generally increase as we support continued growth of operations.

Change in fair value of contingent consideration

Changes in fair value of contingent consideration are adjustments to contingent consideration related to business combinations. We expect these changes to fluctuate significantly from period to period due to fair value adjustments that are dependent on many factors, including the value of our common stock and our assessment of the probability of meeting certain acquisition-related milestones within the terms of the respective acquisition agreements, including certain prescribed deadlines for achievement.

With respect to the ArcherDX final milestone, the liability was reduced to nil as of as of June 30, 2021 from $262.5 million as of March 31, 2021 from $287.7 million as of December 31, 2020, with the offsetting change recorded as changes in fair value of contingent consideration in our consolidated statements of operations. The removal of the liability balance and the associated change in fair value of contingent consideration was a result of our reassessment of the steps necessary to achieve clearance or approval based on FDA feedback received principally in the three months ended June 30, 2021. As a result of our reassessment, we do not believe achievement of the conditions will occur within the specified timeframe prescribed in the acquisition agreement. We expect FDA clearance or approval of a therapy selection IVD at a later date subject to resolution of the necessary steps.

Other income (expense), net

Other income (expense), net, primarily consists of adjustments to the fair value of our stock payable liabilities arising from business combinations, and we expect it to fluctuate significantly from period to period due to the volatility of our common stock. Other income (expense), net also includes income generated from our cash equivalents and marketable securities and amounts received under the CARES Act.

Interest expense

Interest expense is primarily attributable to interest incurred related to our debt financings and finance leases. See Note 8, “Commitments and contingencies” in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report for more details.

Income tax benefit

Since we generally establish a full valuation allowance against our deferred tax balances, our income tax benefit primarily consists of tax impacts of our deferred income tax assessments resulting from our acquisitions.

Critical accounting policies and estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. We evaluate our estimates on an ongoing basis. Our estimates are based on current facts, our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue recognition

We recognize revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers. We utilize the following practical expedients and exemptions:

- Costs to obtain or fulfill a contract are expensed when incurred because the amortization period would have been one year or less, and
- No adjustments to promised consideration were made for financing as we expect, at contract inception, that the period between the transfer of a promised good or service and when the customer pays for that good or service will be one year or less.

Test revenue

Test revenue is comprised of testing services and sales of distributed precision oncology products.

The majority of our test revenue is generated from genetic testing, in addition to somatic testing for therapy selection and personalized cancer monitoring. These testing services provide analysis and associated interpretation of the sequencing of parts of the genome. Test orders are placed under signed requisitions or contractual agreements, and we often enter into contracts with biopharmaceutical partners, other business-to-business customers and insurance companies that include pricing provisions under which such tests are billed. Billing terms are generally net 30 to 60 days.

While the transaction price of diagnostic tests is originally established either via contract or pursuant to our standard list price, we often provide concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered to be variable and revenue is recognized based on an estimate of the consideration to which we will be entitled at an amount for which it is probable that a reversal of cumulative consideration will not occur. Making these estimates requires significant judgments based upon such factors as length of payer relationship, historical payment patterns, changes in contract provisions and insurance reimbursement policies. These judgments are reviewed each reporting period and updated as necessary.

We look to transfer of control in assessing timing of recognition of revenue in connection with each performance obligation. In general, revenue in connection with the service portion of our diagnostic tests is recognized upon delivery of the underlying clinical report or when the report is made available on our web portal. Outstanding performance obligations pertaining to orders received but for which the underlying report has not been issued are generally satisfied within a 30-day period.

We also generate test revenue through the sale of our precision oncology products, which is comprised primarily of sales of our distributed RUO and IVD products for therapy selection. We recognize revenue on these sales once shipment has occurred. Product sales are recorded net of discounts and other deductions. Billing terms are generally net 30 days.

Shipping and handling fees billed to customers are recorded as revenue on the consolidated statements of operations. The associated shipping and handling costs are recorded in cost of revenue.

Other revenue

Other revenue is primarily generated from pharma development services provided to biopharmaceutical companies related to companion diagnostic development as well as through collaboration agreements and genome network contracts.

Contracts for companion diagnostic development consist primarily of milestone-based payments along with annual fees and marked-up pass-through costs. The arrangements are treated as short-term contracts for revenue recognition purposes because they allow termination of the agreements by the customers with 30 to 120 days' written notice without a termination penalty. Upon termination, customers are required to pay for the proportion of services provided under milestones that were in progress. We recognize revenue in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenue over time based on the progress made toward achieving the performance obligation, utilizing input methods, including labor hours expended, tests processed, or time elapsed, that measure our progress toward the achievement of the milestone.

We also enter into collaboration and genome network contracts. Collaboration agreements provide customers with diagnostic testing and related data aggregation reporting services that are provided over the contract term. Collaboration revenue is recognized as the data and reporting services are delivered to the customer. Genome network offerings consist of subscription services related to a proprietary software platform designed to connect patients, clinicians, advocacy organizations, researchers and therapeutic developers to accelerate the understanding, diagnosis and treatment of hereditary disease. Such services are recognized on a straight-line basis over the subscription periods. Amounts due under collaboration and genome network agreements are typically billable on net 30-day terms.

Business combinations

We apply Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC") 805, *Business Combinations*, which requires recognition of assets acquired, liabilities assumed, and contingent consideration at their fair value on the acquisition date with subsequent changes recognized in earnings; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination and expensed as incurred; requires in-process research and development to be capitalized at fair value as an indefinite-lived intangible asset until completion or abandonment; and requires that changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period be recognized as a component of provision for taxes.

We account for acquisitions of entities that include inputs and processes and have the ability to create outputs as business combinations. The tangible and identifiable intangible assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. We base the estimated fair value of identifiable intangible assets acquired in a business combination on third-party valuations that use information and assumptions provided by our management, which consider our estimates of inputs and assumptions that a market participant would use. Any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed is recorded to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, estimated cost savings, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

In circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under ASC 480, *Distinguishing Liabilities from Equity*, we recognize a liability equal to the fair value of the contingent payments we expect to make as of the acquisition date. We remeasure this liability each reporting period and record changes in the fair value in change in fair value of contingent consideration in our consolidated statements of operations.

Transaction costs associated with acquisitions are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in our operating results from the date of acquisition.

Asset acquisitions

In circumstances where substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the asset is not considered a business and we account for the transaction as an asset acquisition. We recognize the assets acquired based on their relative fair value, which generally includes the transaction costs of the asset acquisition, and no gain or loss is recognized unless the fair value of noncash assets given as consideration differs from the assets' carrying amounts. The form of consideration transferred may be cash, liabilities incurred, or equity interests issued.

Goodwill and indefinite lived intangibles

In accordance with ASC 350, *Intangibles - Goodwill and Other* we do not amortize goodwill or other intangible assets with indefinite lives, including in-process research and development, but rather test them for impairment. ASC 350 requires us to perform an impairment review of our goodwill balance at least annually, which we do in the fourth quarter of each year for our single consolidated reporting unit, and whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. We did not incur any goodwill impairment losses in any of the periods presented.

Stock-based compensation

We incur stock-based compensation expense for awards granted to employees and directors and for inducement awards granted in connection with our business acquisitions. Stock-based compensation expense is measured at the date of grant and is based on the estimated fair value of the award. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and restricted stock unit ("RSU") awards, and on an accelerated basis for performance-based restricted stock unit ("PRSU") awards. We recognize stock-based compensation expense associated with PRSU grants when we determine the achievement of performance conditions is probable. In determining the fair value of stock options and employee stock purchase plan ("ESPP") purchases, we estimate the grant date fair value and the resulting stock-based compensation expense using the Black-Scholes option-pricing model. We estimate the grant date fair value of RSU and PRSU awards based on the grant date share price.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions, which determine the fair value of stock-based awards. These assumptions include:

Expected term—The expected term represents the period that stock-based awards are expected to be outstanding. We use the simplified method to determine the expected term, which is based on the mid-point between the vesting date and the end of the contractual term.

Expected volatility—We estimate expected volatility based on the historical volatility of our common stock over a period equal to the expected term of awards and over the expected six-month term ESPP purchase periods.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of an option.

Dividend yield—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to stock-based compensation in future periods.

Income taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Significant judgment is required in determining the net valuation allowance which includes our evaluation of all available evidence including past operating results, estimates on future taxable income and acquisition-related tax assets and liabilities. As of December 31, 2021, we recorded a full valuation allowance on our net deferred tax assets because we expect that it is more likely than not that our deferred tax assets will not be realized in the foreseeable future. Should the actual amounts differ from our estimates, the amount of our valuation allowance could be materially impacted.

Results of operations

A discussion regarding our financial condition and results of operations for the year ended December 31, 2021 compared to the year ended December 31, 2020 is presented below. A discussion regarding our financial condition and results of operations for the year ended December 31, 2020 compared to the year ended December 31, 2019 can be found under Part II, Item 7. in our Annual Report on Form 10-K for the year ended December 31, 2020.

Comparison of the Years Ended December 31, 2021 and 2020

	Year Ended December 31, 2021	Year Ended December 31, 2020	Dollar Change	% Change
Revenue:				
Test revenue	$ 444,072	$ 272,310	$ 171,762	63%
Other revenue	16,377	7,288	9,089	125%
Total revenue	460,449	279,598	180,851	65%
Cost of revenue	348,669	198,275	150,394	76%
Research and development	416,087	240,605	175,482	73%
Selling and marketing	225,910	168,317	57,593	34%
General and administrative	248,070	270,029	(21,959)	(8)%
Change in fair value of contingent consideration	(386,646)	54,544	(441,190)	NM
Loss from operations	(391,641)	(652,172)	260,531	40%
Other income (expense), net	25,678	(32,332)	58,010	NM
Interest expense	(49,900)	(29,766)	(20,134)	(68)%
Net loss before taxes	(415,863)	(714,270)	298,407	42%
Income tax benefit	(36,857)	(112,100)	75,243	67%
Net loss	$ (379,006)	$ (602,170)	$ 223,164	37%

NM - Not Meaningful

Revenue

The increase in revenue of $180.9 million for the year ended December 31, 2021 compared to the same period in 2020 was due primarily to increased billable volume due to growth in our business. Billable volume increased to approximately 1,169,000 during the year ended December 31, 2021 compared to 659,000 in the same period in 2020, an increase of 77% due to growth in the business as well as lower billable volume in the prior year period as a result of the impact of COVID-19. Average revenue per unit decreased to $380 during the year ended December 31, 2021 compared to $413 in the same period in 2020, primarily due to changes in payer and product mix, as well as reductions in pricing for some payers as we focus on providing cost effective genetic testing.

Cost of revenue

The increase in the cost of revenue of $150.4 million for the year ended December 31, 2021 compared to the same period in 2020 was primarily due to increased billable volume. For the year ended December 31, 2021, the number of units billed increased to approximately 1,169,000 from approximately 659,000 for the same period in 2020. Cost per unit was $298 in 2021 compared to $299 in 2020. The slight decrease in cost per unit is primarily attributable to the significant increase in billable volume in 2021. The billable volume during the prior year period was lower as a result of the impact of COVID-19. The decrease was offset by changes in product mix, an increase in amortization of acquired intangible assets of $28.0 million, an increase in stock-based compensation of $10.1 million as well as an increase in write downs of certain inventory items of $9.7 million.

Research and development

The increase in research and development expense of $175.5 million for the year ended December 31, 2021 compared to the same period in 2020 was due to the growth of the business as well as the impact of acquisitions. The increase in research and development expenses principally consisted of the following elements: personnel-related costs increased by $83.3 million as a result of headcount growth; professional fees increased by $32.4 million; lab-related expenses increased by $20.8 million primarily due to costs related to lab services and supplies; technology costs increased by $18.5 million due to higher spending on networking cloud computing services and software licenses; facilities-related expenses increased by $8.3 million primarily due to expansion initiatives; acquisition and other expenses increased by $6.3 million; and depreciation and amortization increased by $5.9 million.

Selling and marketing

The increase in selling and marketing expenses of $57.6 million for the year ended December 31, 2021 compared to the same period in 2020 was primarily due to the growth of the business and our increased spending on sales initiatives subsequent to our cut backs in the second quarter of 2020 in response to COVID-19. The increase in selling and marketing expenses principally consisted of the following elements: personnel-related costs increased by $39.0 million due to increases in headcount and sales commissions; marketing costs increased by $6.3 million principally for branding initiatives and advertising; depreciation and amortization increased by $2.9 million; information technology costs increased by $2.9 million; facilities-related expenses by $2.3 million; professional services and other increased by $2.2 million; and travel and entertainment increased by $2.0 million.

General and administrative

The decrease in general and administrative expenses of $22.0 million for the year ended December 31, 2021 compared to the same period in 2020 was due to the nonrecurring effect of acquisitions in 2020, partially offset by growth in the business. Acquisition-related expenses declined by $105.5 million due to the post-combination expense related to the acceleration of unvested equity from our acquisition of ArcherDX included in the prior year period. These decreases were partially offset by increases due to growth in the business including personnel-related costs, which increased by $49.0 million primarily due to higher headcount; legal fees increased by $14.3 million primarily for litigation-related expenses; professional services increased by $11.8 million related to consulting services; and other corporate expenses increased by $8.4 million.

Change in fair value of contingent consideration

The decrease in the change in fair value of contingent consideration of $441.2 million for the year ended December 31, 2021 compared to the same period in 2020 was due principally to adjustments to decrease our contingent consideration liability related to ArcherDX resulting from a decrease in the value of our common stock and the removal of our contingent consideration liability relating to the outstanding milestone for FDA clearance or approval of a therapy selection IVD. The adjustments to decrease our contingent consideration were due to our determination that this milestone will not be achieved in the timeframe prescribed in the acquisition agreement, although we expect to receive FDA clearance or approval at a later date.

Other income (expense), net

The increase in other income (expense), net of $58.0 million for the year ended December 31, 2021 compared to the same period in 2020 was principally due to fair value adjustments related to our stock payable liabilities resulting from business combinations of $62.7 million due to the decrease in the price of our common stock, partially offset by amounts received under the CARES Act and the net changes in income recognized related to our marketable securities.

Interest expense

The increase in interest expense of $20.1 million for the year ended December 31, 2021 compared to the same period in 2020 was principally due to increased debt outstanding as compared to the prior year period, partially offset by the impact of the adoption of Accounting Standards Update ("ASU") 2020-06, which reduced the interest expense recognized related to our convertible senior notes during 2021. See Note 8, “Commitments and contingencies” in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report.

Income tax benefit

The decrease in income tax benefit of $75.2 million for the year ended December 31, 2021 compared to the same period in 2020 was primarily due to the net deferred tax liabilities assumed in connection with our acquisitions of One Codex, Genosity, Ciitizen and Stratify in 2021 which provided a future source of income to support the realization of our deferred tax assets and resulted in a partial release of our valuation allowance as compared to the partial release of our valuation allowance from our acquisition of YouScript and ArcherDX in 2020. As the short period tax returns for our 2021 acquisitions have not yet been filed, material changes to the tax returns may have a material impact on the net deferred tax liabilities assumed in connection with the acquisition and related income tax benefit.

Liquidity and capital resources

Liquidity and capital expenditures

We have generally incurred net losses since our inception. For the years ended December 31, 2021, 2020 and 2019, our net losses were $379.0 million, $602.2 million and $242.0 million, respectively, and we expect to incur additional losses in the future. At December 31, 2021, we had an accumulated deficit of $1.7 billion. While our revenue has increased over time, we may never achieve revenue sufficient to offset our expenses.

Since inception, our operations have been financed primarily by fees collected from our customers, net proceeds from sales of our capital stock as well as borrowing from debt facilities and the issuance of convertible senior notes.

In April 2020, we issued, in an underwritten public offering, an aggregate of 20.4 million shares of our common stock at a price of $9.00 per share, for gross proceeds of $184.0 million and net proceeds of $173.0 million. In 2020, we issued 3.6 million shares of common stock at an average price of $26.33 per share in an "at the market" offering for aggregate proceeds of $93.7 million and net proceeds of $90.7 million. In January 2021, we issued, in an underwritten public offering, an aggregate of 8.9 million shares of our common stock at a price of $51.50 per share, for gross proceeds of $460.0 million and net proceeds of approximately $434.3 million.

In September 2019, we issued $350.0 million of aggregate principal amount of convertible senior notes due 2024, which bear cash interest at a rate of 2.0% per year. Also in September 2019, we used the funds received through the issuance of our convertible senior notes due 2024 to settle our 2018 Note Purchase Agreement we entered into in November 2018. In April 2021, we issued $1,150.0 million aggregate principal amount of convertible senior notes due 2028, which bear cash interest at a rate of 1.5% per year.

In October 2020 in connection with our acquisition of ArcherDX, we issued $275.0 million of our common stock in a private placement at a price of $16.85 per share. We also entered into a credit facility to borrow $135.0 million. The private placement and credit facility closed concurrently with the merger in October 2020. The terms of this credit facility restrict our ability to incur certain indebtedness, pay dividends, make acquisitions and take other actions.

At December 31, 2021 and 2020, we had $1.1 billion and $360.7 million, respectively, of cash, cash equivalents, restricted cash and marketable securities.

Our primary uses of cash are to fund our operations as we continue to grow our business, enter into partnerships and acquire businesses and technologies. Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We estimate our capital expenditures will be approximately $60.0 million for 2022.

We have incurred substantial losses since inception, and we expect to continue to incur losses in the future. We believe our existing cash, cash equivalents and marketable securities as of December 31, 2021 and fees collected from the sale of our products and services will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

We may need or choose to raise additional funding to finance operations prior to achieving profitability or should we make additional acquisitions. We regularly consider fundraising opportunities and will determine the timing, nature and size of future financings based upon various factors, including market conditions and our operating plans. We may in the future elect to finance operations by selling equity or debt securities or borrowing money. We also may elect to finance future acquisitions. If we issue equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing additional debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. In addition, the terms of additional debt securities or borrowings could impose significant restrictions on our operations. If additional funding is required, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all. If we are unable to obtain additional funding when needed, we may need to curtail planned activities to reduce costs. Doing so will likely have an unfavorable effect on our ability to execute on our business plan and have an adverse effect on our business, results of operations and future prospects.

The following table summarizes our cash flows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Cash used in operating activities	$ (559,815)	$ (298,502)	$ (145,053)
Cash used in investing activities	(204,080)	(400,583)	(280,310)
Cash provided by financing activities	1,565,940	672,993	464,771
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 802,045	$ (26,092)	$ 39,408

Cash flows from operating activities

For the year ended December 31, 2021, cash used in operating activities was $559.8 million and principally resulted from our net loss of $379.0 million, non-cash charges for remeasurements of liabilities associated with business combinations of $411.8 million primarily related to ArcherDX development milestones and a $36.9 million income tax benefit primarily generated from our acquisitions of One Codex, Genosity, Ciitizen and Stratify. These were partially offset by non-cash charges of $180.1 million for stock-based compensation, $80.5 million for depreciation and amortization, $14.2 million for amortization of debt discount and issuance costs related to our outstanding debt, $9.5 million of post-combination expense primarily comprised of hold-back cash consideration related to our acquisition of Ciitizen and the acceleration of unvested equity from our acquisition of One Codex, $6.2 million of amortization of premiums on investment securities and $5.0 million of other adjustments. The net effect on cash for changes in net operating assets was a decrease of cash of $27.6 million due principally to increases in accounts receivable due to timing of collections, inventory and accounts payable, partially offset by increases in accrued liabilities.

For the year ended December 31, 2020, cash used in operating activities was $298.5 million and principally resulted from our net loss of $602.2 million and $112.1 million related to our income tax benefit generated from business combinations completed in 2020 partially offset by noncash charges of $158.7 million for stock-based compensation, $92.3 million in remeasurements of liabilities associated with business combinations such as contingent consideration, $91.0 million related to post-combination expense due to the acceleration of unvested equity in the acquisition of ArcherDX, $39.1 million for depreciation and amortization, $17.2 million of amortization of debt discount and issuance costs and $1.4 million of other adjustments. The net effect on cash for changes in net operating assets was an inflow of cash of $16.0 million due principally to increases in accounts payable and accrued liabilities partially offset by increases in inventory and accounts receivable due to timing of collections.

For the year ended December 31, 2019, cash used in operating activities of $145.1 million principally resulted from our net loss of $242.0 million and $18.5 million related to our income tax benefit generated from business combinations completed in 2019 offset by non-cash charges of $75.9 million for stock-based compensation, $16.2 million for depreciation and amortization, $8.9 million for debt extinguishment costs related to the settlement of our 2018 Note Purchase Agreement and $1.1 million of other adjustments. The net effect on cash for changes in net operating assets was a use of cash of $8.8 million due principally to increases in accrued liabilities which include acquisition-related liabilities for 2019 business acquisitions partially offset by increases in accounts receivable due to timing of collections and increases in prepaid expenses and other current assets.

Cash flows from investing activities

For the year ended December 31, 2021, cash used in investing activities of $204.1 million was primarily due to net cash used to acquire One Codex, Genosity and Ciitizen of $247.4 million and cash used for purchases of property and equipment of $54.7 million, partially offset by proceeds from net maturities and purchases of marketable securities of $99.3 million.

For the year ended December 31, 2020, cash used in investing activities of $400.6 million was primarily related to net cash used to acquire Orbicule BV ("Diploid"), Genelex, YouScript and ArcherDX of $383.8 million, purchases of property and equipment of $22.9 million, and other cash outflows of $4.0 million, all partially offset by net sales and maturities of marketable securities of $10.1 million.

For the year ended December 31, 2019, cash used in investing activities of $280.3 million resulted primarily from purchases of marketable securities exceeding proceeds from maturities and sales of marketable securities by $226.4 million, net cash used to acquire Singular Bio, Jungla Inc., and Clear Genetics, Inc. of $33.8 million and purchases of property and equipment of $20.0 million.

Cash flows from financing activities

For the year ended December 31, 2021, cash provided by financing activities of $1.6 billion primarily consisted of net proceeds from the issuance of convertible senior notes due 2024 of $1.1 billion and the public offering of common stock of $434.3 million as well as cash received from issuances of common stock totaling $23.8 million.

For the year ended December 31, 2020, cash provided by financing activities of $673.0 million consisted of cash received from issuances of common stock totaling $284.2 million, including cash received from shares issued through a private placement in October 2020 upon the close of the ArcherDX acquisition, exercises of stock options and employee stock plan purchases; net proceeds from the public offerings of common stock of $263.7 million; and net proceeds from debt financings of $129.2 million. These cash inflows were partially offset by other cash outflows of $4.1 million.

For the year ended December 31, 2019, cash provided by financing activities of $464.8 million consisted of net proceeds from the issuance of convertible senior notes due 2028 of $339.9 million, net proceeds from the public offerings of common stock of $204.0 million and cash received from issuances of common stock totaling $9.5 million, including cash received from exercises of stock options of $3.5 million and employee stock plan purchases of $5.8 million. These cash inflows were partially offset by payments related to the settlement of our 2018 Note Purchase Agreement through repayment of loan obligations of $75.0 million and payment of debt extinguishment costs of $10.6 million, as well as finance lease payments of $2.1 million.

Contractual obligations

The following table summarizes our contractual obligations, including interest, as of December 31, 2021 (in thousands):

Contractual obligations:	2022	2023 and 2024	2025 and 2026	2027 and beyond	Total
Operating leases	$ 18,470	$ 51,108	$ 50,678	$ 80,464	$ 200,720
Finance leases	4,719	5,891	177	—	10,787
Convertible senior notes	—	349,996	—	1,150,000	1,499,996
2020 Term Loan	—	135,000	—	—	135,000
Purchase commitments	25,893	29,271	614	—	55,778
Total	$ 49,082	$ 571,266	$ 51,469	$ 1,230,464	$ 1,902,281

See Note 8, “Commitments and contingencies” in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report for additional details regarding our leases, convertible senior notes, 2020 Term Loan and purchase commitments.

Off-balance sheet arrangements

We have not entered into any off-balance sheet arrangements.

Recent accounting pronouncements

See “Recent accounting pronouncements” in Note 2, “Summary of significant accounting policies” in Notes to Consolidated Financial Statements for a discussion of recently adopted accounting pronouncements and accounting pronouncements not yet adopted, and their expected effect on our financial position and results of operations.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. Our cash, cash equivalents, restricted cash and marketable securities totaled $1.1 billion at December 31, 2021, and consisted primarily of bank deposits, money market funds, U.S. Treasury notes and U.S. government agency securities. Such interest-bearing instruments carry a degree of risk; however, because our investments are primarily high-quality credit instruments with short-term durations with high-quality institutions, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. At December 31, 2021, a hypothetical 1.0% (100 basis points) increase or decrease in interest rates would not have resulted in a material change in the fair value of our cash equivalents and marketable securities. Fluctuations in the value of our cash equivalents and marketable securities caused by a change in interest rates (gains or losses on the carrying value) are recorded in other comprehensive gain (loss) and are realized if we sell the underlying securities prior to maturity.

Our 2020 Term Loan bears interest at an annual rate equal to three-month LIBOR, subject to a 2.00% LIBOR floor, plus a margin of 8.75% and is therefore sensitive to changes in interest rates. If three-month LIBOR can no longer be determined or if the applicable governmental authority ceases to supervise or sanction such rates, then we will endeavor to agree with the administrative agent, an alternate rate of interest that gives due consideration to the then prevailing market convention for determining interest for comparable loans in the United States; provided that until such alternative rate of interest is agreed, the 2020 Term Loan shall bear interest at the *Wall Street Journal* Prime Rate. We currently do not use interest rate derivative instruments to manage our exposure to interest rate fluctuations.

Although our convertible senior notes are based on a fixed rate, changes in interest rates could impact their fair market value. As of December 31, 2021, the fair market value of the convertible senior notes due 2024 and due 2028 was $325.6 million and $1.2 billion, respectively. For additional information about the convertible senior notes, see Note 8, “Commitments and contingencies” in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report.

ITEM 8. Consolidated Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Invitae Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Invitae Corporation (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 1, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

	Measurement of test revenue billed to insurance carriers
Description of the Matter	During the year ended December 31, 2021, the Company recognized test revenue billed to insurance carriers of $276.9 million. As discussed in Note 2 to the consolidated financial statements, the Company often provides concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered to be variable and revenue is recognized based on an estimate of the consideration to which the Company will be entitled at an amount for which it is probable that a reversal of cumulative consideration will not occur. Auditing the measurement of the Company's test revenue billed to insurance carriers was complex and judgmental due to the significant estimation required in determining the amount expected to be collected. In particular, the estimate of test revenue billed to insurance carriers was affected by assumptions in payer behavior such as changes in historical payment patterns, contract provisions and government and private insurance reimbursement policies.
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 revenue recognition process. As part of our testing, we considered controls over management's review of the significant assumptions and inputs used in the determination of the amount expected to be collected. We also tested controls used by management to compare the current and historical data used in making the estimates for completeness and accuracy. Our audit procedures over the Company's test revenue billed to insurance carriers included, among others, assessing valuation methodologies and models and testing the significant assumptions and the underlying data used by the Company in its analysis. We agreed a sample of transactions to the payer contract terms. We compared the significant assumptions and inputs used by management to changes in the Company's contracted rates, government and private insurance payer collection trends, and other relevant factors. We assessed the historical accuracy of the cash collections used in the Company's revenue models and assessed the completeness of adjustments to estimates of future cash collections as a result of significant contract amendments and changes in collection trends.

	Valuation of intangible assets and resulting goodwill associated with business combinations
Description of the Matter	As described in Note 4 to the consolidated financial statements, the Company completed several business combinations during 2021. As a result of th business combinations, the Company recorded intangibles assets of $193.7 million and goodwill of $420.6 million. . Auditing the Company's accounting for the business combinations was challenging as the determination of the fair value of the intangible assets and resulting goodwill acquired was based on subjective estimates and assumptions. The Company used an income approach to measure the acquired intangible assets. The valuation of the intangible assets and resulting goodwill was subject to higher estimation uncertainty due to management's judg in determining significant assumptions that included assumed revenue growth and discount rates. Changes in these significant assumptions could hav significant effect on the fair value of the intangible assets and resulting goodwill.
How We Addressed the Matter in Our Audit	We tested the design and operating effectiveness of internal controls over the Company's process for accounting for business combinations. For exar we tested controls over management's review of the valuation of intangible assets, including the review of the valuation model and significant assump used. Our audit procedures related to the valuation of intangible assets and resulting goodwill included, among others, utilizing a valuation specialist to assis evaluating the appropriateness of the Company's valuation models and evaluating the reasonableness of significant assumptions used such as the re growth and the discount rates as compared to industry and market data and historical results. We also evaluated whether the significant assumptions were reasonable by comparing them to the past performance of prior business combinations, current industry data and current market forecasts, and whether such assumptions were consistent with evidence obtained in other areas of the audit.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2013.

Redwood City, California

March 1, 2022

INVITAE CORPORATION

Consolidated Balance Sheets

(in thousands, except par value data)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 923,250	$ 124,794
Marketable securities	122,121	229,186
Accounts receivable	66,227	47,722
Inventory	33,516	32,030
Prepaid expenses and other current assets	33,691	20,200
Total current assets	1,178,805	453,932
Property and equipment, net	114,714	66,102
Operating lease assets	121,169	45,109
Restricted cash	10,275	6,686
Intangible assets, net	1,187,994	981,845
Goodwill	2,283,059	1,863,623
Other assets	23,551	13,188
Total assets	$ 4,919,567	$ 3,430,485
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 21,127	$ 25,203
Accrued liabilities	106,453	86,058
Operating lease obligation	12,359	8,789
Finance lease obligation	4,156	1,695
Total current liabilities	144,095	121,745
Operating lease obligation, net of current portion	124,369	48,357
Finance lease obligation, net of current portion	5,683	3,123
Debt	113,391	104,449
Convertible senior notes, net	1,464,138	283,724
Deferred tax liability	51,696	51,538
Other long-term liabilities	37,797	841,256
Total liabilities	1,941,169	1,454,192
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value: 20,000 shares authorized; nil and 125 shares issued and outstanding as of December 31, 2021 and 2020, respectively	—	—
Common stock, $0.0001 par value: 400,000 shares authorized; 228,116 and 185,886 shares issued and outstanding as of December 31, 2021 and 2020, respectively	23	19
Accumulated other comprehensive (loss) income	(7)	1
Additional paid-in capital	4,701,230	3,337,120
Accumulated deficit	(1,722,848)	(1,360,847)
Total stockholders' equity	2,978,398	1,976,293
Total liabilities and stockholders' equity	$ 4,919,567	$ 3,430,485

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

INVITAE CORPORATION

Consolidated Statements of Operations

(in thousands, except per share data)

	Year Ended December 31,		
	2021	2020	2019
Revenue:			
Test revenue	$ 444,072	$ 272,310	$ 212,473
Other revenue	16,377	7,288	4,351
Total revenue	460,449	279,598	216,824
Cost of revenue	348,669	198,275	118,103
Research and development	416,087	240,605	141,526
Selling and marketing	225,910	168,317	122,237
General and administrative	248,070	270,029	78,963
Change in fair value of contingent consideration	(386,646)	54,544	107
Total costs and operating expenses	852,090	931,770	460,936
Loss from operations	(391,641)	(652,172)	(244,112)
Other income (expense), net	25,678	(32,332)	(3,891)
Interest expense	(49,900)	(29,766)	(12,412)
Net loss before taxes	(415,863)	(714,270)	(260,415)
Income tax benefit	(36,857)	(112,100)	(18,450)
Net loss	$ (379,006)	$ (602,170)	$ (241,965)
Net loss per share, basic and diluted	$ (1.80)	$ (4.47)	$ (2.66)
Shares used in computing net loss per share, basic and diluted	210,946	134,587	90,859

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

INVITAE CORPORATION

Consolidated Statements of Comprehensive Loss

(in thousands)

	Year Ended December 31,		
	2021	2020	2019
Net loss	$ (379,006)	$ (602,170)	$ (241,965)
Other comprehensive (loss) income:			
Unrealized (loss) income on available-for-sale marketable securities, net of tax	(8)	10	(4)
Comprehensive loss	$ (379,014)	$ (602,160)	$ (241,969)

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

INVITAE CORPORATION

Consolidated Statements of Stockholders' Equity

(in thousands)

	Year Ended December 31,		
	2021	2020	2019
Common stock:			
Balance, beginning of period	$ 19	$ 10	$ 8
Common stock issued	4	9	2
Balance, end of period	23	19	10
Accumulated other comprehensive (loss) income:			
Balance, beginning of period	1	(9)	(5)
Unrealized (loss) income on available-for-sale marketable securities, net of tax	(8)	10	(4)
Balance, end of period	(7)	1	(9)
Additional paid-in capital:			
Balance, beginning of period	3,337,120	1,138,316	678,548
Common stock issued in private placement, net	—	263,628	—
Common stock issued in connection with public offering, net	434,263	263,685	204,024
Common stock issued on exercise of stock options, net	8,984	10,730	3,456
Common stock issued pursuant to exercises of warrants	1,242	974	181
Common stock issued pursuant to employee stock purchase plan	13,550	8,871	5,833
Common stock issued or issuable pursuant to acquisitions and equity awards issued in connection with such acquisitions	805,124	1,524,227	133,942
Equity component of convertible senior notes, net	—	—	75,488
Warrants issued pursuant to loan agreement	—	27,000	—
Stock-based compensation expense	176,435	110,076	36,844
Reclassification of equity component of convertible senior notes	(75,488)	—	—
Reclassification of stock payable liabilities	—	(10,387)	—
Balance, end of period	4,701,230	3,337,120	1,138,316
Accumulated deficit:			
Balance, beginning of period	(1,360,847)	(758,677)	(516,712)
Cumulative effect of accounting change	17,005	—	—
Net loss	(379,006)	(602,170)	(241,965)
Balance, end of period	(1,722,848)	(1,360,847)	(758,677)
Total stockholders' equity	$ 2,978,398	$ 1,976,293	$ 379,640

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

INVITAE CORPORATION

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31, 2021	2020	2019
Cash flows from operating activities:			
Net loss	$ (379,006)	$ (602,170)	$ (241,965)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	80,472	39,050	16,206
Stock-based compensation	180,075	158,747	75,948
Amortization of debt discount and issuance costs	14,226	17,204	4,416
Remeasurements of liabilities associated with business combinations	(411,842)	92,348	—
Benefit from income taxes	(36,857)	(112,100)	(18,450)
Debt extinguishment costs	—	—	8,926
Post-combination expense for acceleration of unvested equity and deferred stock compensation	9,530	91,021	—
Amortization of premiums and discounts on investment securities	6,221	1,236	(296)
Other	4,983	189	1,391
Changes in operating assets and liabilities, net of businesses acquired:			
Accounts receivable	(16,696)	(2,814)	(6,131)
Inventory	(1,486)	(7,832)	1,645
Prepaid expenses and other current assets	(14,563)	(2,010)	(6,624)
Other assets	(3,274)	895	2,026
Accounts payable	(9,258)	10,186	1,558
Accrued expenses and other long-term liabilities	17,660	17,548	16,297
Net cash used in operating activities	(559,815)	(298,502)	(145,053)
Cash flows from investing activities:			
Purchases of marketable securities	(325,957)	(280,258)	(260,917)
Proceeds from sales of marketable securities	—	12,832	—
Proceeds from maturities of marketable securities	425,293	277,487	34,500
Acquisition of businesses, net of cash acquired	(247,396)	(383,753)	(33,846)
Purchases of property and equipment	(54,720)	(22,865)	(20,047)
Other	(1,300)	(4,026)	—
Net cash used in investing activities	(204,080)	(400,583)	(280,310)
Cash flows from financing activities:			
Proceeds from public offerings of common stock, net	434,263	263,688	204,024
Proceeds from issuance of common stock	23,767	284,203	9,470
Proceeds from issuance of convertible senior notes, net	1,116,427	—	339,900
Proceeds from issuance of debt, net	—	129,214	—
Payments of debt extinguishment costs	—	—	(10,638)
Loan payments	—	—	(75,000)
Finance lease principal payments	(3,759)	(2,655)	(2,075)
Other	(4,758)	(1,457)	(910)
Net cash provided by financing activities	1,565,940	672,993	464,771
Net increase (decrease) in cash, cash equivalents and restricted cash	802,045	(26,092)	39,408
Cash, cash equivalents and restricted cash at beginning of period	131,480	157,572	118,164
Cash, cash equivalents and restricted cash at end of period	$ 933,525	$ 131,480	$ 157,572
Supplemental cash flow information:			
Interest paid	$ 31,400	$ 12,130	$ 4,731
Supplemental cash flow information of non-cash investing and financing activities:			
Equipment acquired through finance leases	$ 8,224	$ 4,463	$ 1,892
Purchases of property and equipment in accounts payable and accrued liabilities	$ 13,222	$ 1,869	$ 2,422
Warrants issued pursuant to debt agreement	$ —	$ 27,000	$ —
Common stock issued for acquisition of businesses	$ 802,073	$ 1,157,958	$ 108,573
Consideration payable for acquisition of businesses	$ 46,649	$ 940,829	$ 21,449
Operating lease assets obtained in exchange for lease obligations, net	$ 88,777	$ 14,058	$ 4,261

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

INVITAE CORPORATION

Notes to Consolidated Financial Statements

1. Organization and description of business

Invitae Corporation ("Invitae," “the Company," "we," "us," and "our") was incorporated in the State of Delaware on January 13, 2010, as Locus Development, Inc. and we changed our name to Invitae Corporation in 2012. We offer high-quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, cardiology, neurology, pediatrics, personalized oncology, metabolic conditions and rare diseases. To augment our offering and realize our mission, we have acquired multiple assets and businesses that further expand our test menu and suite of genome management offerings and accelerated our entry into key genomics markets. We are building a platform to harness genetics on a global scale to diagnose more patients correctly, earlier and bring therapies to market faster. Our genome management offerings will provide information services to the patient that are intended to enhance the customer experience through personalized insights, technology-enabled services and network connections that inform genetic healthcare throughout life. Invitae operates in one segment.

2. Summary of significant accounting policies

Principles of consolidation

Our consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. We base these estimates on current facts, historical and anticipated results, trends and various other assumptions that we believe are reasonable under the circumstances, including assumptions as to future events. Actual results could differ materially from those judgments, estimates and assumptions. We evaluate our estimates on an ongoing basis.

Significant estimates and assumptions made by management include the determination of:

- revenue recognition;
- inventory adjustments;
- the fair value of assets and liabilities associated with business combinations;
- the valuation of our 2.00% convertible senior notes due 2024 issued in September 2019 and our 1.5% convertible senior notes due 2028 issued in April 2021 (collectively, our "Convertible Senior Notes");
- our incremental borrowing rates used to calculate our lease balances;
- stock-based compensation expense and the fair value of awards and warrants issued; and
- income tax uncertainties.

Prior period reclassifications

We have reclassified certain amounts in prior periods to conform with current presentation. During the current period, we have disclosed the change in fair value of our contingent consideration separately in our statements of operations. These amounts are general and administrative in nature and were disclosed in general and administrative expense in previous periods.

Immaterial correction of an error

We determined the historical classification of certain acquisition-related obligations as equity and the subsequent measurement of such obligations was inappropriate and instead should have been classified as liabilities and subsequently measured at fair value with changes recognized in other expense, net during the year ended December 31, 2020. We determined that the impact of the error to previously issued consolidated financial statements was not material and have corrected the immaterial error in the current period financial statements. The impact of this correction was an increase to other long-term liabilities of $10.1 million, a corresponding decrease to additional paid-in capital of $10.4 million and an increase to other income, net of $0.3 million.

Concentrations of credit risk and other risks and uncertainties

Financial instruments that potentially subject us to a concentration of credit risk consist of cash, cash equivalents, marketable securities and accounts receivable. Our cash and cash equivalents are held by financial institutions in the United States. Such deposits may exceed federally insured limits.

Significant customers are those that represent 10% or more of our total revenue for each year presented on the consolidated statements of operations. Our revenue from significant customers as a percentage of our total revenue was as follows:

	Year Ended December 31,		
	2021	2020	2019
Medicare	15 %	19 %	25 %

No customers represented more than 10% of accounts receivable as of December 31, 2021 and 2020.

Cash, cash equivalents, and restricted cash

We consider all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market funds, U.S. Treasury notes and government agency securities.

Restricted cash consists primarily of money market funds that secure irrevocable standby letters of credit that serve as collateral for security deposits for our facility leases.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the consolidated statements of cash flows (in thousands):

	December 31,	
	2021	2020
Cash and cash equivalents	$ 923,250	$ 124,794
Restricted cash	10,275	6,686
Total cash, cash equivalents and restricted cash	$ 933,525	$ 131,480

Restricted cash serves as the security deposit for the Company's leases.

Marketable securities

All marketable securities have been classified as “available-for-sale” and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its marketable debt securities at the time of purchase and reevaluates such designation at each balance sheet date. Short-term marketable securities have maturities one year or less at the balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of other comprehensive loss. Realized gains and losses and impairments, if any, on available-for-sale securities are included in other expense, net. The cost of securities sold is based on the specific-identification method. Interest on marketable securities is included in other income (expense), net.

For marketable securities in an unrealized loss position, we assess our intent to sell, or whether it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis. If either of these criteria are met, the security’s amortized cost basis is written down to fair value through other income (expense), net.

Accounts receivable

We receive payment from patients, biopharmaceutical partners, third-party payers and other business-to-business customers. See Note 3, "Revenue, accounts receivable and deferred revenue" for further information.

Allowances for losses on certain financial assets

We assess our accounts receivables for expected credit losses at each reporting period by disaggregating by payer type and further by portfolios of customers with similar characteristics, such as customer type and geographic location. We then review each portfolio for expected credit losses based on historical payment trends as well as forward looking data and current economic trends. If a credit loss is determined, we record a reduction to our accounts receivable balance with a corresponding general and administrative expense.

We review available-for-sale debt securities in an unrealized loss positions quarterly and assess whether such unrealized loss positions are credit-related. Our expected loss allowance methodology for these securities is developed by reviewing the extent of the unrealized loss, the issuers' credit ratings and any changes in those ratings, as well as reviewing current and future economic market conditions and the issuers' current status and financial condition. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other income (expense), net. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive income (loss).

Deferred revenue

We record a contract liability when cash payments are received or due in advance of our performance related to one or more performance obligations. See Note 3, "Revenue, accounts receivable and deferred revenue" for further information.

Inventory

Our inventory consists of raw materials, work in progress, and finished goods, which are stated at the lower of cost or net realizable value on a first-in, first-out basis. We periodically analyze our inventory levels and expiration dates, and write down inventory that has become obsolete, inventory that has a cost basis in excess of its net realizable value, and inventory in excess of expected sales requirements as cost of revenue. We record an allowance for obsolete inventory using an estimate based on historical trends and evaluation of near-term expirations.

Business combinations

We apply ASC 805, *Business Combinations*, which requires recognition of assets acquired, liabilities assumed, and contingent consideration at their fair value on the acquisition date with subsequent changes recognized in earnings; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination and expensed as incurred; requires in-process research and development to be capitalized at fair value as an indefinite-lived intangible asset until completion or abandonment; and requires that changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period be recognized as a component of provision for taxes.

We account for acquisitions of entities that include inputs and processes and have the ability to create outputs as business combinations. The tangible and identifiable intangible assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. We base the estimated fair value of identifiable intangible assets acquired in a business combination on third-party valuations that use information and assumptions provided by our management, which consider our estimates of inputs and assumptions that a market participant would use. Any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed is recorded to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, estimated cost savings, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

In circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under ASC 480, *Distinguishing Liabilities from Equity*, we recognize a liability equal to the fair value of the contingent payments we expect to make as of the acquisition date. We remeasure this liability each reporting period and record changes in the fair value in change in fair value of contingent consideration in our consolidated statements of operations.

Transaction costs associated with acquisitions are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in our operating results from the date of acquisition.

Asset acquisitions

In circumstances where substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the asset is not considered a business and we account for the transaction as an asset acquisition. We recognize the assets acquired based on their relative fair value, which generally includes the transaction costs of the asset acquisition, and no gain or loss is recognized unless the fair value of noncash assets given as consideration differs from the assets' carrying amounts. The form of consideration transferred may be cash, liabilities incurred, or equity interests issued.

Intangible assets

Amortizable intangible assets include trade names, non-compete agreements, patent licensing agreements, favorable leases, developed technology, customer relationships, and rights to develop new technology acquired as part of business combinations. Customer relationships acquired through our business combinations in 2017 are amortized on an accelerated basis, utilizing free cash flows, over periods ranging from five to 11 years. All other intangible assets subject to amortization are amortized using the straight-line method over their estimated useful lives ranging from five to 15 years. All intangible assets subject to amortization are reviewed for impairment in accordance with ASC 360, *Property, Plant and Equipment.*

Goodwill

In accordance with ASC 350, *Intangibles-Goodwill and Other*, our goodwill is not amortized but is tested for impairment on an annual basis or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. Under ASC 350, we perform annual impairment reviews of our goodwill balance during the fourth fiscal quarter or more frequently if business factors indicate. In testing for impairment, we compare the fair value of our reporting unit to its carrying value including the goodwill of that unit. If the carrying value, including goodwill, exceeds the reporting unit's fair value, we will recognize an impairment loss for the amount by which the carrying amount exceeds the reporting unit's fair value. The loss recognized cannot exceed the total amount of goodwill allocated to that reporting unit. We did not incur any goodwill impairment losses in any of the periods presented.

In-process research and development

Intangible assets related to in-process research and development costs ("IPR&D") are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. During this period, the assets will not be amortized but will be tested for impairment on an annual basis and between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts.

During the fourth quarter and if business factors indicate more frequently, we perform an assessment of the qualitative factors affecting the fair value of our IPR&D projects. If the fair value exceeds the carrying value, there is no impairment. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of an asset to its carrying value, without consideration of any recoverability test. We have not identified any such impairment losses to date.

Leases

Under ASC 842, *Leases*, we determine if an arrangement is a lease at inception. Operating leases are included in operating lease assets and operating lease obligations in our consolidated balance sheets. Finance leases are included in other assets and finance lease obligations in our consolidated balance sheets.

Lease assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at commencement based on the present value of lease payments over the lease term. We generally use our incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a similar term of the lease payments. The operating lease asset also includes any lease payments made and is adjusted for lease incentives. Our lease terms may include options to extend or terminate the lease which are recognized when it is reasonably certain that we will exercise that option. Leases with terms of 12 months or less are not recorded on our balance sheet. Lease expense is recognized on a straight-line basis over the lease terms, or in some cases, the useful life of the underlying asset. We account for the lease and non-lease components as a single lease component.

Property and equipment, net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and seven years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in the consolidated statements of operations in the period realized.

The estimated useful lives of property and equipment are as follows:

Furniture and fixtures	7 years
Automobiles	7 years
Manufacturing and Laboratory equipment	5 years
Computer equipment	3 years
Software	3 years
Leasehold improvements	Shorter of lease term or estimated useful life

Long-lived assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when the total estimated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows or other appropriate measures of fair value. There were no long-lived asset impairment losses recorded for any period presented.

Fair value of financial instruments

Our financial instruments consist principally of cash and cash equivalents, marketable securities, accounts payable, accrued liabilities, finance leases, and liabilities associated with business combinations. The carrying amounts of certain of these financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued and other current liabilities approximate their current fair value due to the relatively short-term nature of these accounts. Based on borrowing rates available to us, the carrying value of finance leases approximate their fair values. Liabilities associated with business combinations are recorded at their estimated fair value.

Revenue recognition

We recognize revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers. We utilize the following practical expedients and exemptions:

- Costs to obtain or fulfill a contract are expensed when incurred because the amortization period would have been one year or less, and
- No adjustments to promised consideration were made for financing as we expect, at contract inception, that the period between the transfer of a promised good or service and when the customer pays for that good or service will be one year or less.

Test revenue

Test revenue is comprised of testing services and sales of distributed precision oncology products.

The majority of our test revenue is generated from genetic testing, in addition to somatic testing for therapy selection and personalized cancer monitoring. These testing services provide analysis and associated interpretation of the sequencing of parts of the genome. Test orders are placed under signed requisitions or contractual agreements, and we often enter into contracts with biopharmaceutical partners, other business-to-business customers and insurance companies that include pricing provisions under which such tests are billed. Billing terms are generally net 30 to 60 days.

While the transaction price of diagnostic tests is originally established either via contract or pursuant to our standard list price, we often provide concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered to be variable and revenue is recognized based on an estimate of the consideration to which we will be entitled at an amount for which it is probable that a reversal of cumulative consideration will not occur. Making these estimates requires significant judgments based upon such factors as length of payer relationship, historical payment patterns, changes in contract provisions and insurance reimbursement policies. These judgments are reviewed each reporting period and updated as necessary.

We look to transfer of control in assessing timing of recognition of revenue in connection with each performance obligation. In general, revenue in connection with the service portion of our diagnostic tests is recognized upon delivery of the underlying clinical report or when the report is made available on our web portal. Outstanding performance obligations pertaining to orders received but for which the underlying report has not been issued are generally satisfied within a 30-day period.

We also generate test revenue through the sale of our precision oncology products, which is comprised primarily of sales of our distributed RUO and IVD products for therapy selection. We recognize revenue on these sales once shipment has occurred. Product sales are recorded net of discounts and other deductions. Billing terms are generally net 30 days.

Shipping and handling fees billed to customers are recorded as revenue on the consolidated statements of operations. The associated shipping and handling costs are recorded as cost of revenue.

Other revenue

Other revenue is primarily generated from pharma development services provided to biopharmaceutical companies related to companion diagnostic development as well as through collaboration agreements and genome network contracts.

Contracts for companion diagnostic development consist primarily of milestone-based payments along with annual fees and marked-up pass-through costs. The arrangements are treated as short-term contracts for revenue recognition purposes because they allow termination of the agreements by the customers with 30 to 120 days' written notice without a termination penalty. Upon termination, customers are required to pay for the proportion of services provided under milestones that were in progress. We recognize revenue in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenue over time based on the progress made toward achieving the performance obligation, utilizing input methods, including labor hours expended, tests processed, or time elapsed, that measure our progress toward the achievement of the milestone.

We also enter into collaboration and genome network contracts. Collaboration agreements provide customers with diagnostic testing and related data aggregation reporting services that are provided over the contract term. Collaboration revenue is recognized as the data and reporting services are delivered to the customer. Genome network offerings consist of subscription services related to a proprietary software platform designed to connect patients, clinicians, advocacy organizations, researchers and therapeutic developers to accelerate the understanding, diagnosis and treatment of hereditary disease. Such services are recognized on a straight-line basis over the subscription periods. Amounts due under collaboration and genome network agreements are typically billable on net 30-day terms.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering our products and services and includes expenses for materials and supplies, personnel-related costs, freight, costs for lab services and clinical trial support, equipment and infrastructure expenses and allocated overhead including rent, information technology costs, equipment depreciation, amortization of acquired intangibles, and utilities.

License Agreements

We have entered and may continue to enter into license agreements to access and utilize certain technology. We evaluate if the license agreement results in the acquisition of an asset or a business and then determine if the acquired asset has the ability to generate revenues or is subject to regulatory approval. When regulatory approval is not required, we record the license as an asset and amortize it over the estimated economic life. When regulatory approval is required, we record the amount paid as a research and development expense.

Income taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Significant judgment is required in determining the net valuation allowance which includes our evaluation of all available evidence including past operating results, estimates on future taxable income and acquisition-related tax assets and liabilities.

We historically established a full valuation allowance against our deferred tax assets due to the uncertainty surrounding realization of such assets. In 2021, we released approximately $37.2 million of our valuation allowance to account for acquired intangibles that support the future realization of some of our deferred tax assets. Due to the overall increase of deferred tax assets, our valuation allowance has also increased from the prior year.

Stock-based compensation

We measure stock-based payment awards made to employees and directors based on the estimated fair values of the awards and recognize the compensation expense over the requisite service period. We use the Black-Scholes option-pricing model to estimate the fair value of stock option awards and ESPP purchases. The fair value of RSU awards with time-based vesting terms is based on the grant date share price. We grant PRSU awards to certain employees, which vest upon the achievement of certain performance conditions subject to the employees' continued service relationship with us. The probability of vesting is assessed at each reporting period and compensation cost is adjusted based on this probability assessment. We recognize such compensation expense on an accelerated vesting method.

Stock-based compensation expense for awards without a performance condition is recognized using the straight-line method. Stock-based compensation expense is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, our stock-based compensation is reduced for estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

We account for stock issued in connection with business combinations based on the fair value on the date of issuance.

Advertising

Advertising expenses are expensed as incurred. We incurred advertising expenses of $20.2 million, $11.4 million and $9.9 million during the years ended December 31, 2021, 2020 and 2019, respectively.

Comprehensive loss

Comprehensive loss is composed of two components: net loss and other comprehensive income (loss). Other comprehensive income (loss) refers to gains and losses that under U.S. GAAP are recorded as an element of stockholders' equity, but are excluded from net loss. Our other comprehensive income (loss) consists of unrealized gains or losses on investments in available-for-sale securities.

Net loss per share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury stock method. Potentially dilutive securities, consisting of preferred stock, options to purchase common stock, common stock warrants, shares of common stock pursuant to ESPP, common stock issuable in connection with our Convertible Senior Notes, RSUs and PRSUs, are considered to be common stock equivalents and were excluded from the calculation of diluted net loss per share because their effect would be antidilutive for all periods presented.

Recent accounting pronouncements

We evaluate all ASUs issued by the FASB for consideration of their applicability. ASUs not included in the disclosures in this report were assessed and determined to be either not applicable or are not expected to have a material impact on our consolidated financial statements.

Recently issued accounting pronouncements not yet adopted

In October 2021, the FASB issued ASU 2021-08, *Business Combinations ("Topic 805"): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers.* The amendments of this ASU require entities to recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC Topic 606, *Revenue from Contracts with Customers*. At the acquisition date, an acquirer should account for the related revenue contracts in accordance with ASC Topic 606 as if it had originated the contracts. The amendments improve comparability after the business combination by providing consistent recognition and measurement guidance for revenue contracts with customers acquired in a business combination and revenue contracts with customers not acquired in a business combination. The amendments in this update should be applied prospectively and are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. We do not expect the adoption of this standard to have a material impact on our consolidated financial statements and related disclosures.

Recently adopted accounting pronouncements

In August 2020, the FASB issued ASU 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for certain convertible instruments, amends the guidance on derivative scope exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share calculations as a result of these changes. This new standard is effective for our interim and annual periods beginning January 1, 2022, and earlier adoption is permitted. We elected to adopt the amendments on a modified retrospective basis effective January 1, 2021, which required a cumulative-effect adjustment to retained earnings. The cumulative-effect adjustment resulted in a decrease in accumulated deficit of $17.0 million related to the reversal of the equity component and associated issuance costs as well as adjustment of the related amortization costs of our convertible senior notes due 2024. Reporting periods beginning on or after January 1, 2021 are presented under this new guidance while prior periods have not been adjusted and continue to be reported in accordance with our historic accounting under U.S. GAAP. See further information about our Convertible Senior Notes in Note 8, "Commitments and contingencies."

3. Revenue, accounts receivable and deferred revenue

Test revenue is generated from sales of diagnostic tests and precision oncology products to four groups of customers: biopharmaceutical partners; patients who pay directly; patients' insurance carriers; and other business-to-business customers (e.g., hospitals, clinics, medical centers). Test revenue is generated in two ways: through a centralized lab and decentralized through the shipment of reactions to biopharmaceutical partners and other business-to-business customers. We refer to the set of reagents needed to perform a next-generation sequencing test as a "reaction." Amounts billed and collected, and the timing of collections, vary based on the type of payer. Other revenue consists principally of revenue recognized under contracts for biopharmaceutical development services and other collaboration and genome network agreements and is accounted for under the provisions provided in ASC Topic 606.

Our revenue as disaggregated by payer category and revenue subtype is as follows (in thousands):

	Patient				
	Insurance	Direct	Biopharma partner	Other business-to-business	Year Ended December 31, 2021
Test revenue:					
Centralized	$ 276,916	$ 41,668	$ 40,181	$ 48,696	$ 407,461
Decentralized	—	—	1,278	35,333	36,611
Total test revenue	276,916	41,668	41,459	84,029	444,072
Other revenue	—	—	11,578	4,799	16,377
Total revenue	$ 276,916	$ 41,668	$ 53,037	$ 88,828	$ 460,449

	Patient				
	Insurance	Direct	Biopharma partner	Other business-to-business	Year Ended December 31, 2020
Test revenue:					
Centralized	$ 181,026	$ 23,972	$ 26,228	$ 32,736	$ 26
Decentralized	—	—	837	7,511	
Total test revenue	181,026	23,972	27,065	40,247	27
Other revenue	—	—	4,488	2,800	
Total revenue	$ 181,026	$ 23,972	$ 31,553	$ 43,047	$ 27

	Patient				
	Insurance	Direct	Biopharma partner	Other business-to-business	Year Ended December 31, 2019
Test revenue:					
Centralized	$ 153,827	$ 17,597	$ 10,876	$ 30,173	$ 21
Total test revenue	153,827	17,597	10,876	30,173	21
Other revenue	—	—	2,077	2,274	
Total revenue	$ 153,827	$ 17,597	$ 12,953	$ 32,447	$ 21

We recognize revenue related to billings based on estimates of the amount that will ultimately be realized. Cash collections for certain tests delivered may differ from rates originally estimated. As a result of new information, we update our estimate quarterly of the amounts to be recognized for previously delivered tests which resulted in the following increases to revenue and decreases to our loss from operations and basic and diluted net loss per share (in millions, except per share amounts):

	Year Ended December 31,		
	2021	2020	2019
Revenue	$ 13.5	$ 4.4	$ 4.1
Loss from operations	$ (13.5)	$ (4.4)	$ (4.1)
Net loss per share, basic and diluted	$ (0.06)	$ (0.03)	$ (0.05)

The increase in revenue from previously delivered tests for the year ended December 31, 2021 as compared to the same period in 2020 and 2019, respectively, was primarily due to increased billable volumes during 2021 and higher average revenue per test across all test categories when compared to initial estimates.

Impact of COVID-19

Our daily test volumes have recovered from the low in March 2020, although the ongoing COVID-19 pandemic continues to impact our business operations and practices. While we expect that it may continue to impact our business, we experienced limited disruption during 2021. We have reviewed and adjusted for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

Approximately 8% of our workforce as of March 31, 2020 was impacted by a reduction in force in April 2020 in an initiative to manage costs and cash burn that resulted in one-time costs in the second quarter of 2020 of $3.8 million. In addition, effective May 2020, we reduced the salaries of our named executive officers by approximately 20%, which reductions ceased as of January 2021.

In March 2020, the CARES Act was signed into law as a stimulus bill intended to bolster the economy, among other things, and provide assistance to qualifying businesses and individuals. The CARES Act included an infusion of funds into the healthcare system. In April 2020, we received $3.8 million as a part of this initiative, and in January 2021, we received an additional $2.3 million. These payments were recognized as other income (expense), net in our consolidated statements of operations during the periods received. At this time, we are not certain of the availability, extent or impact of any future relief provided under the CARES Act.

Accounts receivable

The majority of our accounts receivable represents amounts billed to biopharmaceutical partners and other business-to-business customers for test and other revenue recognized, and estimated amounts to be collected from third-party insurance payers for genetic testing revenue recognized. Also included are amounts due under the terms of collaboration and genome network agreements for diagnostic testing and data aggregation reporting services provided and proprietary platform access rights transferred.

We also record unbilled revenue for revenue recognized but yet to be billed for services provided to biopharmaceutical companies related to companion diagnostic development. This contract receivable was $4.3 million as of both December 31, 2021 and 2020 and was included in prepaid expenses and other current assets on the consolidated balance sheets.

Deferred revenue

We record a contract liability when cash payments are received or due in advance of our performance related to one or more performance obligations. The deferred revenue balance primarily consists of advanced billings for biopharmaceutical development services, including billings at the initiation of a performance-based milestones, and recognized as revenue in the applicable future period when the revenue is earned. Also included are prepayments related to our consumer direct channel. We recognized revenue of $2.9 million and $1.4 million from deferred revenue for the year ended as of December 31, 2021 and 2020, respectively.

4. Business combinations

Singular Bio

In June 2019, we acquired 100% of the fully diluted equity of Singular Bio Inc. ("Singular Bio"), a privately held company developing single molecule detection technology, for approximately $57.3 million, comprised of $53.9 million in the form of 2.5 million shares of our common stock and the remainder in cash.

In June 2019, we granted approximately $90.0 million of RSUs under our 2015 Stock Incentive Plan as inducement awards to new employees who joined Invitae in connection with our acquisition of Singular Bio. $45.0 million of the RSUs are time-based and vested in three equal installments in December 2019, June 2020, and December 2020, subject to the employee's continued service with us ("Time-based RSUs"), and $45.0 million of the RSUs are PRSUs that vest upon the achievement of certain performance conditions. Since the number of awards granted is based on a 30-day volume weighted-average share price with a fixed dollar value, these Time-based RSUs and PRSUs are liability-classified and the fair value is estimated at each reporting period based on the number of shares that are expected to be issued at each reporting date and our closing stock price, which combined are categorized as Level 3 inputs. Therefore, fair value of the RSUs and PRSUs and the number of shares to be issued are not fixed until the awards vest.

During the years ended December 31, 2021 and 2020, we recorded research and development stock-based compensation expense of nil and $29.1 million, respectively, related to the Time-based RSUs, and $1.2 million and $19.4 million, respectively, related to the PRSUs based on our evaluations of the probability of achieving performance conditions. As of December 31, 2021, there was no remaining liability related to the Singular Bio transaction.

Jungla

In July 2019, we acquired 100% of the equity interest of Jungla Inc. ("Jungla"), a privately held company developing a platform for molecular evidence testing in genes, for approximately $59.0 million, comprised of $44.9 million in the form of shares of our common stock and the remainder in cash.

We may be required to pay contingent consideration based on achievement of post-closing development milestones. As of the acquisition date, the fair value of this contingent consideration was $10.7 million, which includes cash and common stock. This fair value measurement is based on significant inputs not observable in the market and, therefore, represents a Level 3 measurement. The material factors that may impact fair value of the contingent consideration, and therefore, this liability, are the probabilities and timing of achieving the related milestones and the discount rate used to estimate fair value. Significant changes in any of the probabilities of success would result in a significant change in the fair value, which is estimated at each reporting date with changes reflected as change in fair value of contingent consideration. The remaining milestone was achieved in July 2021 and the fair value of the contingent consideration was reduced to nil as of December 31, 2021.

Diploid

In March 2020, we acquired 100% of the equity interest of Orbicule BV ("Diploid"), a developer of artificial intelligence software capable of diagnosing genetic disorders using sequencing data and patient information, for approximately $82.3 million in cash and shares of our common stock. Of the stock purchase price consideration issued, approximately 0.4 million shares are subject to a hold-back to satisfy indemnification obligations that may arise. In September 2021, the amounts held back to satisfy indemnification obligations for Diploid were released in full to the former shareholders.

Genelex and YouScript

In April 2020, we acquired 100% of the equity interest of Genelex Solutions, LLC ("Genelex") and YouScript Incorporated ("YouScript") to bring pharmacogenetic testing and integrated clinical decision support to Invitae. We acquired Genelex for approximately $13.2 million, primarily in shares of our common stock. Of the stock purchase price consideration issued, approximately 0.1 million shares were subject to a hold-back to satisfy indemnification obligations that may arise. We acquired YouScript for approximately $52.7 million, including cash consideration of $24.5 million and the remainder in shares of our common stock. Of the purchase price consideration for YouScript, approximately $1.4 million and 0.5 million shares of our common stock are subject to a hold-back to satisfy indemnification obligations that may arise.

As of the acquisition date, we recorded stock payable liabilities of $6.2 million to represent the hold-back obligation to issue shares subject to indemnification claims that may arise. In April 2021, the amounts held back to satisfy indemnification obligations for Genelex were released in full to the former shareholders. As of December 31, 2021, the value of these liabilities were $3.5 million related to YouScript with the $15.4 million change in fair value year over year recorded in other income (expense), net.

We may be required to pay contingent consideration in the form of additional shares of our common stock in connection with the acquisition of Genelex if, within a specified period following the closing, we achieve a certain product milestone, in which case we would issue shares of our common stock with a value equal to a portion of the gross revenues actually received by us for a pharmacogenetic product reimbursed through certain payers during an earn-out period of up to four years. As of the acquisition date, the fair value of this contingent consideration was $2.0 million. This fair value measurement is based on significant inputs not observable in the market and, therefore, represents a Level 3 measurement. The material factors that may impact the fair value of the contingent consideration, and therefore, this liability, are the probabilities and timing of achieving the related milestone, the estimated revenues achieved for a pharmacogenetic product and the discount rate used to estimate the fair value. Significant changes in any of the probabilities of success would result in a significant change in the fair value, which is estimated at each reporting date. As of December 31, 2021, the fair value of this contingent consideration was $1.9 million.

ArcherDX

In October 2020, we acquired ArcherDX Inc. ("ArcherDX"), a genomics analysis company democratizing precision oncology. Under the terms of the agreement, we acquired ArcherDX for upfront consideration consisting of 30.0 million shares of our common stock and $325.0 million in cash, plus up to an additional 27.0 million shares of our common stock payable in connection with the achievement of certain milestones. During the three months ended March 31, 2021, Invitae and the sellers of ArcherDX reached an agreement to reduce the purchase price by $1.2 million based on the final acquired net working capital. This adjustment was recorded during the three months ended March 31, 2021 and reduced the contingent consideration liability and goodwill by approximately $1.2 million.

We were required to pay contingent consideration based on achievement of post-closing development and revenue milestones. As of the acquisition date, the total fair value of the contingent consideration was $945.2 million. Of the five milestones, one milestone was achieved in November 2020, which resulted in the issuance of 5.0 million shares of our common stock and a cash payment of $1.9 million, and three milestones were achieved or deemed to be achieved during the three months ended June 30, 2021, which resulted in the issuance of 13.8 million shares of our common stock and a cash payment of $3.3 million in July 2021. The remaining milestone is based upon receiving FDA clearance or approval of a therapy selection IVD, which per the terms of the acquisition agreement, must be completed by March 31, 2022, subject to certain extensions (the "ArcherDX Final Milestone"). The material factors that may impact the fair value of the contingent consideration, and therefore the liability, are (i) the estimated number of shares to be issued, (ii) the volatility of our common stock, (iii) the probabilities of achievement of milestones within the timeframes prescribed in the acquisition agreement and (iv) discount rates, all of which are Level 3 inputs not supported by market activity. Significant changes in any of these inputs may result in a significant change in fair value, which is estimated at each reporting date. As of December 31, 2020, the fair value of the contingent consideration representing the remaining milestones was $788.3 million. With respect to the ArcherDX Final Milestone, the liability was reduced to nil as of June 30, 2021 from $262.5 million as of March 31, 2021 and $287.7 million as of December 31, 2020, with the offsetting change recorded as changes in fair value of contingent consideration in our consolidated statements of operations. The removal of the liability balance and the associated change in fair value of contingent consideration was a result of our reassessment of the steps necessary to achieve clearance or approval based on FDA feedback received principally in the three months ended June 30, 2021. As a result of our reassessment, we do not believe achievement of the conditions will occur within the specified timeframe prescribed in the acquisition agreement. We expect FDA clearance or approval of a therapy selection IVD at a later date subject to resolution of the necessary steps.

In connection with the acquisition, we granted awards of common stock to new employees who joined Invitae in connection with our acquisition of ArcherDX that vest upon the achievement of the contingent consideration milestones discussed above and are subject to the employees' continued service with us, unless terminated without cause in which case vesting is only dependent on milestone achievement. As the number of shares that are expected to be issued are fixed, the awards are equity-classified. During the year ended December 31, 2021, we recorded a net $41.8 million in stock-based compensation expense related to the ArcherDX milestones, which includes $38.5 million related to milestones achieved in prior periods, $33.0 million due to an accounting modification of certain awards whereby the employees' continued substantive services were no longer required, offset by a reversal of $29.7 million recognized in prior periods related to the determination that the ArcherDX Final Milestone will not be achieved within the specified timeframe prescribed in the acquisition agreement.

One Codex

In February 2021, we acquired 100% of the equity interest of Reference Genomics, Inc. d/b/a One Codex ("One Codex"), a company developing and commercializing products and services relating to microbiome sequencing, analysis and reporting, for upfront consideration consisting of $17.3 million in cash and 1.4 million shares of our common stock, of which approximately 0.2 million shares are subject to a hold-back to satisfy indemnification obligations that may arise following the closing. These shares subject to a hold-back were issued to a third-party at the closing date to hold in escrow until the escrow period is complete, and as such were classified as equity. We included the financial results of One Codex in our consolidated financial statements from the acquisition date, which were not material.

The following table summarizes the purchase price and post-combination expense recorded as a part of the acquisition of One Codex (in thousands):

	Purchase Price	Post-combination Expense
Cash transferred	$ 16,504	$ 783
Hold-back consideration - common stock	8,113	359
Common stock transferred	58,774	2,600
Total	$ 83,391	$ 3,742

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by us. While we believe that our estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed through our acquisition of One Codex at the date of acquisition (in thousands):

Cash	$ 1,549
Accounts receivable	684
Developed technology	23,841
Customer relationships	440
Total identifiable assets acquired	26,514
Other liabilities	(415)
Deferred tax liability	(6,150)
Net identifiable assets acquired	19,949
Goodwill	63,442
Total purchase price	$ 83,391

Based on the guidance provided in ASC 805, we accounted for the acquisition of One Codex as a business combination and determined that 1) One Codex was a business that combines inputs and processes to create outputs, and 2) substantially all of the fair value of gross assets acquired was not concentrated in a single identifiable asset or group of similar identifiable assets.

We measured the identifiable assets and liabilities assumed at their acquisition date fair values separately from goodwill, which represent Level 3 fair value measurements. The intangible assets acquired were developed technology related to One Codex's microbiome and infectious disease platform and its customer relationships in place at time of acquisition. The fair value of the intangible assets was estimated using an income approach with an estimated useful life of nine years.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of One Codex resulted in the recognition of $63.4 million of goodwill, which we believe relates primarily to expansion of the acquired technology to apply to new areas of genetic testing. The goodwill created as a result of the acquisition of One Codex is not deductible for tax purposes.

Genosity

In April 2021, we acquired 100% of the fully diluted equity of Genosity Inc. ("Genosity"), a company providing genomic laboratory services, for approximately $196.0 million, consisting of approximately $120.0 million in cash and 1.9 million shares of our common stock. In connection with this transaction, we granted RSUs having a value of up to $5.0 million to certain continuing employees and recognized $0.8 million in stock-based compensation expense for the year ended December 31, 2021. We included the financial results of Genosity in our consolidated financial statements from the acquisition date, which were not material.

The following table summarizes the purchase price recorded as a part of the acquisition of Genosity (in thousands):

	Purchase Price
Cash transferred	$ 119,959
Hold-back and other consideration	8,774
Common stock transferred	67,308
Total	$ 196,041

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by us. While we believe that our estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed through our acquisition of Genosity at the date of acquisition (in thousands):

Cash	$ 906
Accounts receivable	355
Developed technology	76,500
Other assets	3,732
Total identifiable assets acquired	81,493
Other liabilities	(2,852)
Deferred tax liability	(17,600)
Net identifiable assets acquired	61,041
Goodwill	135,000
Total purchase price	$ 196,041

Based on the guidance provided in ASC 805, we accounted for the acquisition of Genosity as a business combination and determined that 1) Genosity was a business that combines inputs and processes to create outputs, and 2) substantially all of the fair value of gross assets acquired was not concentrated in a single identifiable asset or group of similar identifiable assets. Pursuant to the terms of the acquisition, a provision was incorporated to provide additional shares in the event that our common stock share price decreased after the acquisition, but prior to filing a resale registration statement. At the time of the acquisition, we estimated this provision to be $7.0 million. On filing the resale registration statement during the period ended June 30, 2021, the fair value was $3.2 million; the difference of $3.8 million was recorded in general and administrative expense.

Our purchase price allocation for the acquisition is preliminary and subject to revision as additional information about fair value of assets and liabilities becomes available, primarily related to our deferred tax liability assumed in connection with the acquisition. Additional information that existed as of the acquisition date but at the time was unknown to us may become known to us during the remainder of the measurement period, a period not to exceed 12 months from the acquisition date.

We measured the identifiable assets and liabilities assumed at their acquisition date fair values separately from goodwill, which represent Level 3 fair value measurements. The intangible assets acquired were developed technology related to Genosity's genomic laboratory services and sequencing software in place at the time of acquisition. The fair value of the intangible assets was estimated using an income approach with an estimated useful life of 12 years.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of Genosity resulted in the recognition of $135.0 million of goodwill, which we believe relates primarily to expansion of the acquired technology to apply to new areas of genetic testing. The goodwill created as a result of the acquisition of Genosity is not deductible for tax purposes.

Ciitizen

In September 2021, we acquired 100% of the equity of Ciitizen Corporation ("Ciitizen"), a patient-centric health technology company, for approximately $308.3 million, consisting of approximately $87.4 million in cash and 6.3 million shares of our common stock, of which approximately $10.4 million in cash and 0.8 million shares are subject to a hold-back to satisfy indemnification obligations that may arise following the closing. As of December 31, 2021, the value of the stock payable liability was $12.1 million with the $10.6 million change recorded in other income (expense), net. In connection with this transaction, we granted RSUs having a value of up to $246.9 million to certain continuing employees. For the year ended December 31, 2021, we recorded stock-based compensation expense of $24.4 million primarily in research and development expense. We included the financial results of Ciitizen in our consolidated financial statements from the acquisition date, which were not material.

The following table summarizes the purchase price recorded as a part of the acquisition of Ciitizen (in thousands):

		Purchase Price
Cash transferred	$	87,361
Hold-back and other consideration		34,161
Common stock transferred		186,778
Total	$	308,300

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by us. While we believe that our estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed through our acquisition of Ciitizen at the date of acquisition (in thousands):

Cash	$	274
Accounts receivable		748
Other receivables		688
Developed technology		92,900
Other assets		970
Total identifiable assets acquired		95,580
Other liabilities		(2,550)
Deferred tax liability		(6,900)
Net identifiable assets acquired		86,130
Goodwill		222,170
Total purchase price	$	308,300

Based on the guidance provided in ASC 805, we accounted for the acquisition of Ciitizen as a business combination and determined that 1) Ciitizen was a business that combines inputs and processes to create outputs, and 2) substantially all of the fair value of gross assets acquired was not concentrated in a single identifiable asset or group of similar identifiable assets.

Our purchase price allocation for the acquisition is preliminary and subject to revision as additional information about fair value of assets and liabilities becomes available, primarily related to certain aspects of our deferred tax liability assumed in connection with the acquisition. Additional information that existed as of the acquisition date but at the time was unknown to us may become known to us during the remainder of the measurement period, a period not to exceed 12 months from the acquisition date.

We measured the identifiable assets and liabilities assumed at their acquisition date fair values separately from goodwill, which represent Level 3 fair value measurements. The intangible asset acquired were developed technology related to Ciitizen's patient data platform. The fair value of the intangible assets was estimated using an income approach with an estimated useful life of 12 years.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of Ciitizen resulted in the recognition of $222.2 million of goodwill, which we believe relates primarily to expansion of the acquired technology to apply to new areas of patient-centric consumer health tech company. The goodwill created as a result of the acquisition of Ciitizen is not deductible for tax purposes.

5. Goodwill and intangible assets

Goodwill

The changes in the carrying amounts of goodwill were as follows (in thousands):

Balance as of December 31, 2020	$	1,863,623
Goodwill adjustment		(1,176)
Goodwill acquired		420,612
Balance as of December 31, 2021	$	2,283,059

Intangible assets

The following table presents details of our acquired intangible assets as of December 31, 2021 (in thousands):

	Cost	Accumulated Amortization	Net	Weighted-Average Useful Life (in Years)	Weighted-Average Estimated Remaining Useful Life (in Years)
Customer relationships	$ 41,515	$ (13,096)	$ 28,419	10.8	7.8
Developed technology	662,106	(81,902)	580,204	10.2	9.1
Non-compete agreement	286	(286)	—	0.0	0.0
Tradename	21,085	(2,207)	18,878	12.0	10.8
Patent licensing agreement	495	(136)	359	15.0	10.9
Right to develop new technology	19,359	(1,613)	17,746	15.0	13.8
In-process research and development	542,388	—	542,388	n/a	n/a
	$ 1,287,234	$ (99,240)	$ 1,187,994	10.4	9.2

Acquisition-related intangibles included in the above table are generally finite-lived, other than in-process research and development, which has an indefinite life, and are carried at cost less accumulated amortization. Customer relationships related to our 2017 business combinations are being amortized on an accelerated basis in proportion to estimated cash flows. All other finite-lived acquisition-related intangibles are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized. Amortization expense was $58.8 million, $26.6 million, and $7.7 million for the years ended December 31, 2021, 2020 and 2019, respectively. Amortization expense is recorded to cost of revenue, research and development, sales and marketing and general and administrative expense.

The following table summarizes our estimated future amortization expense of intangible assets with finite lives as of December 31, 2021 (in thousands):

2022	$	73,706
2023		72,693
2024		72,414
2025		70,661
2026		70,627
Thereafter		285,505
Total estimated future amortization expense	$	645,606

In December 2021, we acquired 100% of the equity interest of Stratify Genomics Inc., a cancer risk stratification company, for $29.0 million consisting of 1.0 million shares of common stock, $4.2 million in assumed liabilities, and $8.0 million in cash. We accounted for this transaction as an asset acquisition, as substantially all of the fair value is concentrated in the developed technology acquired. As goodwill is not recorded under an asset acquisition, an $8.7 million deferred tax liability arising from book/tax basis differences increased the value of the assets acquired above the purchase price. As a result, the fair value of the developed technology is $37.5 million, which will be amortized over eight years to cost of revenue. The remaining purchase price of $0.2 million is the fair value of cash and cash equivalents.

In July 2021, we acquired 100% of the equity interest of Medneon LLC, a digital health artificial intelligence company, for $34.1 million consisting of 0.4 million shares of common stock, $4.9 million in assumed liabilities, and $12.9 million in cash. We accounted for this transaction as an asset acquisition, as substantially all of the fair value is concentrated in the developed technology acquired. The fair value the of the developed technology is $33.9 million, which will be amortized over eight years to cost of revenue. The remaining purchase price of $0.2 million is the fair value of cash and cash equivalents.

In December 2020, we entered into an agreement to acquire technology focused on informing clinical decisions for $2.9 million. We accounted for this transaction as an asset acquisition of developed technology, which will be amortized over eight years to research and development expense.

6. Balance sheet components

Inventory

Inventory consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Raw materials	$ 27,178	$ 21,324
Work in progress	5,342	8,847
Finished goods	996	1,859
Total inventory	$ 33,516	$ 32,030

Property and equipment, net

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

	December 31, 2021	December 31, 2020
Leasehold improvements	$ 31,159	$ 26,516
Laboratory equipment	61,317	45,342
Computer equipment	15,452	10,939
Furniture and fixtures	2,130	1,967
Construction-in-progress	52,039	12,061
Other	925	624
Total property and equipment, gross	163,022	97,449
Accumulated depreciation and amortization	(48,308)	(31,347)
Total property and equipment, net	$ 114,714	$ 66,102

Depreciation expense was $18.1 million, $10.5 million and $7.1 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Accrued compensation and related expenses	$ 35,877	$ 25,221
Accrued expenses	32,136	14,933
Compensation and other liabilities associated with business combinations	11,622	25,600
Deferred revenue	9,431	6,378
Accrued interest	6,646	2,333
Other accrued liabilities	10,741	11,593
Total accrued liabilities	$ 106,453	$ 86,058

Other long-term liabilities

Other long-term liabilities consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Compensation and other liabilities associated with business combinations, non-current	$ 27,919	$ 825,976
Deferred revenue, non-current	663	1,380
Other	9,215	13,900
Total other long-term liabilities	$ 37,797	$ 841,256

7. Fair value measurements

Financial assets and liabilities are recorded at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The authoritative guidance establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity.

The three-level hierarchy for the inputs to valuation techniques is summarized as follows:

Level 1—Observable inputs such as quoted prices (unadjusted) for identical instruments in active markets.

Level 2—Observable inputs such as quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-derived valuations whose significant inputs are observable.

Level 3—Unobservable inputs that reflect the reporting entity's own assumptions.

The following tables set forth the fair value of our consolidated financial instruments that were measured at fair value on a recurring basis (in thousands):

	December 31, 2021						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	$ 913,990	$ —	$ —	$ 913,990	$ 913,990	$ —	$ —
U.S. Treasury notes	111,187	—	(6)	111,181	111,181	—	—
U.S. government agency securities	10,941	—	(1)	10,940	—	10,940	—
Total financial assets	$ 1,036,118	$ —	$ (7)	$ 1,036,111	$ 1,025,171	$ 10,940	$ —
Financial liabilities:							
Stock payable liability				$ 20,925	$ —	$ —	$ 20,925
Contingent consideration				1,875	—	—	1,875
Total financial liabilities				$ 22,800	$ —	$ —	$ 22,800

	December 31, 2021
Reported as:	
Cash equivalents	$ 903,715
Restricted cash	10,275
Marketable securities	122,121
Total cash equivalents, restricted cash, and marketable securities	$ 1,036,111
Other long-term liabilities	$ 22,800

	December 31, 2020						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level
Financial assets:							
Money market funds	$ 83,109	$ —	$ —	$ 83,109	$ 83,109	$ —	$
U.S. Treasury notes	164,894	7	(15)	164,886	164,886	—	
U.S. government agency securities	64,291	9	—	64,300	—	64,300	
Total financial assets	$ 312,294	$ 16	$ (15)	$ 312,295	$ 247,995	$ 64,300	$
Financial liabilities:							
Stock payable liability				$ 39,237	$ —	$ —	$ 3
Contingent consideration				$ 796,639	$ —	$ —	$ 79
Total financial liabilities				$ 835,876	$ —	$ —	$ 83

	December 31, 2020
Reported as:	
Cash equivalents	$ 7
Restricted cash	[illegible]
Marketable securities	22
Total cash equivalents, restricted cash, and marketable securities	$ 31
Accrued liabilities	$ 1
Other long-term liabilities	82
Total liabilities	$ 83

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented. The total fair value of investments with unrealized losses at December 31, 2021 was $122.1 million. Our debt securities of U.S. government agencies are classified as Level 2 as they are valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to benchmark yields, interest rate curves, reported trades, broker/dealer quotes and reference data. None of the available-for-sale securities held as of December 31, 2021 have been in an unrealized loss position for more than one year. At December 31, 2021, the remaining contractual maturities of available-for-sale securities ranged from zero to three months. Interest income generated from our investments was $6.9 million and $4.0 million during the years ended December 31, 2021 and 2020, respectively.

Stock payable liabilities relate to certain indemnification hold-backs resulting from business combinations that are settled in shares of our common stock. We elected to account for these liabilities using the fair value option due to the inherent nature of the liabilities and the changes in value of the underlying shares that will ultimately be issued to settle the liabilities. The estimated fair value of these liabilities is classified as Level 3 and determined based upon the number of shares that are issuable to the sellers and the quoted closing price of our common stock as of the reporting date. The number of shares that will ultimately be issued is subject to adjustment for indemnified claims that existed as of the closing date for each acquisition. Changes in the number of shares issued and share price can significantly affect the estimated fair value of the liabilities. During the year ended December 31, 2021, the change in fair value related to stock payable liabilities recorded to other income (expense), net was expense of $25.2 million.

8. Commitments and contingencies

Leases

In 2015, we entered into an operating lease agreement for our headquarters and main production facility in San Francisco, California which commenced in 2016. This lease expires in 2026 and we may renew the lease for an additional ten years. This optional period was not considered reasonably certain to be exercised and therefore we determined the lease term to be a ten-year period expiring in 2026. In connection with the execution of the lease, we provided a security deposit of approximately $4.6 million which is included in restricted cash in our consolidated balance sheets. We also have other operating leases for office and laboratory space domestically and internationally. We expect to enter into new leases and modify existing leases as we support continued growth of our operations.

We have entered into various finance lease agreements to obtain laboratory equipment. The terms of our finance leases are generally three years and are typically secured by the underlying equipment. The portion of the future payments designated as principal repayment and related interest was classified as a finance lease obligation on our consolidated balance sheets. Finance lease assets are recorded within other assets on our consolidated balance sheets.

Supplemental information regarding our operating and finance leases were as follows:

	Year Ended December 31,	
	2021	2020
Weighted-average remaining lease term:		
Operating leases	9.0 years	5.4 years
Finance leases	2.4 years	2.6 years
Weighted-average discount rate:		
Operating leases	7.0 %	10.6 %
Finance leases	7.2 %	4.8 %
Cash payments included in the measurement of lease liabilities (in millions):		
Operating leases	$ 18.3	$ 11.6
Finance leases	$ 2.9	$ 2.0

The components of lease costs, which were included in cost of revenue, research and development, selling and marketing and general and administrative expenses on our consolidated statements of operations, were as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Operating lease costs	$ 21,151	$ 11,329	$ 10,329
Sublease income	—	—	(173)
Finance lease costs:			
Amortization of right-of-use assets	3,488	2,084	1,546
Interest on lease liabilities	496	—	—
Total lease costs	$ 25,135	$ 13,413	$ 11,702

Future payments under operating and finance leases as of December 31, 2021 are as follows (in thousands):

	Operating leases	Finance leases
2022	$ 18,470	$ 4,719
2023	23,108	4,133
2024	28,000	1,758
2025	26,647	177
2026	24,031	—
Thereafter	80,464	—
Future non-cancelable minimum lease payments	200,720	10,787
Less: interest	(63,992)	(948)
Total lease liabilities	136,728	9,839
Less: current portion	(12,359)	(4,156)
Lease obligations, net of current portion	$ 124,369	$ 5,683

Debt financing

In November 2018, we entered into a Note Purchase Agreement (the "2018 Note Purchase Agreement") pursuant to which we were eligible to borrow an aggregate principal amount up to $200.0 million over a seven year maturity term which included an initial borrowing of $75.0 million in November 2018.

In September 2019, we settled our obligations under the 2018 Note Purchase Agreement in full for $85.7 million, which included repayment of principal of $75.0 million, accrued interest of $2.4 million, and prepayment fees of $8.9 million which were recorded as debt extinguishment costs in other expense, net in our consolidated statement of operations during the year ended December 31, 2019.

In October 2020, we entered into a credit agreement with a financial institution under which we borrowed $135.0 million (the "2020 Term Loan") concurrent with the closing of the ArcherDX acquisition. The 2020 Term Loan is secured by a first priority lien on all of our and our subsidiaries' assets, and is guaranteed by us and our subsidiaries. The 2020 Term Loan bears interest at an annual rate equal to three-month LIBOR, subject to a 2.00% LIBOR floor, plus a margin of 8.75%. If three-month LIBOR can no longer be determined or if the applicable governmental authority ceases to supervise or sanction such rates, then we will endeavor to agree with the administrative agent, an alternate rate of interest that gives due consideration to the then prevailing market convention for determining interest for comparable loans in the United States, provided that until such alternative rate of interest is agreed, the 2020 Term Loan shall bear interest at the *Wall Street Journal* Prime Rate. The three-month LIBOR is expected to be available and representative through June 30, 2023. The 2020 Term Loan will mature on (i) June 1, 2024 if at such time our 2024 Notes (defined below) are outstanding and are due to mature on September 1, 2024 (provided that if, prior to such date, the maturity date of at least 80% of the 2024 Notes is extended to a date that is prior to September 1, 2025 the maturity date for the 2020 Term Loan will be automatically extended to a date that is 90 days prior to such 2024 Notes maturity date as extended), or (ii) otherwise, on June 1, 2025. The full amount of the 2020 Term Loan is due upon maturity. If the 2020 Term Loan is prepaid (whether such prepayment is optional or mandatory), we must pay a prepayment fee of 6% if the prepayment occurs prior to the third anniversary of the closing date or 4% if the prepayment occurs after the third anniversary of the closing date and we must also pay a make-whole fee if the prepayment occurs prior to the second anniversary of the closing date. In connection with the 2020 Term Loan, we issued warrants to purchase 1.0 million shares of our common stock with an exercise price of $16.85 per share, exercisable through October 2027. The warrants, which were classified as equity, were recorded at an amount based on the allocated proceeds and do not require subsequent remeasurement. In October 2020, these warrants were exercised in full through net settlement resulting in the issuance of 0.7 million shares.

The credit agreement contains customary events of default and covenants, including among others, covenants limiting our ability to incur debt, incur liens, undergo a change in control, merge with or acquire other entities, make investments, pay dividends or other distributions to holders of our equity securities, repurchase stock, and dispose of assets, in each case subject to certain customary exceptions. In addition, the credit agreement contains financial covenants that require us to maintain a minimum cash balance and minimum quarterly revenue levels.

Debt discounts, including debt issuance costs, related to the 2020 Term Loan of $32.8 million were recorded as a direct deduction from the debt liability and are being amortized to interest expense over the term of the 2020 Term Loan. Interest expense related to our debt financings, excluding the impact of our convertible senior notes, was $23.7 million, $7.4 million and $5.7 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Convertible Senior Notes

Convertible senior notes due 2024

In September 2019, we issued, at par value, $350.0 million aggregate principal amount of 2.00% convertible senior notes due 2024 (the "2024 Notes") in a private offering. The 2024 Notes are our senior unsecured obligations and will mature on September 1, 2024, unless earlier converted, redeemed or repurchased. The 2024 Notes bear cash interest at a rate of 2.0% per year, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on March 1, 2020.

Upon conversion, the 2024 Notes will be convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The initial conversion rate for the 2024 Notes is 33.6293 shares of our common stock per $1,000 principal amount of the 2024 Notes (equivalent to an initial conversion price of approximately $29.74 per share of common stock).

If we undergo a fundamental change (as defined in the indenture governing the 2024 Notes), the holders of the 2024 Notes may require us to repurchase all or any portion of their 2024 Notes for cash at a repurchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased plus accrued and unpaid interest to, but excluding, the redemption date.

The 2024 Notes will be convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding March 1, 2024, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on December 31, 2019 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the 2024 Notes on each applicable trading day; (2) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of 2024 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (3) if we call any or all of the 2024 Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or (4) upon the occurrence of specified corporate events. On or after March 1, 2024 until the close of business on the business day immediately preceding the maturity date, holders may convert their 2024 Notes at any time, regardless of the foregoing circumstances. These notes were convertible at the option of the holders during the quarters beginning on January 1, 2021 and April 1, 2021 due to the sale price of our common stock during the quarter ended December 31, 2020 and March 31, 2021, respectively. No holders converted their notes during the twelve months ended December 31, 2021.

We may not redeem the 2024 Notes prior to September 6, 2022. We may redeem for cash all or any portion of the 2024 Notes, at our option, on or after September 6, 2022 and on or before the 30th scheduled trading day immediately before the maturity date if the last reported sale price of the common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption at a redemption price equal to 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

Convertible senior notes due 2028

In April 2021, we issued, at 99% of par value, $1,150.0 million aggregate principal amount of 1.5% convertible senior notes due 2028 (the "2028 Notes") in a private offering. The 2028 Notes are our senior unsecured obligations and will mature on April 1, 2028, unless earlier converted, redeemed or repurchased. The 2028 Notes bear cash interest at a rate of 1.5% per year, payable semi-annually in arrears on April 1 and October 1 of each year, beginning on October 1, 2021. Upon conversion, the 2028 Notes will be convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

The 2028 Notes will be convertible at the option of the holder at any time until the second scheduled trading day prior to the maturity date, including in connection with a redemption by us. The 2028 Notes will be convertible into shares of our common stock based on an initial conversion rate of 23.1589 shares of common stock per $1,000 principal amount of the 2028 Notes (which is equal to an initial conversion price of $43.18 per share), in each case subject to customary anti-dilution and other adjustments as a result of certain extraordinary transactions.

We may not redeem the 2028 Notes prior to April 6, 2025. On or after April 6, 2025, the 2028 Notes will be redeemable by us in the event that the closing sale price of our common stock has been at least 150% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide the redemption notice at a redemption price of 100% of the principal amount of such 2028 Notes, plus accrued and unpaid interest to, but excluding, the redemption date.

With certain exceptions, upon a change of control of the Company or the failure of our common stock to be listed on certain stock exchanges, the holders of the 2028 Notes may require that we repurchase all or part of the principal amount of the Notes at a repurchase price of 100% of the principal amount of the 2028 Notes to be repurchased, plus unpaid interest to, but excluding, the maturity date.

Convertible senior notes

We adopted the provisions of ASU 2020-06 on January 1, 2021; see further information in Note 2, "Summary of significant accounting policies." Our Convertible Senior Notes consisted of the following (in thousands):

	December 31,	
	2021	2020
Outstanding principal	$ 1,499,996	$ 350,000
Unamortized debt discount and issuance costs	(35,858)	(66,276)
Net carrying amount, liability component	$ 1,464,138	$ 283,724

As of December 31, 2021, the fair value of the 2024 Notes and 2028 Notes was $325.6 million and $1.2 billion, respectively. The estimated fair value of the 2024 Notes and 2028 Notes, which use Level 2 fair value inputs, was determined based on the estimated or actual bid prices in an over-the-counter market and/or market conditions including the price and volatility of our common stock and comparable company information. We recognized $24.9 million and $22.0 million of interest expense related to our convertible senior notes during the years ended December 31, 2021 and 2020, respectively. Of the interest expense recognized during the years ended December 31, 2021 and 2020, $5.3 million and $1.9 million, respectively, was related to amortization of issuance costs and the remainder was related to contractual interest incurred.

Other commitments

In the normal course of business, we enter into various purchase commitments primarily related to service agreements and laboratory supplies. At December 31, 2021, our total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year were as follows (in thousands):

2022	25,893
2023	21,904
2024	7,367
2025	614
2026	—
Thereafter	—
Total	$ 55,778

Guarantees and indemnification

As permitted under Delaware law and in accordance with our bylaws, we indemnify our directors and officers for certain events or occurrences while the officer or director is or was serving in such capacity. The maximum amount of potential future indemnification is unlimited; however, we maintain director and officer liability insurance. This insurance allows the transfer of the risk associated with our exposure and may enable us to recover a portion of any future amounts paid. We believe the fair value of these indemnification agreements is minimal. Accordingly, we did not record any liabilities associated with these indemnification agreements at December 31, 2021 or 2020.

Contingencies

We are and may from time to time be involved in various legal proceedings and claims arising in the ordinary course of business. Legal proceedings, including litigation, government investigations and enforcement actions could result in material costs, occupy significant management resources and entail civil and criminal penalties, even if we ultimately prevail. If an investigation results in a proceeding against us, an adverse outcome could include us being required to pay treble damages, and incur attorneys' fees, civil or criminal penalties and other adverse actions that could materially and adversely affect our business, financial condition and results of operations. While we believe any such claims are unsubstantiated, and we believe we are in compliance with applicable laws and regulations applicable to our business, the resolution of any such claims could be material.

We were not a party to any material legal proceedings at December 31, 2021, or at the date of this report except for matters listed below. We cannot currently predict the outcome of these actions.

Natera, Inc.

On January 27, 2020, Natera filed a lawsuit against ArcherDX (a subsidiary of Invitae effective October 2, 2020) in the United States District Court for the District of Delaware, alleging that ArcherDX's products using AMP chemistry, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814. On March 25, 2020, ArcherDX filed an answer denying Natera's allegations and asserting certain affirmative defenses and counterclaims, including that U.S. Patent No. 10,538,814 is invalid and not infringed. On April 15, 2020, Natera filed an answer denying ArcherDX's counterclaims and filed an amended complaint alleging that ArcherDX's products using AMP chemistry, including our therapy selection IVDs, PCM, LiquidPlex, ArcherMET, FusionPlex, and VariantPlex, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, U.S. Patent No. 10,590,482, and U.S. Patent No. 10,597,708, each of which are held by Natera. Natera seeks, among other things, damages and other monetary relief, costs and attorneys' fees, and an order enjoining ArcherDX from further infringement of such patents. On May 13, 2020, ArcherDX filed an answer to Natera's amended complaint denying Natera's allegations and asserting certain affirmative defenses and counterclaims, including that the asserted patents are invalid and not infringed. On June 3, 2020, Natera filed an answer denying ArcherDX's counterclaims. On June 4, 2020, ArcherDX filed a motion seeking dismissal of Natera's infringement claims against our therapy selection IVDs, PCM, and ArcherMET, and for a judgment that U.S. Patent

No. 10,538,814, U.S. Patent No. 10,557,172, and U.S. Patent No. 10,590,482 are invalid. On August 6, 2020, Natera filed another complaint against ArcherDX in the United States District Court for the District of Delaware alleging that ArcherDX's products using AMP chemistry, including our therapy selection IVDs, PCM, LiquidPlex, ArcherMET, and VariantPlex, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,731,220. Natera seeks, among other things, damages and other monetary relief, costs and attorneys' fees, and an order enjoining ArcherDX from further infringement of the patent. On October 13, 2020, the court issued an order denying ArcherDX's motion for dismissal of Natera's infringement claims against our therapy selection IVDs, PCM, and ArcherMET, and declined to enter judgment that U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, and U.S. Patent No. 10,590,482 are invalid. On January 12, 2021, the court issued an order granting Natera leave to amend its complaint to add Invitae as a co-defendant and plead allegations that ArcherDX and Invitae induce end-users to infringe the patents-in-suit. Natera filed its Second Amended Complaint on the same day, with service completed on January 15, 2021. ArcherDX and Invitae filed answers to the Second Amended Complaint on January 26, 2021 and February 5, 2021, respectively, denying Natera's allegations and restating certain affirmative defenses and counterclaims of non-infringement and invalidity. The litigations have now been consolidated for all purposes. A claim construction order was issued on June 28, 2021. On October 27, 2021, Natera filed its Third Amended Complaint to add a Certificate of Correction to U.S. Patent No. 10,590,482. On November 3, 2021, ArcherDX filed its Answer and Counterclaims to Natera's Third Amended Complaint, adding an inequitable conduct defense and declaratory judgment counterclaims. Discovery concluded in December 2021. On January 21, 2022, Natera, ArcherDX and Invitae moved for summary judgment, wherein Natera seeks a determination on certain legal and equitable defenses and ArcherDX and Invitae seek a determination of non-infringement and invalidity of the asserted patents. Trial is scheduled for May 2022.

In addition, on October 6, 2020, Natera filed a complaint against Genosity in the United States District Court for the District of Delaware, alleging that Genosity's use of its AsTra products, and the manufacture, use, sale, and offer for sale of such products, infringes U.S. Patent No. 10,731,220. Natera's complaint further alleges that Genosity's accused products use ArcherDX's ctDNA and region-specific primers. Genosity filed an answer to the complaint on February 15, 2021, denying Natera's allegations and setting forth affirmative defenses and counterclaims of non-infringement, invalidity and unenforceability due to inequitable conduct. On March 8, 2021, Natera filed a motion to dismiss and strike certain affirmative defenses and counterclaims brought by Genosity relating to inequitable conduct; the court has not yet issued a decision. No case schedule has been set.

QIAGEN Sciences

On July 10, 2018, ArcherDX and the General Hospital Corporation d/b/a Massachusetts General Hospital, which we refer to as MGH, filed a lawsuit in the United States District Court for the District of Delaware against QIAGEN Sciences, LLC, QIAGEN LLC, QIAGEN Beverly, Inc., QIAGEN Gaithersburg, Inc., QIAGEN GmbH and QIAGEN N.V., which is collectively referred to herein as QIAGEN, and a named QIAGEN executive who was a former member of ArcherDX's board of directors, alleging several causes of action, including infringement of the '810 Patent, trade secret misappropriation, breach of fiduciary duty, false advertising, tortious interference and deceptive trade practices. The '810 Patent relates to methods for preparing a nucleic acid for sequencing and aspects of ArcherDX's AMP technology. On October 30, 2019, with the permission of the Court, ArcherDX amended ArcherDX's complaint to add a claim for infringement of the '597 Patent. The '597 Patent relates to methods of preparing and analyzing nucleic acids, such as by enriching target sequences prior to sequencing, and aspects of ArcherDX's AMP technology. The QIAGEN products that ArcherDX alleges infringe the '810 Patent and the '597 Patent include, but are not limited to, QIAseq Targeted DNA Panels, QIAseq Targeted RNAscan Panels, QIAseq Index Kits and QIAseq Immune Repertoire RNA Library Kits. ArcherDX is seeking, among other things, damages for ArcherDX's lost profits due to QIAGEN's infringement and a permanent injunction enjoining QIAGEN from marketing and selling the infringing products and from using ArcherDX's trade secrets. On December 5, 2019, QIAGEN and the named QIAGEN executive submitted their answer denying the allegations in ArcherDX's complaint and asserting affirmative defenses that, among other things, the '810 Patent and '597 Patent are not infringed by QIAGEN's products, that both patents are invalid, and that the complaint fails to state any claim for which relief may be granted. On March 1, 2021, each of ArcherDX and QIAGEN moved for summary judgment on issues relating to infringement and validity of ArcherDX's patents, breach of fiduciary duty and trade secret misappropriation. On June 18, 2021, ArcherDX informed the court that it would not assert the following claims to streamline the issues for trial: trade secret misappropriation, false advertising, deceptive trade practices, and tortious interference. The court denied QIAGEN's motion for summary judgment on trade secret misappropriation as moot on June 21, 2021, denied QIAGEN's motion for summary judgment on breach of fiduciary duty on July 26, 2021, and granted QIAGEN's motion for summary judgment of no literal infringement of the '810 Patent on August 21, 2021. Trial proceeded on August 23 through August 27, 2021, resulting in a unanimous jury verdict, which found that: (i) all asserted claims of the '810 and '597 Patents are valid, (ii) QIAGEN willfully infringed the asserted claims of the '810 patent (under the doctrine of equivalents) and the '597 patent (literal infringement), and (iii) ArcherDX and MGH are entitled to recover approximately $4.7 million in damages. Both parties filed post-trial motions on October 21, 2021, in which (x) Qiagen seeks to overturn the jury verdict by requesting judgment as a matter of law or, in the alternative, a new trial or altered judgment on the issues of non-infringement, invalidity and damages, and (y) ArcherDX seeks a permanent injunction on infringing products and services approved for clinical diagnosis by a regulatory authority, ongoing royalty for products not enjoined, supplemental damages, interest and enhanced damages.

9. Stockholders' equity

Shares outstanding

Shares of convertible preferred and common stock were as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Convertible preferred stock:			
Shares outstanding, beginning of period	125	125	3,459
Conversion into common stock	(125)	—	(3,334)
Shares outstanding, end of period	—	125	125
Common stock:			
Shares outstanding, beginning of period	185,886	98,796	75,481
Common stock issued in private placement	—	16,320	—
Common stock issued in connection with public offering	8,932	24,005	11,136
Common stock issued on exercise of stock options, net	2,068	2,659	468
Common stock issued pursuant to vesting of RSUs	4,325	5,304	2,683
Common stock issued pursuant to exercises of warrants	208	968	31
Common stock issued pursuant to employee stock purchase plan	654	671	455
Common stock issued pursuant to acquisitions	25,918	37,163	5,208
Common stock issued upon conversion of preferred stock	125	—	3,334
Shares outstanding, end of period	228,116	185,886	98,796

Convertible preferred stock

In August 2017, in a private placement to certain accredited investors, we issued shares of our Series A convertible preferred stock which are convertible into common stock on a one-for-one basis, subject to adjustment for events such as stock splits, combinations and the like. The Series A convertible preferred stock is a non-voting common stock equivalent with a par value of $0.0001 and has the right to receive dividends first or simultaneously with payment of dividends on common stock. In the event of any liquidation or dissolution of the Company, the Series A preferred stock is entitled to receive $0.001 per share prior to the payment of any amount to any holders of capital stock ranking junior to the Series A preferred stock and thereafter shall participate pari passu with the holders of our common stock (on an as-if-converted-to-common-stock basis). During the year ended December 31, 2021, 124,913 shares of Series A convertible preferred stock were converted into 124,913 shares of common stock. As of December 31, 2021, there were no shares of Series A convertible preferred stock outstanding.

Sales Agreement

In May 2021, we entered into a sales agreement (the "2021 Sales Agreement") with Cowen and Company, LLC ("Cowen") under which we may offer and sell from time to time at our sole discretion shares of our common stock through Cowen as our sales agent, in an aggregate amount not to exceed $400.0 million. Per the terms of the agreement, Cowen will receive a commission of up to 3% of the gross proceeds of the sales price of all shares sold through it as sales agent under the 2021 Sales Agreement.

In August 2018, we entered into a Common Stock Sales Agreement (the "2018 Sales Agreement") with Cowen under which we may have offered and sold from time to time at our sole discretion shares of our common stock through Cowen as our sales agent, in an aggregate amount not to exceed $75.0 million. Per the terms of the agreement, Cowen received a commission equal to 3% of the gross proceeds of the sales price of all shares sold through it as sales agent under the 2018 Sales Agreement. In March 2019, we amended the 2018 Sales Agreement to increase the aggregate amount of our common stock to be sold under this agreement to an amount not to exceed

$175.0 million. During 2018, 2019 and 2020, we sold 8.7 million shares of our common stock for gross proceeds of the full $175.0 million under this agreement, and generated net proceeds of $169.1 million.

Public offerings

In January 2021, we sold, in an underwritten public offering, an aggregate of 8.9 million shares of our common stock at a price of $51.50 per share, for gross proceeds of $460.0 million and net proceeds of approximately $434.3 million after deducting underwriting discounts and commissions and offering expenses.

In April 2020, we sold, in an underwritten public offering, an aggregate of 20.4 million shares of our common stock at a price of $9.00 per share, for gross proceeds of $184.0 million and net proceeds of $173.0 million after deducting underwriting discounts and commissions and offering expenses.

Private placement

In connection with our acquisition of ArcherDX, in June 2020 we entered into a definitive agreement to sell $275.0 million in common stock in a private placement at a price of $16.85 per share. We received net proceeds of $263.7 million after deducting placement fees and offering expenses upon the closing of the private placement in October 2020, concurrently with our acquisition of ArcherDX.

10. Stock incentive plans

Stock incentive plans

In 2010, we adopted the 2010 Incentive Plan (the “2010 Plan”). The 2010 Plan provides for the granting of stock-based awards to employees, directors and consultants under terms and provisions established by our Board of Directors. Under the terms of the 2010 Plan, options may be granted at an exercise price not less than the fair market value of our common stock. For employees holding more than 10% of the voting rights of all classes of stock, the exercise prices for incentive and nonstatutory stock options must be at least 110% of fair market value of our common stock on the grant date, as determined by our Board of Directors. The terms of options granted under the 2010 Plan may not exceed ten years.

In January 2015, we adopted the 2015 Stock Incentive Plan (the “2015 Plan”), which became effective upon the closing of our initial public offering. Shares outstanding under the 2010 Plan were transferred to the 2015 Plan upon effectiveness of the 2015 Plan. The 2015 Plan provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 through January 1, 2025. In addition, shares subject to awards under the 2010 Plan that are forfeited or terminated will be added to the 2015 Plan. The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, stock units, stock appreciation rights and other forms of equity compensation, all of which may be granted to employees, including officers, non-employee directors and consultants. Additionally, the 2015 Plan provides for the grant of cash-based awards.

Options granted generally vest over a period of four years. Typically, the vesting schedule for options granted to newly hired employees provides that 1/4 of the award vests upon the first anniversary of the employee’s date of hire, with the remainder of the award vesting monthly thereafter at a rate of 1/48 of the total shares subject to the option. All other options typically vest in equal monthly installments over the four-year vesting schedule. Upon the acquisition of ArcherDX in October 2020, any option that was outstanding was converted into a fully vested option to purchase a share of our common stock, which resulted in the issuance of options to purchase 3.7 million shares of our common stock.

RSUs generally vest over a period of three years. Typically, the vesting schedule for RSUs provides that 1/3 of the award vests upon each anniversary of the grant date, with certain awards that include a portion that vests immediately upon grant. We have certain awards granted in connection with our management incentive plan that vest over a period of two years. In June 2019, we granted Time-based RSUs in connection with the acquisition of Singular Bio which vest in three equal installments over a period of 18 months and PRSUs that vest based on the achievement of performance conditions; see further details in Note 4, "Business combinations." In December 2020, we granted RSUs in connection with an asset acquisition which vest in two equal installments in December 2021 and December 2022, subject to the employees' continued service with us.

Under our management incentive compensation plan, in July 2019 we granted PRSUs to our executive officers as well as other specified senior level employees based on the level of achievement of a specified 2019 revenue goal. One-third of the 0.8 million shares that were ultimately awarded under this plan vested during the year ended December 31, 2020 and the remaining shares will vest through March 2022. In June 2020, we granted 0.3 million PRSUs under this plan which are based on the level of achievement of a specified 2020 cash burn goal. Upon achievement of the specified 2020 cash burn goal, 0.3 million shares were ultimately awarded and began vesting in

2021 over a one year period. These PRSUs had a grant date fair value of $4.2 million based on an estimated issuance of 0.3 million shares and expectation of the performance conditions. During the year ended December 31, 2021, $2.7 million was recorded as stock-based compensation expense related to the awards.

Activity under the 2010 Plan and the 2015 Plan is set forth below (in thousands, except per share amounts and years):

	Shares Available For Grant	Stock Options Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Balance at December 31, 2020	7,447	4,877	$ 7.75	6.8	$ 166,130
Additional shares reserved	17,138	—			
Options granted	(267)	267	$ 32.25		
Options cancelled	42	(42)	$ 25.24		
Options exercised	—	(2,068)	$ 4.34		
RSUs and PRSUs granted	(15,322)	—			
RSUs and PRSUs cancelled	1,204	—			
Balance at December 31, 2021	10,242	3,034	$ 11.98	5.5	$ 16,431
Options exercisable at December 31, 2021		2,598	$ 9.75	4.9	$ 15,989
Options vested and expected to vest at December 31, 2021		3,009	$ 11.93	5.4	$ 16,401

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of our common stock for stock options that were in-the-money.

The weighted-average fair value of options to purchase common stock granted was $22.46, $10.10 and $14.52 in the years ended December 31, 2021, 2020 and 2019, respectively.

The total grant-date fair value of options to purchase common stock vested was $2.4 million, $2.8 million and $4.3 million in the year ended December 31, 2021, 2020, and 2019, respectively.

The intrinsic value of options to purchase common stock exercised was $55.0 million, $104.4 million and $6.3 million in the years ended December 31, 2021, 2020 and 2019, respectively.

The following table summarizes RSU, including PRSU, activity (in thousands, except per share data):

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance at December 31, 2020	6,602	$ 12.89
RSUs granted	6,468	$ 30.01
Time-based RSUs and PRSUs granted - variable	8,645	$ 31.23
PRSUs granted	209	$ 34.75
RSUs vested	(4,473)	$ 22.16
RSUs cancelled	(1,204)	$ 26.11
Balance at December 31, 2021	16,247	$ 26.21

2015 ESPP

In January 2015, we adopted the 2015 ESPP, which became effective upon the closing of the IPO. Employees participating in the ESPP may purchase common stock at 85% of the lesser of the fair market value of common stock on the purchase date or last trading day preceding the offering date. At December 31, 2021, cash received from payroll deductions pursuant to the ESPP was $3.0 million.

The ESPP provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 and continuing through January 1, 2025. At December 31, 2021, a total of 2.1 million shares of common stock are reserved for issuance under the ESPP.

Stock-based compensation

We use the grant date fair value of our common stock to value options when granted. In determining the fair value of stock options and ESPP purchases, we use the Black-Scholes option-pricing model and, for stock options, the assumptions discussed below. Each of these inputs is subjective and its determination generally requires significant judgment. The fair value of RSU and PRSU awards is based on the grant date share price. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and RSUs and on an accelerated basis for PRSUs.

Expected term—The expected term represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method (based on the midpoint between the vesting date and the end of the contractual term).

Expected volatility—We estimate expected volatility based on the historical volatility of our common stock over a period equal to the expected term of stock option grants and RSUs and over the expected six-month term ESPP purchase periods.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

Dividend yield—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

The fair value of share-based payments for stock options granted to employees and directors was estimated on the date of grant using the Black-Scholes option-pricing model based on the following assumptions:

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	6.0	6.0	6.0
Expected volatility	73.5%	71.0%	64.2%
Risk-free interest rate	1.1%	0.5%	2.6%

The fair value of shares purchased pursuant to the ESPP is estimated using the Black-Scholes option pricing model. For the years ended December 31, 2021, 2020 and 2019, the weighted-average grant date fair value per share for the ESPP was $8.10, $10.98 and $6.05, respectively.

The fair value of the shares purchased pursuant to the ESPP was estimated using the following assumptions:

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	0.5	0.5	0.5
Expected volatility	66.1%	105.7%	66.3%
Risk-free interest rate	0.0%	0.1%	2.0%

The following table summarizes stock-based compensation expense for the years ended December 31, 2021, 2020 and 2019, included in the consolidated statements of operations (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Cost of revenue	$ 12,033	$ 8,713	$ 4,563
Research and development	92,407	91,762	52,450
Selling and marketing	15,641	14,418	7,641
General and administrative	59,994	43,854	11,294
Total stock-based compensation expense	$ 180,075	$ 158,747	$ 75,948

At December 31, 2021, unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was $5.8 million, which we expect to recognize on a straight-line basis over a weighted-average period of 2.3 years. Unrecognized compensation expense related to RSUs, including PRSUs, and awards that are contingently issuable upon the completion of certain milestones related to our acquisitions of ArcherDX and IntelliGene Health Informatics, LLC at December 31, 2021, net of estimated forfeitures, was $327.4 million, which we expect to recognize on a straight-line basis over a weighted-average period of 2.0 years.

11. Income taxes

We recorded a benefit for income taxes in the years ended December 31, 2021, 2020 and 2019. The components of net loss before taxes by U.S. and foreign jurisdictions are as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
United States	$ 414,657	$ 712,409	$ 260,531
Foreign	1,206	1,861	(116)
Total	$ 415,863	$ 714,270	$ 260,415

The components of the provision for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Current:			
Foreign	2,069	171	85
Total current benefit for income taxes	2,069	171	85
Deferred:			
Federal	(28,348)	(94,279)	(16,011)
State	(8,809)	(17,730)	(2,524)
Foreign	(1,769)	(262)	—
Total deferred benefit for income taxes	(38,926)	(112,271)	(18,535)
Total income tax benefit	$ (36,857)	$ (112,100)	$ (18,450)

The following table presents a reconciliation of the tax expense computed at the statutory federal rate and our tax expense for the periods presented:

	Year Ended December 31,		
	2021	2020	2019
U.S. federal taxes at statutory rate	21.0 %	21.0 %	21.0 %
State taxes (net of federal benefit)	7.3 %	3.4 %	3.7 %
Stock-based compensation	(1.2)%	(1.6)%	1.3 %
Research and development credits	3.8 %	1.1 %	— %
Non-deductible expenses	(0.9)%	(0.7)%	(1.6)%
Foreign tax differential	(0.1)%	— %	— %
Acquisition contingent liabilities	18.5 %	(0.8)%	— %
Change in valuation allowance	(39.5)%	(6.7)%	(17.3)%
Total	8.9 %	15.7 %	7.1 %

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	As of December 31, 2021	As of December 31, 2020
Deferred tax assets:		
Net operating loss carryforwards	$ 530,663	$ 337,866
Tax credits	36,188	19,969
Revenue recognition differences	2,560	9,099
Leasing liabilities	34,403	14,274
Accruals and other	36,689	37,677
Gross deferred tax assets	640,503	418,885
Valuation allowance	(386,950)	(209,308)
Total deferred tax assets	253,553	209,577
Deferred tax liabilities:		
Amortization and depreciation	(271,517)	(233,150)
Convertible Senior Notes	—	(14,658)
Leasing Assets	(33,732)	(13,307)
Total deferred tax liabilities	(305,249)	(261,115)
Net deferred tax liabilities	$ (51,696)	$ (51,538)

In December 2017, the Tax Cuts and Jobs Act of 2017 (the “Tax Act”) was signed into law making significant changes to the Internal Revenue Code. Changes included among other items, a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%. Although the Tax Act was generally effective January 1, 2018, GAAP required recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017. As a result of the lower corporate tax rate enacted as part of the Tax Act, during 2017, the Company recorded a provisional estimate to reduce deferred tax assets by $48.8 million offset by a corresponding reduction in the valuation allowance resulting in no net impact to our income tax benefit or expense.

In December 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In accordance with SAB 118, during 2017, we recorded a provisional estimate which resulted in a $48.8 million reduction in deferred tax assets and in the fourth quarter of 2018, we completed our analysis of the impact of the Tax Act and determined that no material adjustments were required to the provisional amounts previously recorded.

The Company historically established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding realization of such assets. In 2021 the Company released approximately $37.2 million of its valuation allowance to account for acquired intangibles that support the future realization of some of the Company's deferred tax assets. Due to the overall increase of deferred tax assets, the Company's valuation allowance also increased from the prior year. The Company's valuation allowance increased by $177.6 million, $64.0 million, and $23.4 million during the years ended December 31, 2021, 2020, and 2019, respectively.

As of December 31, 2021, the Company had net operating loss carryforwards of approximately $2.2 billion and $1.3 billion available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. Of the $2.2 billion, $284.9 million will begin to expire in 2030 while $1.9 billion have no expiration date. The state net operating loss carryforwards will begin to expire in 2030.

As of December 31, 2021, the Company had research and development credit carryforwards of approximately $58.3 million and $25.2 million available to reduce our future tax liability, if any, for federal and state income tax purposes, respectively. The federal credit carryforwards begin to expire in 2030. California credit carryforwards have no expiration date.

Internal Revenue Code ("IRC") section 382 places a limitation (the “Section 382 limitation” or “annual limitation”) on the amount of taxable income that can be offset by net operating loss carryforwards after a change in control (generally greater than 50% change in ownership) of a loss corporation. Similar provisions exist for states. In addition, and as a result of the acquisitions of Good Start Genetics and CombiMatrix in 2017, acquisitions of Singular Bio, Jungla, and Clear Genetics in 2019, acquisitions of YouScript and ArcherDX in 2020, and acquisitions of One

Codex, Genosity, Ciitizen, and Stratify in 2021, tax loss carryforwards from acquired entities are also subject to the Section 382 limitation due to the change in control in the acquired entities in the current year.

In addition, as a result of equity issued in connection with various acquisitions, the Company also performed a section 382 analysis in 2021 with respect to our operating loss and credit carryforwards. The Company concluded while an ownership change occurred in 2020 as defined under IRC section 382, none of the Company's net operating loss carryforwards would expire unused solely as a result of annual limitations imposed on the use of the carryforwards under IRC sections 382 and 383.

Our policy with respect to undistributed foreign subsidiaries' earnings is to consider those earnings to be indefinitely reinvested. As a result of the enactment in the Tax Cuts and Job Acts of 2017, if and when funds are actually distributed in the form of dividends or otherwise, we expect minimal tax consequences, except for withholding taxes, which would be applicable in some jurisdiction.

As of December 31, 2021, we had unrecognized tax benefits of $46.7 million, which primarily relates to research and development credits, $1.9 million of which would currently affect the Company's effective tax rate if recognized due to the Company's valuation allowance against its deferred tax assets. During the year, the Company benchmarked the reserves of similar tax positions within the industry based on IRS and state audits of comparable companies. Based on its analysis, the Company decreased its unrecognized tax benefits to more closely align with other comparable companies within the industry. As these reserves relate primarily to research and development credits which have a full valuation allowance, such adjustments did not impact the Company's income tax provision. Unrecognized tax benefits are not expected to materially change in the next 12 months.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Year ended December 31,		
	2021	2020	2019
Unrecognized tax benefits, beginning of period	$ 21,965	$ 26,985	$ 16,375
Gross increases—current period tax positions	18,165	8,368	10,311
Gross increases—prior period tax positions	6,539	53	299
Gross decreases—prior period tax positions	—	(13,441)	—
Unrecognized tax benefits, end of period	$ 46,669	$ 21,965	$ 26,985

The Company's policy is to include penalties and interest expense related to income taxes as a component of tax expense. The Company has not accrued interest and penalties related to the unrecognized tax benefits reflected in the financial statements for the years ended December 31, 2021, 2020 and 2019.

The Company's major tax jurisdictions are the United States and California. All of the Company's tax years will remain open for examination by the Federal and state tax authorities for three and four years, respectively, from the date of utilization of the net operating loss or research and development credit. The Company does not have any tax audits pending.

12. Net loss per share

The following table presents the calculation of basic and diluted net loss per share (in thousands, except per share data):

	Year ended December 31,		
	2021	2020	2019
Net loss	$ (379,006)	$ (602,170)	$ (241,965)
Shares used in computing net loss per share, basic and diluted	210,946	134,587	90,859
Net loss per share, basic and diluted	$ (1.80)	$ (4.47)	$ (2.66)

The following common stock equivalents have been excluded from diluted net loss per share because their inclusion would be anti-dilutive (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Shares of common stock subject to outstanding options	4,069	6,878	3,662
Shares of common stock subject to outstanding warrants	29	405	592
Shares of common stock subject to outstanding RSUs	9,146	5,590	5,293
Shares of common stock subject to outstanding PRSUs	737	1,658	1,860
Shares of common stock pursuant to ESPP	425	294	239
Shares of common stock underlying Series A convertible preferred stock	93	125	702
Shares of common stock subject to Convertible Senior Notes conversion	38,403	8,371	3,612
Total shares of common stock equivalents	52,902	23,321	15,960

13. Geographic information

Revenue by country is determined based on the billing address of the customer and is summarized as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
United States	$ 404,013	$ 255,680	$ 202,550
Canada	7,553	4,529	4,356
Rest of world	48,883	19,389	9,918
Total revenue	$ 460,449	$ 279,598	$ 216,824

As of December 31, 2021, 2020 and 2019, our long-lived assets were primarily located in the United States other than operating lease assets representing our right-of-use for leased facilities in Australia, Belgium and Israel.

14. Selected quarterly data (unaudited)

The following table summarizes our quarterly financial information for 2021 and 2020 (in thousands, except per share amounts):

	Three Months Ended			
	March 31, 2021	June 30, 2021	September 30, 2021	December 31, 2021
Revenue	$ 103,621	$ 116,312	$ 114,395	$ 126,121
Cost of revenue	$ 75,491	$ 89,331	$ 87,741	$ 96,106
(Loss) income from operations	$ (112,364)	$ 128,609	$ (193,312)	$ (214,574)
Net (loss) income	$ (109,492)	$ 133,786	$ (198,176)	$ (205,124)
Net loss per share, basic[(1)]	$ (0.56)	$ 0.66	$ (0.91)	$ (0.90)
Net loss per share, diluted[(1)]	$ (0.56)	$ 0.53	$ (0.91)	$ (0.90)

	Three Months Ended			
	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020
Revenue	$ 64,248	$ 46,191	$ 68,728	$ 100,431
Cost of revenue	$ 40,422	$ 42,952	$ 46,643	$ 68,258
Loss from operations	$ (97,784)	$ (142,082)	$ (80,823)	$ (331,483)
Net loss	$ (98,527)	$ (166,403)	$ (102,902)	$ (234,338)
Net loss per share, basic and diluted[(1)]	$ (0.99)	$ (1.29)	$ (0.78)	$ (1.30)

(1) Net loss (income) per share is computed independently for each of the quarters presented. Therefore, the sum of quarterly net loss per share information may not equal annual net loss per share.

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

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer) have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation described in Item 9A above that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's annual report on internal control over financial reporting

Our management is responsible for establishing and maintaining internal control over our financial reporting. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Projections of any evaluation of the effectiveness of internal control 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 policies or procedures may deteriorate. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework (2013 Framework). Based on the assessment using those criteria, our management concluded that, as of December 31, 2021, our internal control over financial reporting was effective. Our independent registered public accounting firm, Ernst & Young LLP, has issued an audit report with respect to our internal control over financial reporting, which appears in Part II, Item 8. of this Annual Report on Form 10-K.

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Invitae Corporation

Opinion on Internal Control Over Financial Reporting

We have audited Invitae Corporation's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Invitae Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Invitae Corporation as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements") and our report dated March 1, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's 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

Redwood City, California

March 1, 2022

ITEM 9B. Other Information

None.

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 with respect to directors is incorporated by reference from the information under the caption “Election of Directors,” contained in our proxy statement to be filed with the Securities and Exchange Commission no later than 120 days from the end of our fiscal year ended December 31, 2021 in connection with the solicitation of proxies for our 2022 Annual Meeting of Stockholders, or the Proxy Statement. Certain information required by this item concerning executive officers is set forth in Part I of this Report under the caption “Information about our executive officers” and is incorporated herein by reference.

There have been no material changes to the procedures by which stockholders may recommend nominees to our Board of Directors.

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16(a) of the Exchange Act. To the extent disclosure for delinquent reports is being made, it can be found under the caption “Delinquent Section 16(a) Reports” in the Proxy Statement and is incorporated herein by reference.

Our board of directors has adopted a Code of Business Conduct and Ethics that applies to each of our directors, officers and employees. The Code of Business Conduct and Ethics set forth the basic principles that guide the business conduct of our employees. Our board of directors has also adopted a Code of Ethics for Senior Financial Officers applicable to our Chief Executive Officer and Chief Financial Officer as well as other key management employees addressing ethical issues. The Code of Business Conduct and Ethics and the Code of Ethics for Senior Financial Officers are each posted on our website www.invitae.com. The Code of Business Conduct and Ethics and the Code of Ethics for Senior Financial Officers can only be amended by the approval of a majority of our board of directors. Any waiver to the Code of Business Conduct and Ethics for an executive officer or director or any waiver of the Code of Ethics for Senior Financial Officers may only be granted by our board of directors or our nominating and corporate governance committee and must be timely disclosed as required by applicable law. We have implemented whistleblower procedures that establish formal protocols for receiving and handling complaints from employees. Any concerns regarding accounting or auditing matters reported under these procedures will be communicated promptly to our audit committee. Stockholders may request a free copy of our Code of Business Conduct and Ethics and Code of Ethics foe Senior Financial Officers by contacting Invitae Corporation, Attention: Chief Financial Officer, 1400 16th Street, San Francisco, California 94103. None of the materials on, or accessible through, our website is part of this report or incorporated by reference herein.

To date, there have been no waivers under our Code of Business Conduct and Ethics or Code of Ethics for Senior Financial Officers. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics or Code of Ethics for Senior Financial Officers or waivers of such codes granted to executive officers and directors on our website at http://www.invitae.com within four business days following the date of such amendment or waiver.

Our Board of Directors has appointed an Audit Committee, comprised of Christine M. Gorjanc, Geoffrey S. Crouse and Kimber D. Lockhart. The Board of Directors has determined that each of Ms. Gorjanc and Mr. Crouse qualifies as an "audit committee financial expert" under the definition outlined by the Securities and Exchange Commission. In addition, each of the members of the Audit Committee qualifies as an "independent director" under the current rules of the New York Stock Exchange and Securities and Exchange Commission rules and regulations.

ITEM 11. Executive Compensation

The information required by this item is incorporated by reference from the information under the captions “Election of Directors-Director Compensation,” “Election of Directors—Compensation Committee Interlocks and Insider Participation” and “Executive Compensation” contained in the Proxy Statement.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated by reference to the disclosure appearing under the headings “Security Ownership of Certain Beneficial Owners and Management” and “Executive Compensation—Equity Compensation Plan Information” contained in the Proxy Statement.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference from the information under the captions “Certain Relationships and Related Transactions,” "Corporate Governance" and “Director Independence” contained in the Proxy Statement.

ITEM 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference from the information under the caption “Ratification of the Appointment of Independent Registered Public Accounting Firm” contained in the Proxy Statement.

PART IV

ITEM 15. Exhibit and Financial Statement Schedules

(a) Documents filed as part of this report

1. *Financial Statements:* Reference is made to the Index to Financial Statements of Invitae Corporation included in Item 8. of Part II hereof.
2. *Financial Statement Schedules:* All schedules have been omitted because they are not required, not applicable, or the required information is included in the financial statements or notes thereto.
3. *Exhibits*: See Item 15(b) below. Each management contract or compensating plan or arrangement required to be filed has been identified.

(b) Exhibits

		Incorporated by Reference			
Exhibit Number	**Exhibit Description**	**Form**	**Exhibit**	**Filing Date**	**Filed Herein**
2.1@	Agreement and Plan of Merger and Plan of Reorganization, dated as of June 21, 2020, by and among Invitae Corporation, Apollo Merger Sub A Inc., Apollo Merger Sub B LLC, ArcherDX, Inc. and Kyle Lefkoff, solely in his capacity as holders' representative.	8-K	2.1	6/24/2020	
2.2@	Stock Purchase and Merger Agreement, dated as of July 11, 2019, by and among Invitae Corporation, Jumanji, LLC, Jungla Inc., and Fortis Advisors LLC.	10-Q	2.2	8/6/2019	
2.3@^	Agreement and Plan of Merger, dated as of November 8, 2019, by and among Invitae Corporation, Catalina Merger Sub A Inc., Catalina Merger Sub B LLC, Clear Genetics, Inc. and Shareholder Representative Services LLC.	10-K	2.3	3/2/2020	
2.4@^	Share Purchase Agreement, dated as of March 10, 2020, by and among Invitae Corporation, Invitae Netherlands, B.V. and Peter Schols.	10-Q	2.1	5/11/2020	
2.5@^	Agreement and Plan of Merger, dated as of March 10, 2020, by and among Invitae Corporation, Yasawa Merger Sub A Inc., Yasawa Merger Sub B LLC, YouScript Incorporated, and Fortis Advisors LLC, as representative of YouScript Incorporated's stockholders.	10-Q	2.1	8/4/2020	
2.6@^	Unit Purchase Agreement, dated as of March 10, 2020, by and among Invitae Corporation, David Colaizzi, Chris Howlett, Anthony Muhlenkamp, Gerald Schneider, and Matt Lehrian.	10-Q	2.2	8/4/2020	
3.1	Restated Certificate of Incorporation.	8-K	3.1	2/23/2015	
3.1.1	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Invitae Corporation.	8-K	3.1	8/1/2017	
3.2	Amended and Restated Bylaws.	8-K	3.2	2/23/2015	
4.1	Form of Common Stock Certificate.	10-K	4.1	2/26/2021	
4.2	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	4.2	3/2/2020	
4.3	Indenture dated as of September 10, 2019, between Invitae Corporation and U.S. Bank National Association, as trustee (including form of Note).	8-K	4.1	9/11/2019	
4.4	Indenture, dated as of April 8, 2021, between Invitae Corporation and U.S. Bank National Association (including form of Note).	8-K	4.1	4/8/2021	
4.5	Amended and Restated Registration Rights Agreement, dated as of July 31, 2017.	8-K	10.4	8/1/2017	
4.6	Registration Rights Agreement, dated as of October 2, 2020, by and among Invitae Corporation and the investors party thereto.	8-K	10.2	10/5/2020	
4.7	Registrations Rights Agreement, dated as of February 8, 2021, by and among the Invitae Corporation and certain securityholders of Reference Genomics, Inc. d/b/a One Codex.				X

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herein
		Form	Exhibit	Filing Date	
4.8	Registration Rights Agreement, dated as of September 13, 2021, by and among Invitae Corporation and certain stockholders of Ciitizen Corporation.				X
10.1	Form of Indemnification Agreement between Invitae Corporation and its officers and directors.	S-1 (File No. 333-201433)	10.1	1/9/2015	
10.2	Lease Agreement dated as of September 2, 2015 by and between Invitae Corporation and 1400 16th Street LLC.	8-K	10.1	9/4/2015	
10.3	Lease Agreement, dated as of April 20, 2021, by and between Invitae Corporation and APB Owned LLC.	8-K	10.1	4/23/2021	
10.4@^	Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent.	8-K	10.3	10/5/2020	
10.5	Amendment No. 1, dated as of April 3, 2021, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent, to Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent.	8-K	10.2	4/5/2021	
10.6	Amendment No. 2, dated as of September 20, 2021, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent, to Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent.	10-Q	10.1	11/9/2021	
10.7#	Invitae Corporation 2015 Stock Incentive Plan, as amended and restated as of August 31, 2021.	10-Q	10.3	11/9/2021	
10.8#	Form of Notice of Stock Option Grant and Non-Qualified Stock Option Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan.	S-1 (File No. 333-201433)	10.6	2/11/2015	
10.9#	Form of Notice of Restricted Stock Award and Restricted Stock Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan.	S-1 (File No. 333-201433)	10.7	2/11/2015	
10.10#	Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan.	8-K	10.1	8/6/2015	
10.11#	Form of Notice of Time-Based Restricted Stock Unit Award and Time-Based Restricted Stock Unit Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan (Inducement).	10-Q	10.2	8/6/2019	
10.12#	Form of Notice of Performance-Based Restricted Stock Unit Award and Performance-Based Restricted Stock Unit Agreement for awards under the Invitae Corporation 2015 Stock Incentive Plan (Inducement).	10-Q	10.3	8/6/2019	
10.13#	Form of Global Restricted Stock Unit Agreement under the Invitae Corporation 2015 Stock Incentive Plan.	10-Q	10.4	11/9/2021	
10.14#	Invitae Corporation Employee Stock Purchase Plan, as amended and restated as of October 14, 2021.	10-Q	10.2	11/9/2021	
10.15#	ArcherDX, Inc. 2015 Equity Incentive Plan, as amended, and forms of agreements thereunder.	10-K	10.21	2/26/2021	
10.16#	Stratify Genomics Inc. 2018 Equity Incentive Plan, as amended by Amendment No. 1 and Amendment No. 2.				X

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herein
		Form	Exhibit	Filing Date	
10.17	Form of Warrant to Purchase Common Stock between Oxford Capital, LLC and Invitae Corporation.	10-K	10.14	3/16/2017	
10.18	Sales Agreement, dated May 4, 2021, between Invitae Corporation and Cowen and Company, LLC.	8-K	1.1	5/4/2021	
10.19#	Offer Letter, dated as of June 1, 2020, by and between Invitae Corporation and Kenneth D. Knight.	8-K	10.1	6/26/2020	
10.20#	Offer Letter, dated May 19, 2021, between Invitae Corporation and Roxi Wen.	8-K	10.1	6/11/2021	
10.21#	Change in Control and Severance Agreement, between Invitae Corporation and Sean George.	10-Q	10.5	8/9/2021	
10.22#	Form of Change in Control and Severance Agreement, between Invitae Corporation and certain officers.	10-Q	10.6	8/9/2021	
10.23	Securities Purchase Agreement, dated as of June 21, 2020, by and among Invitae Corporation and the investors identified therein.	8-K	10.1	6/24/2020	
10.24	Support Agreement, dated as of September 23, 2020, by and among Invitae Corporation and certain securityholders of ArcherDX, Inc.	8-K	10.4	10/5/2020	
10.25	Investment Agreement, dated as of April 3, 2021, by and among Invitae Corporation and parties listed therein (including form of Indenture relating to 1.50% Convertible Senior Notes due 2028).	8-K	10.1	4/5/2021	
21.1	List of Subsidiaries.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney (contained on the signature page to this Form 10-K).				X
31.1	Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Principal Financial and Accounting Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).				X
32.2	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).				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				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase				X
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document and included as Exhibit 101).				

#	Indicates management contract or compensatory plan or arrangement.
@	The schedules and exhibits to this agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.
^	Portions of this exhibit have been redacted in accordance with Item 601(b)(2)(ii) and Item 601(b)(10)(iv) of Regulation S-K.

Copies of the above exhibits not contained herein are available to any stockholder, upon payment of a reasonable per page fee, upon written request to: Chief Financial Officer, Invitae Corporation, 1400 16th Street, San Francisco, California 94103.

(c) Financial Statement Schedules: Reference is made to Item 15(a) 2 above.

ITEM 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

INVITAE CORPORATION

By: /s/ Sean E. George, Ph.D.

Sean E. George, Ph.D.
President and Chief Executive Officer

Date: March 1, 2022

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Sean E. George and Yafei (Roxi) Wen, and each of them, his true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their 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 report has been signed below by the following persons, on behalf of the registrant on the dates and the capacities indicated.

Signature	Title	Date
/s/ Sean E. George, Ph.D. Sean E. George, Ph.D.	President and Chief Executive Officer (Principal Executive Officer) and Director	March 1, 2022
/s/ Yafei (Roxi) Wen Yafei (Roxi) Wen	Chief Financial Officer (Principal Financial Officer)	March 1, 2022
/s/ Robert F. Werner Robert F. Werner	Chief Accounting Officer (Principal Accounting Officer)	March 1, 2022
/s/ Eric Aguiar, M.D. Eric Aguiar, M.D.	Director	March 1, 2022
/s/ Geoffrey S. Crouse Geoffrey S. Crouse	Director	March 1, 2022
/s/ Christine M. Gorjanc Christine M. Gorjanc	Director	March 1, 2022
/s/ Kimber D. Lockhart Kimber D. Lockhart	Director	March 1, 2022
/s/ Chitra Nayak Chitra Nayak	Director	March 1, 2022

REGISTRATION RIGHTS AGREEMENT

This Registration Rights Agreement (this "Agreement") is made and entered into as of February 8, 2021 (the "Effective Date") by and among Invitae Corporation, a Delaware corporation (the "Company"), and certain securityholders of Reference Genomics, Inc. d/b/a One Codex, a Delaware corporation ("One Codex") listed on Exhibit A hereto (each such securityholder, as well as any permitted transferee of Registrable Securities (as defined below) hereunder, in each case to the extent holding Registrable Securities, a "Holder" and collectively, the "Holders"). Terms used but not otherwise defined herein shall have the meaning ascribed to such terms in the Merger Agreement (as defined below).

RECITALS

WHEREAS, the Company, One Codex, Orion Merger Sub A Inc., a Delaware corporation and wholly owned subsidiary of the Company ("Merger Sub A"), Orion Merger Sub B LLC, a Delaware limited liability company and wholly owned subsidiary of the Company ("Merger Sub B"), and Fortis Advisors LLC, a Delaware limited liability company, as Holders' Representative (as defined therein), have entered into that certain Agreement and Plan of Merger dated as of February 3, 2021 (the "Merger Agreement"), pursuant to which (i) Merger Sub A will be merged with and into One Codex, and One Codex shall continue as the surviving entity and wholly owned subsidiary of the Company (the "Reverse Merger") and (ii) promptly thereafter as part of the same overall transaction, and in all cases on the Closing Date, One Codex will be merged with and into Merger Sub B, and Merger Sub B shall continue as the surviving entity and wholly owned subsidiary of the Company (the "Forward Merger" and, together with the Reverse Merger, the "Mergers");

WHEREAS, in connection with the Mergers and pursuant to the Merger Agreement, the Company issued to the Holders at the Closing shares of the Company's common stock, par value $0.0001 per share, identified on Exhibit A hereto as Stock Consideration Shares (the "Shares") pursuant to the Merger Agreement; and

WHEREAS, in connection with the consummation of the transactions contemplated by the Merger Agreement, the Company agreed to grant certain registration rights to the Holders as set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the parties agree as follows:

ARTICLE I
DEFINITIONS

Section 1.1 Definitions. For purposes of this Agreement, the following terms and variations thereof have the meanings set forth below:

"Affiliate" means, with respect to any person, any other person that, directly or indirectly, controls, or is controlled by, or is under common control with, such person. For this purpose: (a) "control" (including, with its correlative meanings, "controlled by" and "under

common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of management or policies of a Person, whether through the ownership of securities or partnership or other ownership interests, by contract or otherwise; and (b) "person" means any natural person, corporation, limited liability company, partnership, association, trust or other entity.

"Agreement" has the meaning set forth in the preamble.

"Business Day" means any day, other than a Saturday, Sunday or one on which banks are authorized by law to be closed in New York, New York.

"Company" has the meaning set forth in the preamble.

"Company Indemnitee" has the meaning set forth in Section 4.1(b).

"Effective Date" has the meaning set forth in the preamble.

"Effectiveness Period" has the meaning set forth in Section 3.1(b).

"Exchange Act" means the Securities Exchange Act of 1934.

"Grace Period" has the meaning set forth in Section 3.2(h).

"Holder" has the meaning set forth in the preamble.

"Holder Indemnitee" has the meaning set forth in Section 4.1(a).

"Indemnified Party" has the meaning set forth in Section 4.1(c).

"Indemnifying Party" has the meaning set forth in Section 4.1(c).

"Merger Agreement" has the meaning set forth in the recitals.

"One Codex" has the meaning set forth in the preamble.

"Registrable Securities" means the Shares issued to the Holders pursuant to the Merger Agreement and any securities issued or issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect to such securities; provided, however, that Registrable Securities shall cease to be Registrable Securities with respect to a particular Holder when (i) such securities have been disposed of in accordance with the Registration Statement or pursuant to Rule 144; (ii) such securities may be sold pursuant to Rule 144 without any limitation as to manner-of-sale restrictions or volume limitations; or (iii) such securities cease to be outstanding.

"Registration Expenses" means all expenses incurred by the Company in effecting the registration pursuant to this Agreement, including all registration and filing fees, printing

expenses, fees and disbursements of counsel for the Company, "blue sky" fees and expenses, and expenses of the Company's independent registered public accounting firm in connection with any regular or special reviews or audits incident to or required by any such registration, but shall not include Selling Expenses.

"Registration Statement" has the meaning set forth in Section 3.1.

"Rule 144" means Rule 144 under the Securities Act or any successor or other similar rule, regulation or interpretation of the SEC that may at any time permit the sale of Registrable Securities to the public without registration.

"Rule 405" means Rule 405 under the Securities Act or any successor or other similar rule.

"Rule 415" means Rule 415 under the Securities Act or any successor or other similar rule providing for offering securities on a continuous or delayed basis.

"Rule 424" means Rule 424 under the Securities Act or any successor or other similar rule.

"Shares" has the meaning set forth in the recitals.

"SEC" means the Securities and Exchange Commission.

"Securities Act" means the Securities Act of 1933.

"Selling Expenses" means all discounts, selling commissions, fees of selling brokers, dealer managers and similar securities industry professionals and stock transfer taxes applicable to the sale of Registrable Securities and fees and disbursements of counsel for any Holder (other than the fees and disbursements of counsel for the Company included in Registration Expenses).

"Transfer" means, directly or indirectly, to sell, transfer, assign, pledge, encumber, hypothecate or similarly dispose of (by merger, testamentary disposition, operation of law or otherwise), either voluntarily or involuntarily, or to enter into any contract, option or other arrangement or understanding with respect to the sale, transfer, assignment, pledge, encumbrance, hypothecation or similar disposition of (by merger, testamentary disposition, operation of law or otherwise) any Shares.

"Violation" has the meaning set forth in Section 4.1(a).

ARTICLE II
TRANSFER RESTRICTIONS

Section 2.1 General Transfer Restrictions. The right of any Holder to Transfer any Shares held by it is subject to the restrictions set forth below.

(a) Each Holder acknowledges that the Shares have not been registered under the Securities Act and may not be Transferred except pursuant to an effective registration statement under the Securities Act or pursuant to an exemption from registration under the Securities Act. Each Holder covenants that the Shares will only be disposed of pursuant to an effective registration statement under, and in compliance with the requirements of, the Securities Act or pursuant to an available exemption from the registration requirements of the Securities Act, and in compliance with any applicable state and foreign securities laws. In connection with any Transfer of the Shares other than a Transfer (i) pursuant to an effective registration statement, (ii) to the Company, (iii) pursuant to Rule 144 or (iv) if Holder is a venture capital or private equity fund, a customary distribution to its partners or members for no consideration, the Company may require the Holder to provide to the Company an opinion of counsel selected by the Holder and reasonably acceptable to the Company, the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such Transfer does not require registration under the Securities Act; provided, however, that prior to any transfer pursuant to clause (iv) above, each transferee shall agree in writing to be bound by this Agreement (it being understood that the rights of the transferor under this Agreement shall likewise be deemed assigned to such transferee upon such transfer).

(b) Each Holder agrees to the affixing, so long as is required by this Section 2.1, of the following legend on any certificate or book-entry position evidencing any of the Shares:

> THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY STATE SECURITIES LAWS AND MAY NOT BE TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR AN EXEMPTION THEREFROM UNDER THE ACT AND THE RULES AND REGULATIONS THEREUNDER AND APPLICABLE STATE SECURITIES LAWS.

Certificates or book-entry positions evidencing the Shares shall not be required to contain such legend or any other legend (i) following any sale of such Shares pursuant to an effective registration statement (including the Registration Statement described in Section 3.1) covering the resale of the Shares, (ii) following any sale of such Shares pursuant to Rule 144 or if the Shares are transferrable by a person who is not an Affiliate of the Company or the applicable Holder pursuant to Rule 144 without any volume or manner of sale restrictions thereunder, (iii) if Holder is not an Affiliate of the Company, six (6) months following the Closing, provided, however, that in the case of (i), (ii) and (iii), above, the Holder provides the Company with customary legal representation letters reasonably acceptable to the Company, or (iv) if the Holder provides the Company with a legal opinion reasonably acceptable to the Company to the effect that the legend is not required under applicable requirements of the Securities Act. Whenever such restrictions shall cease and terminate as to any Shares the Holder of such securities shall be entitled to receive from the Company upon a written request in writing, without expense, new securities of like tenor not bearing the legend set forth herein, and such new securities shall be issued promptly, but in no event less than five (5) Business Days after a written request to remove such legends.

(c) Notwithstanding anything herein to the contrary, following registration of the Shares, each Holder agrees not to sell any Shares issued to such Holder if the sales of such shares would, when combined with the sale of any other Shares by such Holder in any one (1) day period, exceed five percent (5%) of the average daily trading volume of the Company's common stock on the New York Stock Exchange over the five (5) trading days preceding such date of sale; provided, however, that if the aggregate number of Shares represents less than fifty percent (50%) of the average daily trading volume of the Company's common stock on the New York Stock Exchange over the five (5) trading days preceding the Closing Date (the "Average Volume"), such resale volume limitations shall not apply. If the aggregate number of Shares issued to a Holder represents more than the Average Volume, the Company may place such legends or stock transfer restrictions on the Shares as shall be appropriate for enforcing the provisions of this Section 2(c).

ARTICLE III
REGISTRATION AND PROCEDURES

Section 3.1 S-3 Registration.

(a) In compliance with the terms of this Agreement, the Company shall prepare and file with the SEC a registration statement on Form S-3ASR (or such other form that the Company is then eligible to use if not eligible to use Form S-3ASR) covering the resale as a secondary offering to be made on a continuous basis pursuant to Rule 415 of all Registrable Securities. The registration statement (or new registration statement) required to be filed pursuant to this Section 3.1, together with any amendments and supplements to such registration statement, including post-effective amendments, and all exhibits and all materials incorporated by reference in such registration statement other than a registration statement on Form S-4 or S-8, is referred to herein as the "Registration Statement."

(b) The Company shall exercise commercially reasonable efforts to prepare and file the Registration Statement with the SEC no later than fifteen (15) Business Days after the Closing Date; provided, however, that no filing of such Registration Statement shall be required (i) during any period in which the Company's insider trading policy would prohibit executive officers of the Company from trading in the Company's securities, or (ii) prior to the date which is two (2) days following the Company's first filing with the SEC after the Closing Date of an Annual Report on Form 10-K or a Quarterly Report on Form 10-Q. Subject to the terms of this Agreement, the Company shall use commercially reasonable efforts to have the Registration Statement declared effective as soon as practicable after such filing if not otherwise effective upon filing and to keep the Registration Statement continuously effective and in compliance with the Securities Act and usable for resale of Registrable Securities covered thereby from the date of its initial effectiveness until the earlier of (i) the date on which such Registrable Securities have been disposed of in accordance with the Registration Statement or pursuant to Rule 144 or (ii) such Registrable Securities may be sold pursuant to Rule 144 without any limitation as to manner-of-sale restrictions or volume limitations (such period, the "Effectiveness Period"); provided, however, that nothing in this Agreement shall require the Company to maintain any Registration Statement once the Shares cease to be Registrable Securities.

(c) It shall be a condition precedent to the obligations of the Company to take any action pursuant to Section 3.1 or Section 3.2 with respect to Registrable Securities of a Holder that the Holder shall furnish to the Company such information regarding such Holder as required under Section 3.4(a).

Section 3.2 Registration Procedures; Company Obligations. The Company shall use commercially reasonable efforts to effect the registration of the Registrable Securities in accordance with Section 3.1, and in connection therewith shall have the following obligations:

(a) No later than the first Business Day after the Registration Statement becomes effective, the Company shall file with the SEC the final prospectus included therein pursuant to Rule 424. The Registration Statement, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto, shall comply as to form and content with the applicable requirements of the Securities Act and shall not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading.

(b) Subject to Section 3.2(h), the Company shall prepare and file with the SEC such amendments and supplements to the Registration Statement and the prospectus used in connection with the Registration Statement as may be necessary to keep the Registration Statement effective and usable for resale of the Registrable Securities covered thereby at all times during the Effectiveness Period. The Company shall use commercially reasonable efforts to cause any post-effective amendment to the Registration Statement that is not effective upon filing to become effective as soon as practicable after such filing. No later than the first Business Day after a post-effective amendment to the Registration Statement becomes effective, the Company shall file with the SEC the final prospectus or prospectus supplement included therein pursuant to Rule 424.

(c) The Company shall as promptly as practicable notify the Holders of the time when the Registration Statement becomes effective or an amendment or supplement to any prospectus forming a part of such Registration Statement has been filed. The Company shall furnish to the Holders, without charge, such documents, including copies of any preliminary prospectus or final prospectus contained in the Registration Statement or any amendments or supplements thereto, as such Holder may reasonably request from time to time in order to facilitate the disposition of the Registrable Securities covered by the Registration Statement.

(d) The Company shall use commercially reasonable efforts to register or qualify, and cooperate with the Holders of Registrable Securities covered by the Registration Statement in connection with the registration or qualification of such Registrable Securities for offer and sale under the securities or "blue sky" laws of each state and other jurisdiction of the United States as any such Holder reasonably requests in writing, and do any and all other things reasonably necessary or advisable to keep such registration or qualification in effect; provided, however, that the Company shall not be required to qualify generally to do business in any jurisdiction where it is not then so qualified or take any action which would subject it to taxation or general service of process in any such jurisdiction where it is not then so subject.

(e) The Company shall promptly notify (which notice shall be accompanied by an instruction to suspend the use of the prospectus) the Holders when a prospectus relating thereto is required to be delivered under the Securities Act of the happening of any event as a result of which any prospectus included in, or relating to, the Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading (provided that in no event shall such notice contain any material, non-public information), and, subject to Section 3.2(h), promptly prepare and file with the SEC a supplement to the related prospectus or amendment to such Registration Statement or any other required document so that, as thereafter delivered to the Holders, the prospectus will not contain an untrue statement of a material fact or omit to state any material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(f) The Company shall use commercially reasonable efforts to prevent the issuance of any stop order or other suspension of effectiveness of the Registration Statement, or the suspension of the qualification of any of the Registrable Securities for sale in any jurisdiction and, if such an order or suspension is issued, to obtain the withdrawal of such order or suspension as soon as reasonably practicable and to notify the Holders of the issuance of such order and the resolution thereof or its receipt of actual notice of the initiation or threat of any proceeding for such purpose.

(g) The Company shall use commercially reasonable efforts to cause the Registrable Securities covered by the Registration Statement to be (i) listed on the New York Stock Exchange and (ii) reflected in the stock ledger maintained by the Company's transfer agent.

(h) Notwithstanding anything in this Agreement to the contrary, at any time after the Registration Statement becomes effective the Company may delay the disclosure of material, non-public information concerning the Company or any of its subsidiaries if the Board of Directors of the Company has a valid business reason for determining that disclosure of such information is not in the best interests of the Company and such disclosure is not otherwise required (a "Grace Period"); provided, however, that the Company shall promptly (i) provide written notice to the Holders of the Grace Period (provided that in no event shall such notice contain any material, non-public information) and the date on which the Grace Period will begin, (ii) use commercially reasonable efforts to terminate a Grace Period as promptly as possible, and (iii) provide written notice to the Holders of the date on which the Grace Period ends; provided, further, that no Grace Period shall exceed thirty (30) consecutive days and during any twelve (12) month period such Grace Periods shall not exceed an aggregate of sixty (60) days; provided, further, the Company shall not register any securities for its own account or that of any other existing or prospective stockholder during such Grace Period. The provisions of Section 3.2(e) shall not be applicable during any Grace Period. Upon expiration of a Grace Period, the Company shall again be bound by the provisions of Section 3.2(e) with respect to the information giving rise thereto unless such material, non-public information is no longer applicable.

Section 3.3 Current Public Information. During the Effectiveness Period, the Company shall use commercially reasonable efforts to (i) make and keep public information available, as those terms are defined in Rule 144, until all the Registrable Securities cease to be Registrable Securities, and so long as a Holder owns any Registrable Securities, furnish to such Holder upon request a written statement by the Company as to its satisfaction of the current public information requirements of Rule 144 and (ii) file with the SEC in a timely manner all reports and other documents required to be filed by the Company under the Securities Act and the Exchange Act.

Section 3.4 Obligations of the Holders.

(a) Each Holder shall furnish in writing to the Company such information regarding such Holder, the Registrable Securities held by such Holder and the intended method of disposition of the Registrable Securities held by such Holder as shall be reasonably required to effect the registration of such Registrable Securities and shall execute, or shall cause to be executed, such customary documents in connection with such registration as the Company may reasonably request. In connection therewith, as promptly as reasonably practicable after execution of this Agreement (but in no event later than ten (10) Business Days prior to the first anticipated filing date of the Registration Statement), each Holder shall complete, execute and deliver to the Company a selling securityholder notice and questionnaire in the form attached hereto as Exhibit B. At least five (5) Business Days prior to the first anticipated filing date of the Registration Statement, the Company shall notify each Holder of any additional information the Company requires from such Holder, and such Holder shall provide such information to the Company at least three (3) Business Days prior to the first anticipated filing date of the Registration Statement.

(b) Each Holder agrees to cooperate with the Company as reasonably requested by the Company in connection with the preparation and filing of the Registration Statement.

(c) Upon receipt of written notice from the Company of any event of the kind described in Section 3.2(e) or Section 3.2(f) or written notice of any Grace Period, each Holder shall forthwith discontinue disposition of Registrable Securities until such Holder has received copies of a supplemented or amended prospectus or until such Holder is advised in writing by the Company that the use of the prospectus may be resumed or that the Grace Period has ended. If so directed by the Company, such Holder shall use its commercially reasonable efforts to return to the Company (at the Company's expense) all copies of the prospectus covering such Registrable Securities current at the time of receipt of such notice other than permanent file copies then in such Holder's possession.

(d) No Holder shall use any free writing prospectus (as defined in Rule 405) in connection with the sale of Registrable Securities without the prior written consent of the Company.

(e) Each Holder covenants and agrees that it will comply with the prospectus delivery requirements of the Securities Act as applicable to it or an exemption therefrom in connection with sales of Registrable Securities pursuant to any Registration Statement.

Section 3.5 Expenses of Registration. All Registration Expenses incurred in connection with any registration, qualification or compliance hereunder shall be borne by the Company. All Selling Expenses incurred in connection with the sale of any Registrable Securities shall be borne by the Holders of such Registrable Securities in proportion the Registrable Securities owned by such Holders.

Section 3.6 Transfer of Registration Rights. The rights contained in Section 3.1 hereof to cause the Company to register the Registrable Securities, and the other rights set forth in this Article III, may be assigned or otherwise conveyed by any Holder to any transferee of the Registrable Securities if the Transfer was permitted under Article II and the transferee agrees with the Company in writing to be bound by this Agreement.

ARTICLE IV
INDEMNIFICATION AND CONTRIBUTION

Section 4.1 Indemnification. In the event any Registrable Securities are included in the Registration Statement:

(a) The Company shall indemnify and hold harmless each Holder of Registrable Securities and such Holder's officers, directors, employees, partners, members, agents (including brokers), representatives and Affiliates and each person, if any, who controls such Holder within the meaning of the Securities Act or the Exchange Act (each, a "Holder Indemnitee"), against any losses, claims, damages, liabilities or expenses to which they may become subject under the Securities Act, the Exchange Act or other federal or state law, insofar as such losses, claims, damages, or liabilities (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (collectively, a "Violation"): (i) an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto or any documents incorporated therein by reference, (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading, and (iii) a violation or alleged violation by the Company or its agents of any rule or regulation promulgated under the Securities Act or the Exchange Act applicable to the Company or its agents and relating to action or inaction required of the Company in connection with the Registration Statement, and the Company will pay to each such Holder Indemnitee, as accrued, any legal or other expenses reasonably incurred by he, she or it in connection with investigating or defending any such loss, claim, damage, liability, action or expense; provided, however, that the indemnification contained in this Section 4.1(a) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability, action or expense if such settlement is effected without the consent of the Company (which consent shall not be unreasonably withheld, conditioned or delayed), nor shall the Company be liable for any such loss, claim, damage, liability, action or expense to the extent that it arises out of or is based upon a Violation which occurs (A) in reliance upon and in conformity with written information furnished by a Holder to the Company, (B) in connection with any failure of such person to deliver or cause to be delivered a prospectus made available by the Company in a timely manner, (C) in connection with any offers or sales effected by or on behalf of any Holder Indemnitee in violation of Section 3.4(c) of this Agreement, or (D)

as a result of offers or sales effected by or on behalf of any Holder Indemnitee by means of a free writing prospectus (as defined in Rule 405) that was not authorized in writing by the Company. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of any such Holder Indemnitee, and shall survive the transfer of such securities by such Holder, and any termination of this Agreement.

(b) Each Holder, severally and not jointly, shall indemnify and hold harmless the Company and each of its officers, directors, employees, agents, representatives and Affiliates and persons, if any, who control the Company within the meaning of the Securities Act or the Exchange Act (each, a "Company Indemnitee"), against any losses, claims, damages, liabilities or expenses to which any of the Company Indemnitees may become subject under the Securities Act, the Exchange Act or other federal or state law, insofar as such losses, claims, damages, or liabilities (or actions in respect thereof) arise out of or are based upon any (i) untrue statement or alleged untrue statement of a material fact regarding such Holder and provided in writing by such Holder which is contained in the Registration Statement, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto, (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading, in each case to the extent (and only to the extent) that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, preliminary or final prospectus, amendment or supplement thereto, in reliance upon and in conformity with written information furnished by such Holder to the Company, (iii) a violation or alleged violation by a Holder of any rule or regulation promulgated under the Securities Act or the Exchange Act applicable to such Holder and relating to action or inaction required of such Holder in connection with the registration of such Holder's Registrable Securities or (iv) in connection with any offer or sales effected by or on behalf of such Holder in violation of Section 3.4(c) of this Agreement, and each Holder will pay, as accrued, any legal or other expenses reasonably incurred by any Company Indemnitee pursuant to this Section 4.1(b), in connection with investigating or defending any such loss, claim, damage, liability, action or expense as a result of a Holder's untrue statement or omission or violation; provided, however, that the indemnification contained in this Section 4.1(b) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability, action or expense if such settlement is effected without the consent of such Holder (which consent shall not be unreasonably withheld, conditioned or delayed). Notwithstanding the foregoing, the amount any Holder will be obligated to pay pursuant to this Section 4.1(b) and Section 4.2 will be limited to an amount equal to the gross proceeds actually received by such Holder for the sale of the Registrable Securities pursuant to the Registration Statement which gives rise to such obligation to indemnify and/or contribute (net of all expenses paid by such Holder in connection with any claim relating to this Section 4.1(b) and Section 4.2 and the aggregate amount of any damages which such Holder has otherwise been required to pay in respect of such loss, liability, claim, damage, or expense or any substantially similar loss, liability, claim, damage, or expense arising from the sale of such Registrable Securities). Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of any such Company Indemnitee, and shall survive the transfer of such securities by such Holder, and any termination of this Agreement.

(c) Promptly after receipt by a party to this Agreement entitled to indemnity hereunder (an "Indemnified Party") under this Section 4.1 of notice of the commencement of any

action (including any governmental action), such Indemnified Party will, if a claim in respect thereof is to be made against any party to this Agreement from whom indemnification may be sought under this Section 4.1 (an "Indemnifying Party"), deliver to the Indemnifying Party a written notice of the commencement thereof and the Indemnifying Party shall have the right to participate in, and, to the extent the Indemnifying Party so desires, jointly with any other Indemnifying Party similarly noticed, to assume the defense thereof with counsel reasonably satisfactory to the Indemnifying Party; provided, however, that an Indemnified Party (together with all other Indemnified Parties which may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the reasonable fees and expenses of such counsel to be paid by the Indemnifying Party, if (i) the Indemnifying Party shall have failed to assume the defense of such claim within seven (7) days after receipt of notice of the claim and to employ counsel reasonably satisfactory to such Indemnified Party, as the case may be; or (ii) in the reasonable opinion of counsel retained by the Indemnified Party, representation of such Indemnified Party by such counsel would be inappropriate due to actual or potential differing interests (including the availability of differing legal defenses) between such Indemnified Party and any other party represented by such counsel in such proceeding. It is understood that the Indemnifying Party shall not, in connection with any proceeding in the same jurisdiction, be liable for fees or expenses of more than one separate counsel at any time for all such Indemnified Parties. The Indemnified Party shall cooperate fully with the Indemnifying Party in connection with any negotiation or defense of any such action or claim by the Indemnifying Party and shall furnish to the Indemnifying Party all information reasonably available to the Indemnified Party which relates to such action or claim. The Indemnifying Party shall keep the Indemnified Party reasonably apprised of the status of the defense or any settlement negotiations with respect thereto. No Indemnifying Party will, except with the consent of the Indemnified Party, consent to entry of any judgment or enter into any settlement that does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnified Party of a release from all liability in respect of such action or claim. No Indemnifying Party shall be liable for any settlement of any action, claim or proceeding effected without its prior written consent; provided, however, that the Indemnifying Party shall not unreasonably withhold, delay or condition its consent. The failure to deliver written notice to the Indemnifying Party within a reasonable time of the commencement of any such action shall not relieve such Indemnifying Party of any liability to the Indemnified Party under this Section 4.1, except to the extent such failure to give notice has a material adverse effect on the ability of the Indemnifying Party to defend such action.

Section 4.2 Contribution. If the indemnification provided for in Section 4.1 is held by a court of competent jurisdiction to be unavailable to an Indemnified Party with respect to any loss, liability, claim, damage, or expense referred to therein, then the Indemnifying Party, in lieu of indemnifying such Indemnified Party hereunder, shall contribute to the amount paid or payable by such Indemnified Party as a result of such loss, liability, claim, damage, or expense in such proportion as is appropriate to reflect the relative fault of the Indemnifying Party on the one hand and of the Indemnified Party on the other in connection with the statements or omissions that resulted in such loss, liability, claim, damage, or expense as well as any other relevant equitable considerations. The relative fault of the Indemnifying Party and of the Indemnified Party shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the Indemnifying Party or by the Indemnified Party and the parties' relative intent, knowledge, access

to information, and opportunity to correct or prevent such statement or omission. Notwithstanding the foregoing, the amount any Holder will be obligated to severally and not jointly contribute pursuant to this Section 4.2, together with Holder's liability under Section 4.1(b), will be limited to an amount equal to the gross proceeds received by a Holder for the sale of the Registrable Securities pursuant to the Registration Statement which gives rise to such obligation to contribute and/or indemnify (net of all expenses paid by such Holder in connection with any claim relating to Section 4.1(b) and this Section 4.2 and the aggregate amount of any damages which such Holder has otherwise been required to pay in respect of such loss, liability, claim, damage, or expense or any substantially similar loss, liability, claim, damage, or expense arising from the sale of such Registrable Securities). No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution hereunder from any person who was not guilty of such fraudulent misrepresentation.

ARTICLE V
GENERAL PROVISIONS

Section 5.1 Entire Agreement. This Agreement (including Exhibit A hereto) constitutes the entire understanding and agreement between the parties as to the matters covered herein and supersedes and replaces any prior understanding, agreement or statement of intent, in each case, written or oral, of any and every nature with respect thereto.

Section 5.2 Notices. All notices, waivers, consents and other communications to any party hereunder shall be in writing and shall be deemed given (i) when personally delivered, (ii) when receipt is electronically confirmed, if sent by email of a .pdf document, (iii) one (1) Business Day after deposit with a nationally recognized overnight courier, specifying next day delivery, with proof of receipt or (iv) three (3) Business Days after being sent by registered or certified mail, return receipt requested and postage prepaid. The addresses, email addresses and facsimile numbers for such notices and communications are those set forth on the signature pages hereof, or such other address, email address or facsimile numbers as may be designated in writing hereafter, in the same manner, by any such person.

Section 5.3 Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed an original copy of this Agreement and all of which, when taken together, shall constitute one instrument. The exchange of copies of this Agreement and manually executed signature pages by transmission by email of a .pdf of a handwritten original signature or signatures to the other parties hereto shall constitute effective execution and delivery of this Agreement and may be used in lieu of the original Agreement for all purposes. The signature of a party hereto transmitted by electronic means shall be deemed to be an original signature for any purpose.

Section 5.4 Amendment; Waiver. This Agreement may be amended or modified, and any provision hereof may be waived, in whole or in part, at any time pursuant to an agreement in writing executed by the Company and Holders holding a majority of the Registrable Securities at such time. Any failure by any party at any time to enforce any of the provisions of this Agreement shall not be construed a waiver of such provision or any other provisions hereof.

Section 5.5 Severability. If a court of competent jurisdiction finds that any term or provision of this Agreement is invalid, illegal or unenforceable under any Law or public policy, the remaining provisions of this Agreement shall remain in full force and effect if the economic and legal substance of this Agreement and the Transactions shall not be affected in any manner materially adverse to any party hereto. Any such term or provision found to be illegal, invalid or unenforceable only in part or in degree shall remain in full force and effect to the extent not invalid, illegal or unenforceable. Upon the determination that any term or provision is invalid, illegal or unenforceable, the parties hereto intend that such provision shall be construed by modifying or limiting it so as to be valid and enforceable to the maximum extent possible under applicable Law and compatible with the consummation of the Transactions as originally intended.

Section 5.6. Governing Law; Venue. This Agreement and all claims or causes of action (whether sounding in contract or tort) arising under or related to this Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, without regard to any rule or principle that might refer the governance or construction of this Agreement to the Laws of another jurisdiction. In any action or proceeding between any of the parties hereto arising under or related to this Agreement, each of the parties hereto (i) knowingly, voluntarily, irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the state or federal courts located in the City and County of San Francisco, California, and each of the Parties hereby irrevocably submits to the exclusive jurisdiction of the aforesaid courts, (ii) agrees that all claims in respect of any such action or proceeding shall be heard and determined exclusively in accordance with clause (i) of this Section 5.6, (iii) waives any objection to the laying of venue of any such action or proceeding in such courts, including any objection that any such action or proceeding has been brought in an inconvenient forum or that the court does not have jurisdiction over any party hereto and (iv) agrees that service of process upon such party in any such action or proceeding shall be effective if such process is given as a notice in accordance with Section 5.2. The parties hereto agree that any party hereto may commence a proceeding in a court other than the above-named courts solely for the purpose of enforcing an order or judgment issued by one of the above-named courts.

Section 5.7 Specific Performance. Each party acknowledges and agrees that the other parties hereto would be irreparably harmed and would not have any adequate remedy at law in the event that any of the provisions of this Agreement were not performed by such first party in accordance with their specific terms or were otherwise breached by such first party. Accordingly, each party agrees that the other parties hereto shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement, this being in addition to any other remedy to which such parties are entitled at law or in equity.

(Next Page is Signature Page)

IN WITNESS WHEREOF, each of the parties has executed this Agreement as of the date first written above.

COMPANY:

INVITAE CORPORATION

By: /s/ Sean E. George, Ph.D.
Name: Sean E. George, Ph.D.
Title: President and Chief Executive Officer

Address for Notice:

1400 16th Street
San Francisco, California 94103
Attn: General Counsel
Facsimile No.: (415) 276-4164

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Austin Davis-Richardson
By: /s/ Austin Davis-Richardson
Name: Austin Davis-Richardson
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Alena Kuczynski
By: /s/ Alena Kuczynski
Name: Alena Kuczynski
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Anastasia Potts
By: /s/ Anastasia Potts
Name: Anastasia Potts
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Brett Camarda
By: /s/ Brett Camarda
Name: Brett Camarda
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Brian Fish
By: /s/ Brian Fish
Name: Brian Fish
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Bryan Jonathan Balin

By: /s/ Bryan Jonathan Balin
Name: Bryan Jonathan Balin
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Christopher Smith
By: /s/ Christopher Smith
Name: Christopher Smith
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Cindy Zhou Wang
By: /s/ Cindy Zhou Wang
Name: Cindy Zhou Wang
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Data Collective III, L.P.
on behalf of itself and as nominee for
certain affiliated entities

By: Data Collective III GP, LLC
Its: General Partner

By: /s/ Zachary Bogue
Name: Zachary Bogue
Title: Managing Member

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: DENA CO., LTD.
By: /s/ Isao Moriyasu
Name: Isao Moriyasu
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Denise Lynch
By: /s/ Denise Lynch
Name: Denise Lynch
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: FUNDAMENTAL VENTURES GP I LLC
By: /s/ Charles J. Pinto
Name: Charles J. Pinto
Title: Managing Member

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Gerrit Gerritsen
By: /s/ Gerrit Gerritsen
Name: Gerrit Gerritsen
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Healthy Ventures Fund I, LLC
By: Healthy Ventures I GP, LLC,
its General Partner

By: /s/ Anya Schiess
Name: Anya Schiess
Title: Managing Director

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Jai Ram Rideout
By: /s/ Jai Ram Rideout
Name: Jai Ram Rideout
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Jeremy Mason-Herr
By: /s/ Jeremy Mason-Herr
Name: Jeremy Mason-Herr
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Kim Polese
By: /s/ Kim Polese
Name: Kim Polese
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Matthew Sweeney
By: /s/ Matthew Sweeney
Name: Matthew Sweeney
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: MOUNT PLEASANT VENTURES, LLC
By: /s/ Abhishek Pandey
Name: Abhishek Pandey
Title: CEO, Mount Pleasant Ventures, LLC

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Nathaniel Bailey
By: /s/ Nathaniel Bailey
Name: Nathaniel Bailey
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Nicholas Greenfield

By: /s/ Nicholas Greenfield

Name: Nicholas Greenfield

Title:

Address for Notice:

Telephone No.:

Facsimile No.:

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Niklas Krumm

By: /s/ Niklas Krumm

Name: Niklas Krumm

Title:

Address for Notice:

Telephone No.:

Facsimile No.:

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Palm Drive Ventures I LP
By: Palm Drive Ventures GP LLC, its General Partner,
By: Palm Drive Capital LLC, its manager,
Name: Hendrick Lee
By: /s/ Hendrick Lee
Name: Hendrick Lee
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Pawel Koniecany

By: /s/ Pawel Konieczny

Name: Pawel Konieczny

Title:

Address for Notice:

Telephone No.:

Facsimile No.:

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Petras Zdanavičius
By: /s/ Petras Zdanavičius
Name: Petras Zdanavičius
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Roderick Bovee
By: /s/ Roderick Bovee
Name: Roderick Bovee
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Samuel Minot
By: /s/ Samuel Minot
Name: Samuel Minot
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: TING YIN KWAN AND JANICE POMAN CHAN, TTEES UTD 4/17/13
By: /s/ Eric Kwan
Name: Eric Kwan
Title: Trustee

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Vincent Prouillet
By: /s/ Vincent Prouillet
Name: Vincent Prouillet
Title:

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Y COMBINATOR S2014, LLC
By: /s/ Kirsty Nathoo
Name: Kirsty Nathoo
Title: CFO

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: YCVC Fund I, L.P.
By: YCVC Fund GP, LLC
By: /s/ Kirsty Nathoo
Name: Kirsty Nathoo
Title: Chief Financial Officer

Address for Notice:

Telephone No.:
Facsimile No.:
Email Address:

REGISTRATION RIGHTS AGREEMENT

This Registration Rights Agreement (this "Agreement") is made and entered into as of September 13, 2021 (the "Effective Date") by and among Invitae Corporation, a Delaware corporation (the "Company"), and certain securityholders of Ciitizen Corporation, a Delaware corporation ("Ciitizen") listed on Exhibit A hereto (each such securityholder, as well as any permitted transferee of Registrable Securities (as defined below) hereunder, in each case to the extent holding Registrable Securities, a "Holder" and collectively, the "Holders"). Terms used but not otherwise defined herein shall have the meaning ascribed to such terms in the Merger Agreement (as defined below).

RECITALS

WHEREAS, the Company, Ciitizen, Cayman Merger Sub A Inc., a Delaware corporation and wholly owned subsidiary of the Company ("Merger Sub A"), Cayman Merger Sub B LLC, a Delaware limited liability company and wholly owned subsidiary of the Company ("Merger Sub B"), and Fortis Advisors LLC as the Holders' Representative (as defined therein), have entered into that certain Agreement and Plan of Merger dated as of September 6, 2021 (the "Merger Agreement"), pursuant to which (i) Merger Sub A will be merged with and into Ciitizen, and Ciitizen shall continue as the surviving entity and wholly owned subsidiary of the Company (the "Reverse Merger") and (ii) promptly thereafter as part of the same overall transaction, and in all cases on the Closing Date, Ciitizen will be merged with and into Merger Sub B, and Merger Sub B shall continue as the surviving entity and wholly owned subsidiary of the Company (the "Forward Merger" and, together with the Reverse Merger, the "Mergers");

WHEREAS, in connection with the Mergers and pursuant to the Merger Agreement, the Company issued to the Holders at the Closing shares of the Company's common stock, par value $0.0001 per share, identified on Exhibit A hereto as Stock Consideration Shares (the "Shares") pursuant to the Merger Agreement; and

WHEREAS, in connection with the consummation of the transactions contemplated by the Merger Agreement, the Company agreed to grant certain registration rights to the Holders as set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the parties agree as follows:

ARTICLE I
DEFINITIONS

Section 1.1 Definitions. For purposes of this Agreement, the following terms and variations thereof have the meanings set forth below:

"Affiliate" means, with respect to any person, any other person that, directly or indirectly, controls, or is controlled by, or is under common control with, such person. For this purpose: (a) "control" (including, with its correlative meanings, "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause

the direction of management or policies of a Person, whether through the ownership of securities or partnership or other ownership interests, by contract or otherwise; and (b) "person" means any natural person, corporation, limited liability company, partnership, association, trust or other entity.

"Agreement" has the meaning set forth in the preamble.

"Business Day" means any day, other than a Saturday, Sunday or one on which banks are authorized by law to be closed in New York, New York.

"Ciitizen" has the meaning set forth in the preamble.

"Company" has the meaning set forth in the preamble.

"Company Indemnitee" has the meaning set forth in Section 4.1(b).

"Effective Date" has the meaning set forth in the preamble.

"Effectiveness Period" has the meaning set forth in Section 3.1(b).

"Exchange Act" means the Securities Exchange Act of 1934.

"Grace Period" has the meaning set forth in Section 3.2(h).

"Holder" has the meaning set forth in the preamble.

"Holder Indemnitee" has the meaning set forth in Section 4.1(a).

"Indemnified Party" has the meaning set forth in Section 4.1(c).

"Indemnifying Party" has the meaning set forth in Section 4.1(c).

"Merger Agreement" has the meaning set forth in the recitals.

"Registrable Securities" means, at any time, the Shares issued to the Holders pursuant to the Merger Agreement and any securities issued or issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect to such securities; provided, however, that Registrable Securities shall cease to be Registrable Securities with respect to a particular Holder when (i) such securities have been disposed of in accordance with the Registration Statement or pursuant to Rule 144; (ii) such securities may be sold pursuant to Rule 144 without any manner-of-sale restrictions or volume limitations; or (iii) such securities cease to be outstanding.

"Registration Expenses" means all expenses incurred by the Company in effecting the registration pursuant to this Agreement, including all registration and filing fees, printing expenses, fees and disbursements of counsel for the Company, "blue sky" fees and expenses, and

expenses of the Company's independent registered public accounting firm in connection with any regular or special reviews or audits incident to or required by any such registration, but shall not include Selling Expenses.

"Registration Statement" has the meaning set forth in Section 3.1.

"Rule 144" means Rule 144 under the Securities Act or any successor or other similar rule, regulation or interpretation of the SEC that may at any time permit the sale of Registrable Securities to the public without registration.

"Rule 405" means Rule 405 under the Securities Act or any successor or other similar rule.

"Rule 415" means Rule 415 under the Securities Act or any successor or other similar rule providing for offering securities on a continuous or delayed basis.

"Rule 424" means Rule 424 under the Securities Act or any successor or other similar rule.

"Shares" has the meaning set forth in the recitals.

"SEC" means the Securities and Exchange Commission.

"Securities Act" means the Securities Act of 1933.

"Selling Expenses" means all discounts, selling commissions, fees of selling brokers, dealer managers and similar securities industry professionals and stock transfer taxes applicable to the sale of Registrable Securities and fees and disbursements of counsel for any Holder (other than the fees and disbursements of counsel for the Company included in Registration Expenses).

"Transfer" means, directly or indirectly, to sell, transfer, assign, pledge, encumber, hypothecate or similarly dispose of (by merger, testamentary disposition, operation of law or otherwise), either voluntarily or involuntarily, or to enter into any contract, option or other arrangement or understanding with respect to the sale, transfer, assignment, pledge, encumbrance, hypothecation or similar disposition of (by merger, testamentary disposition, operation of law or otherwise) any Shares.

"Violation" has the meaning set forth in Section 4.1(a).

ARTICLE II
TRANSFER RESTRICTIONS

Section 2.1 General Transfer Restrictions. The right of any Holder to Transfer any Shares held by it is subject to the restrictions set forth below.

(a) Each Holder acknowledges that the Shares have not been registered under the Securities Act and may not be Transferred except pursuant to an effective registration statement under the Securities Act or pursuant to an exemption from registration under the Securities Act. Each Holder covenants that the Shares will only be disposed of pursuant to an effective registration statement under, and in compliance with the requirements of, the Securities Act or pursuant to an available exemption from the registration requirements of the Securities Act, and in compliance with any applicable state and foreign securities laws. In connection with any Transfer of the Shares other than a Transfer (i) pursuant to an effective registration statement, (ii) to the Company, or (iii) pursuant to Rule 144, the Company may require the Holder to provide to the Company an opinion of counsel selected by the Holder and reasonably acceptable to the Company, the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such Transfer does not require registration under the Securities Act.

(b) Each Holder agrees to the affixing, so long as is required by this Section 2.1, of the following legend on any certificate or book-entry position evidencing any of the Shares:

> THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY STATE SECURITIES LAWS AND MAY NOT BE TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR AN EXEMPTION THEREFROM UNDER THE ACT AND THE RULES AND REGULATIONS THEREUNDER AND APPLICABLE STATE SECURITIES LAWS.

Certificates or book-entry positions evidencing the Shares shall not be required to contain such legend or any other legend, and the Company shall remove or direct its transfer agent to remove any such legend or any other legend, (i) following any sale of such Shares pursuant to an effective registration statement (including the Registration Statement described in Section 3.1) covering the resale of the Shares, (ii) following any sale of such Shares pursuant to Rule 144 or if the Shares are transferrable by a person who is not an Affiliate of the Company or the applicable Holder pursuant to Rule 144 without any volume or manner of sale restrictions thereunder, (iii) if Holder is not an Affiliate of the Company, six (6) months following the Closing, provided, however, that in the case of (i), (ii) and (iii), above, the Holder provides the Company with customary representation letters reasonably acceptable to the Company, or (iv) if the Holder provides the Company with a legal opinion reasonably acceptable to the Company to the effect that the legend is not required under applicable requirements of the Securities Act. Whenever such restrictions shall cease and terminate as to any Shares, the Holder of such securities shall be entitled to receive from the Company upon a written request in writing, without expense, new securities of like tenor not bearing the legend set forth herein.

(c) Notwithstanding anything herein to the contrary, for a period of 90 days following the Closing Date each Holder agrees not to sell any Shares issued to such Holder if the sales of such Shares would, when combined with the sale of any other Shares by such Holder in any one (1) day period, exceed five percent (5%) of the average daily trading volume of the Company's common stock on the New York Stock Exchange over the five (5) trading days immediately preceding such date of sale; provided, however, that if the aggregate number of Shares

represents less than fifty percent (50%) of the average daily trading volume of the Company's common stock on the New York Stock Exchange over the five (5) trading days preceding the Closing Date (the "Average Volume"), such resale volume limitations shall not apply. The Company may place such legends or stock transfer restrictions on the Shares as shall be appropriate for enforcing the provisions of this Section 2(c).

ARTICLE III
REGISTRATION AND PROCEDURES

Section 3.1 S-3 Registration.

(a) In compliance with the terms of this Agreement, the Company shall prepare and file with the SEC a registration statement on Form S-3ASR (or, if the Company is not then eligible to use Form S-3ASR, Form S-3, Form S-1 or other available form) covering the resale as a secondary offering to be made on a continuous basis pursuant to Rule 415 of all Registrable Securities. The registration statement required to be filed pursuant to this Section 3.1, together with any amendments and supplements to such registration statement, including post-effective amendments, and all exhibits and all materials incorporated by reference in such registration statement, is referred to herein as the "Registration Statement."

(b) The Company shall exercise commercially reasonable efforts to prepare and file the Registration Statement with the SEC no later than fifteen (15) Business Days after the Closing Date; provided, however, that no filing of such Registration Statement shall be required: (i) during any period in which the Company's insider trading policy would prohibit executive officers of the Company from trading in the Company's securities or in which the Registration Statement should not be filed or an offering of the Shares thereunder should not be made pursuant to any provision of the Securities Act or the Exchange Act or any rule or regulation thereunder; or (ii) if the Closing Date occurs after September 13, 2021, at any time prior to the date which is two (2) Business Days following the Company's first filing with the SEC after the Closing Date of an Annual Report on Form 10-K or a Quarterly Report on Form 10-Q. Subject to the terms of this Agreement, the Company shall use commercially reasonable efforts to have the Registration Statement declared effective as soon as practicable after such filing if not otherwise effective upon filing and to keep the Registration Statement continuously effective and in compliance with the Securities Act and usable for resale of Registrable Securities covered thereby from the date of its initial effectiveness until the earlier of (i) the date on which such Registrable Securities have been disposed of in accordance with the Registration Statement or pursuant to Rule 144 or (ii) such Registrable Securities may be sold pursuant to Rule 144 without any limitation as to manner-of-sale restrictions or volume limitations (such period, the "Effectiveness Period"); provided, however, that nothing in this Agreement shall require the Company to maintain any Registration Statement once all Shares cease to be Registrable Securities.

(c) It shall be a condition precedent to the obligations of the Company to take any action pursuant to Section 3.1 or Section 3.2 with respect to Registrable Securities of a Holder that the Holder shall furnish to the Company such information regarding such Holder as required under Section 3.4(a).

Section 3.2 Registration Procedures; Company Obligations. The Company shall use commercially reasonable efforts to effect the registration of the Registrable Securities in accordance with Section 3.1, and in connection therewith shall have the following obligations:

(a) No later than the first Business Day after the Registration Statement becomes effective, the Company shall file with the SEC the final prospectus included therein pursuant to Rule 424. The Registration Statement, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto, shall comply as to form and content with the applicable requirements of the Securities Act and shall not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading.

(b) Subject to Section 3.2(h), the Company shall prepare and file with the SEC such amendments and supplements to the Registration Statement and the prospectus used in connection with the Registration Statement as may be necessary to keep the Registration Statement effective and usable for resale of the Registrable Securities covered thereby at all times during the Effectiveness Period. The Company shall use commercially reasonable efforts to cause any post-effective amendment to the Registration Statement that is not effective upon filing to become effective as soon as practicable after such filing. No later than the first Business Day after a post-effective amendment to the Registration Statement becomes effective, the Company shall file with the SEC the final prospectus or prospectus supplement included therein pursuant to Rule 424.

(c) The Company shall as promptly as practicable notify the Holders of the time when the Registration Statement becomes effective or an amendment or supplement to any prospectus forming a part of such Registration Statement has been filed. The Company shall furnish to the Holders, without charge, such documents, including copies of any preliminary prospectus or final prospectus contained in the Registration Statement or any amendments or supplements thereto, as such Holder may reasonably request from time to time in order to facilitate the disposition of the Registrable Securities covered by the Registration Statement.

(d) The Company shall use commercially reasonable efforts to register or qualify, and cooperate with the Holders of Registrable Securities covered by the Registration Statement in connection with the registration or qualification of such Registrable Securities for offer and sale under the securities or "blue sky" laws of each state and other jurisdiction of the United States as any such Holder reasonably requests in writing, and do any and all other things reasonably necessary or advisable to keep such registration or qualification in effect; provided, however, that the Company shall not be required to qualify generally to do business in any jurisdiction where it is not then so qualified or take any action which would subject it to taxation or general service of process in any such jurisdiction where it is not then so subject.

(e) The Company shall promptly notify (which notice shall be accompanied by an instruction to suspend the use of the prospectus) the Holders when a prospectus relating thereto is required to be delivered under the Securities Act of the happening of any event as a result of which any prospectus included in, or relating to, the Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated

therein, or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading (provided that in no event shall such notice contain any material, non-public information), and, subject to Section 3.2(h), promptly prepare and file with the SEC a supplement to the related prospectus or amendment to such Registration Statement or any other required document so that, as thereafter delivered to the Holders, the prospectus will not contain an untrue statement of a material fact or omit to state any material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(f) The Company shall use commercially reasonable efforts to prevent the issuance of any stop order or other suspension of effectiveness of the Registration Statement, or the suspension of the qualification of any of the Registrable Securities for sale in any jurisdiction and, if such an order or suspension is issued, to obtain the withdrawal of such order or suspension as soon as reasonably practicable and to notify the Holders of the issuance of such order and the resolution thereof or its receipt of actual notice of the initiation or threat of any proceeding for such purpose.

(g) The Company shall use commercially reasonable efforts to cause the Registrable Securities covered by the Registration Statement to be (i) listed on the New York Stock Exchange and (ii) reflected in the stock ledger maintained by the Company's transfer agent.

(h) Notwithstanding anything in this Agreement to the contrary, at any time after the Registration Statement becomes effective the Company may delay the disclosure of material, non-public information concerning the Company or any of its subsidiaries if the Board of Directors of the Company has a valid business reason for determining that disclosure of such information is not in the best interests of the Company and such disclosure is not otherwise required (a "Grace Period"); provided, however, that the Company shall promptly (i) provide written notice to the Holders of the Grace Period (provided that in no event shall such notice contain any material, non-public information) and the date on which the Grace Period will begin, (ii) use commercially reasonable efforts to terminate a Grace Period as promptly as possible, and (iii) provide written notice to the Holders of the date on which the Grace Period ends; provided, further, that no Grace Period shall exceed thirty (30) consecutive days and during any twelve (12) month period such Grace Periods shall not exceed an aggregate of sixty (60) days; provided, further, the Company shall not register any securities for its own account or that of any other stockholder during such Grace Period. The provisions of Section 3.2(e) shall not be applicable during any Grace Period. Upon expiration of a Grace Period, the Company shall again be bound by the provisions of Section 3.2(e) with respect to the information giving rise thereto unless such material, non-public information is no longer applicable.

Section 3.3 Current Public Information. During the Effectiveness Period, the Company shall use commercially reasonable efforts to (i) make and keep public information available, as those terms are defined in Rule 144, until all the Registrable Securities cease to be Registrable Securities, and so long as a Holder owns any Registrable Securities, furnish to such Holder upon request a written statement by the Company as to its satisfaction of the current public information requirements of Rule 144 and (ii) file with the SEC in a timely manner all reports and

other documents required to be filed by the Company under the Securities Act and the Exchange Act.

Section 3.4 Obligations of the Holders.

(a) Each Holder shall furnish in writing to the Company such information regarding such Holder, the Registrable Securities held by such Holder and the intended method of disposition of the Registrable Securities held by such Holder as shall be reasonably required to effect the registration of such Registrable Securities and shall execute, or shall cause to be executed, such customary documents in connection with such registration as the Company may reasonably request. In connection therewith, upon the execution of this Agreement, each Holder shall complete, execute and deliver to the Company a selling securityholder notice and questionnaire in the form attached hereto as Exhibit B. At least five (5) Business Days prior to the first anticipated filing date of the Registration Statement, the Company shall notify each Holder of any additional information the Company requires from such Holder, and such Holder shall provide such information to the Company at least three (3) Business Days prior to the first anticipated filing date of the Registration Statement.

(b) Each Holder agrees to cooperate with the Company as reasonably requested by the Company in connection with the preparation and filing of the Registration Statement.

(c) Upon receipt of written notice from the Company of any event of the kind described in Section 3.2(e) or Section 3.2(f) or written notice of any Grace Period, each Holder shall forthwith discontinue disposition of Registrable Securities until such Holder has received copies of a supplemented or amended prospectus or until such Holder is advised in writing by the Company that the use of the prospectus may be resumed or that the Grace Period has ended. If so directed by the Company, such Holder shall use its commercially reasonable efforts to return to the Company (at the Company's expense) all copies of the prospectus covering such Registrable Securities current at the time of receipt of such notice other than permanent file copies then in such Holder's possession.

(d) No Holder shall use any free writing prospectus (as defined in Rule 405) in connection with the sale of Registrable Securities without the prior written consent of the Company.

(e) Each Holder covenants and agrees that it will comply with the prospectus delivery requirements of the Securities Act as applicable to it or an exemption therefrom in connection with sales of Registrable Securities pursuant to any Registration Statement.

Section 3.5 Obligations of the Company. Company agrees that, except to the extent required by law, the Registration Statement will not specifically list as selling securityholders any passive limited partners of any stockholder of the Company that is a venture capital fund who receives unregistered Company stock on the Closing Date.

Section 3.6 Expenses of Registration. All Registration Expenses incurred in connection with any registration, qualification or compliance hereunder shall be borne by the Company. All Selling Expenses incurred in connection with any registration hereunder shall be

borne by the Holders of the Registrable Securities so registered in proportion to the Registrable Securities owned by such Holders.

Section 3.7 Transfer of Registration Rights. The rights contained in Section 3.1 hereof to cause the Company to register the Registrable Securities, and the other rights set forth in this Article III, may be assigned or otherwise conveyed by any Holder to any transferee of the Registrable Securities if the Transfer was permitted under Article II and the transferee agrees with the Company in writing to be bound by this Agreement.

ARTICLE IV
INDEMNIFICATION AND CONTRIBUTION

Section 4.1 Indemnification. In the event any Registrable Securities are included in the Registration Statement:

(a) The Company shall indemnify and hold harmless each Holder of Registrable Securities and such Holder's officers, directors, employees, partners, members, agents (including brokers), representatives and Affiliates and each person, if any, who controls such Holder within the meaning of the Securities Act or the Exchange Act (each, a "Holder Indemnitee"), against any losses, claims, damages, liabilities or expenses to which they may become subject under the Securities Act, the Exchange Act or other federal or state law, insofar as such losses, claims, damages, or liabilities (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (collectively, a "Violation"): (i) an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto or any documents incorporated therein by reference, (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading, and (iii) a violation or alleged violation by the Company or its agents of any rule or regulation promulgated under the Securities Act or the Exchange Act applicable to the Company or its agents and relating to action or inaction required of the Company in connection with the Registration Statement, and the Company will pay to each such Holder Indemnitee, as accrued, any legal or other expenses reasonably incurred by he, she or it in connection with investigating or defending any such loss, claim, damage, liability, action or expense; provided, however, that the indemnification contained in this Section 4.1(a) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability, action or expense if such settlement is effected without the consent of the Company (which consent shall not be unreasonably withheld, conditioned or delayed), nor shall the Company be liable for any such loss, claim, damage, liability, action or expense to the extent that it arises out of or is based upon a Violation which occurs (A) in reliance upon and in conformity with written information furnished by a Holder to the Company specifically for use therein, (B) in connection with any failure of such person to deliver or cause to be delivered a prospectus made available by the Company in a timely manner, (C) in connection with any offers or sales effected by or on behalf of any Holder Indemnitee in violation of Section 3.4(c), or (D) as a result of offers or sales effected by or on behalf of any Holder Indemnitee by means of a free writing prospectus (as defined in Rule 405) that was not authorized in writing by the Company. Such indemnity shall remain in full force and effect regardless of any investigation

made by or on behalf of any such Holder Indemnitee, and shall survive the transfer of such securities by such Holder, and any termination of this Agreement.

(b) Each Holder, severally and not jointly, shall indemnify and hold harmless the Company and each of its officers, directors, employees, agents, representatives and Affiliates and persons, if any, who control the Company within the meaning of the Securities Act or the Exchange Act (each, a "Company Indemnitee"), against any losses, claims, damages, liabilities or expenses to which any of the Company Indemnitees may become subject under the Securities Act, the Exchange Act or other federal or state law, insofar as such losses, claims, damages, or liabilities (or actions in respect thereof) arise out of or are based upon (i) any untrue statement or alleged untrue statement of a material fact regarding such Holder and provided in writing by such Holder which is contained in the Registration Statement, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto, (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading, in each case to the extent (and only to the extent) that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, preliminary or final prospectus, amendment or supplement thereto, in reliance upon and in conformity with written information furnished by such Holder to the Company specifically for use therein, (iii) a violation or alleged violation by a Holder of any rule or regulation promulgated under the Securities Act or the Exchange Act applicable to such Holder and relating to action or inaction required of such Holder in connection with the registration of such Holder's Registrable Securities or (iv) any offer or sale effected by or on behalf of such Holder in violation of Section 3.4(c), and each Holder will pay, as accrued, any legal or other expenses reasonably incurred by any Company Indemnitee pursuant to this Section 4.1(b), in connection with investigating or defending any such loss, claim, damage, liability, action or expense as a result of a Holder's untrue statement or omission or violation; provided, however, that the indemnification contained in this Section 4.1(b) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability, action or expense if such settlement is effected without the consent of such Holder (which consent shall not be unreasonably withheld, conditioned or delayed). Notwithstanding the foregoing, the amount any Holder will be obligated to pay pursuant to this Section 4.1(b) and Section 4.2 will be limited to an amount equal to the net proceeds (after Selling Expenses) actually received by such Holder for the sale of the Registrable Securities pursuant to the Registration Statement which gives rise to such obligation to indemnify and/or contribute (net of all expenses paid by such Holder in connection with any claim relating to this Section 4.1(b) and Section 4.2 and the aggregate amount of any damages which such Holder has otherwise been required to pay in respect of such loss, liability, claim, damage, or expense or any substantially similar loss, liability, claim, damage, or expense arising from the sale of such Registrable Securities). Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of any such Company Indemnitee, and shall survive the transfer of such securities by such Holder, and any termination of this Agreement.

(c) Promptly after receipt by a party to this Agreement entitled to indemnity hereunder (an "Indemnified Party") under this Section 4.1 of notice of the commencement of any action (including any governmental action), such Indemnified Party will, if a claim in respect thereof is to be made against any party to this Agreement from whom indemnification may be

sought under this Section 4.1 (an "**Indemnifying Party**"), deliver to the Indemnifying Party a written notice of the commencement thereof and the Indemnifying Party shall have the right to participate in, and, to the extent the Indemnifying Party so desires, jointly with any other Indemnifying Party similarly noticed, to assume the defense thereof with counsel reasonably satisfactory to the Indemnifying Party; provided, however, that an Indemnified Party (together with all other Indemnified Parties which may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the reasonable fees and expenses of such counsel to be paid by the Indemnifying Party, if (i) the Indemnifying Party shall have failed to assume the defense of such claim within seven (7) days after receipt of notice of the claim and to employ counsel reasonably satisfactory to such Indemnified Party, as the case may be; or (ii) in the reasonable opinion of counsel retained by the Indemnified Party, representation of such Indemnified Party by such counsel would be inappropriate due to actual or potential differing interests (including the availability of differing legal defenses) between such Indemnified Party and any other party represented by such counsel in such proceeding. It is understood that the Indemnifying Party shall not, in connection with any proceeding in the same jurisdiction, be liable for fees or expenses of more than one separate counsel at any time for all such Indemnified Parties. The Indemnified Party shall cooperate fully with the Indemnifying Party in connection with any negotiation or defense of any such action or claim by the Indemnifying Party and shall furnish to the Indemnifying Party all information reasonably available to the Indemnified Party which relates to such action or claim. The Indemnifying Party shall keep the Indemnified Party reasonably apprised of the status of the defense or any settlement negotiations with respect thereto. No Indemnifying Party will, except with the consent of the Indemnified Party, consent to entry of any judgment or enter into any settlement that does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnified Party of a release from all liability in respect of such action or claim. No Indemnifying Party shall be liable for any settlement of any action, claim or proceeding effected without its prior written consent; provided, however, that the Indemnifying Party shall not unreasonably withhold, delay or condition its consent. The failure to deliver written notice to the Indemnifying Party within a reasonable time of the commencement of any such action shall not relieve such Indemnifying Party of any liability to the Indemnified Party under this Section 4.1, except to the extent such failure to give notice has a material adverse effect on the ability of the Indemnifying Party to defend such action.

Section 4.2 Contribution. If the indemnification provided for in Section 4.1 is held by a court of competent jurisdiction to be unavailable to an Indemnified Party with respect to any loss, liability, claim, damage, or expense referred to therein, then the Indemnifying Party, in lieu of indemnifying such Indemnified Party hereunder, shall contribute to the amount paid or payable by such Indemnified Party as a result of such loss, liability, claim, damage, or expense in such proportion as is appropriate to reflect the relative fault of the Indemnifying Party on the one hand and of the Indemnified Party on the other in connection with the statements or omissions that resulted in such loss, liability, claim, damage, or expense as well as any other relevant equitable considerations. The relative fault of the Indemnifying Party and of the Indemnified Party shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the Indemnifying Party or by the Indemnified Party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission. Notwithstanding the foregoing, the amount any Holder will be obligated to severally and not jointly contribute

pursuant to this Section 4.2, together with Holder's liability under Section 4.1(b), will be limited to an amount equal to the net proceeds (after Selling Expenses) received by a Holder for the sale of the Registrable Securities pursuant to the Registration Statement which gives rise to such obligation to contribute and/or indemnify (net of all expenses paid by such Holder in connection with any claim relating to Section 4.1(b) and this Section 4.2 and the aggregate amount of any damages which such Holder has otherwise been required to pay in respect of such loss, liability, claim, damage, or expense or any substantially similar loss, liability, claim, damage, or expense arising from the sale of such Registrable Securities). No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution hereunder from any person who was not guilty of such fraudulent misrepresentation.

ARTICLE V
GENERAL PROVISIONS

Section 5.1 Entire Agreement. This Agreement (including Exhibit A hereto) constitutes the entire understanding and agreement between the parties as to the matters covered herein and supersedes and replaces any prior understanding, agreement or statement of intent, in each case, written or oral, of any and every nature with respect thereto.

Section 5.2 Notices. All notices, waivers, consents and other communications to any party hereunder shall be in writing and shall be deemed given (i) when personally delivered, (ii) when receipt is electronically confirmed, if sent by email of a .pdf document, (iii) one (1) Business Day after deposit with a nationally recognized overnight courier, specifying next day delivery, with proof of receipt or (iv) three (3) Business Days after being sent by registered or certified mail, return receipt requested and postage prepaid. The addresses, email addresses and facsimile numbers for such notices and communications are those set forth on the signature pages hereof, or such other address, email address or facsimile numbers as may be designated in writing hereafter, in the same manner, by any such person.

Section 5.3 Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed an original copy of this Agreement and all of which, when taken together, shall constitute one instrument. The exchange of copies of this Agreement and manually executed signature pages by transmission by email of a .pdf of a handwritten original signature or signatures to the other parties hereto shall constitute effective execution and delivery of this Agreement and may be used in lieu of the original Agreement for all purposes. The signature of a party hereto transmitted by electronic means shall be deemed to be an original signature for any purpose.

Section 5.4 Amendment; Waiver. This Agreement may be amended or modified, and any provision hereof may be waived, in whole or in part, at any time pursuant to an agreement in writing executed by the Company and Holders holding a majority of the Registrable Securities at such time. Any failure by any party at any time to enforce any of the provisions of this Agreement shall not be construed a waiver of such provision or any other provisions hereof.

Section 5.5 Severability. If a court of competent jurisdiction finds that any term or provision of this Agreement is invalid, illegal or unenforceable under any Law or public policy, the remaining provisions of this Agreement shall remain in full force and effect if the economic

and legal substance of this Agreement and the Transactions shall not be affected in any manner materially adverse to any party hereto. Any such term or provision found to be illegal, invalid or unenforceable only in part or in degree shall remain in full force and effect to the extent not invalid, illegal or unenforceable. Upon the determination that any term or provision is invalid, illegal or unenforceable, the parties hereto intend that such provision shall be construed by modifying or limiting it so as to be valid and enforceable to the maximum extent possible under applicable Law and compatible with the consummation of the Transactions as originally intended.

Section 5.6. Governing Law; Venue. This Agreement and all claims or causes of action (whether sounding in contract or tort) arising under or related to this Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, without regard to any rule or principle that might refer the governance or construction of this Agreement to the Laws of another jurisdiction. In any action or proceeding between any of the parties hereto arising under or related to this Agreement, each of the parties hereto (i) knowingly, voluntarily, irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the state or federal courts located in the City and County of San Francisco, California, and each of the Parties hereby irrevocably submits to the exclusive jurisdiction of the aforesaid courts, (ii) agrees that all claims in respect of any such action or proceeding shall be heard and determined exclusively in accordance with clause (i) of this Section 5.6, (iii) waives any objection to the laying of venue of any such action or proceeding in such courts, including any objection that any such action or proceeding has been brought in an inconvenient forum or that the court does not have jurisdiction over any party hereto and (iv) agrees that service of process upon such party in any such action or proceeding shall be effective if such process is given as a notice in accordance with Section 5.2. The parties hereto agree that any party hereto may commence a proceeding in a court other than the above-named courts solely for the purpose of enforcing an order or judgment issued by one of the above-named courts.

Section 5.7 Specific Performance. Each party acknowledges and agrees that the other parties hereto would be irreparably harmed and would not have any adequate remedy at law in the event that any of the provisions of this Agreement were not performed by such first party in accordance with their specific terms or were otherwise breached by such first party. Accordingly, each party agrees that the other parties hereto shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement, this being in addition to any other remedy to which such parties are entitled at law or in equity.

(Next Page is Signature Page)

IN WITNESS WHEREOF, each of the parties has executed this Agreement as of the date first written above.

COMPANY:

INVITAE CORPORATION

By: /s/ Sean E. George
Name: Sean E. George, Ph.D.
Title: President and Chief Executive Officer

Address for Notice:

1400 16th Street
San Francisco, California 94103
Attn: General Counsel
Facsimile No.: (415) 276-4164

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Adam Sand __________________

By: /s/ Adam Sand________________
Name:
Title:

Address for Notice: ________________________

Telephone No.: ________________________

Facsimile No.: ________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

AH Bio Fund I, L.P.
for itself and as nominee for AH Bio Fund I-B, L.P.
By: AH Equity Partners Bio I, L.L.C. Its
Name: general partner

By: /s/ Scott Kupor
Name: Scott Kupor
Title: Chief Operating Officer

Address for Notice: ______________________

Telephone No.: ______________________

Facsimile No.: ______________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

AH Bio Fund II, L.P.
for itself and as nominee for AH Bio Fund II-B, L.P.
By: AH Equity Partners Bio II, L.L.C. Its
Name: general partner

By: /s/ Scott Kupor
Name: Scott Kupor
Title: Chief Operating Officer

Address for Notice: ____________________

Telephone No.: ____________________

Facsimile No.: ____________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Anil Sethi ____________________

By: /s/ Anil Sethi __________________
Name:
Title:

Address for Notice: ____________________________

Telephone No.: ____________________________

Facsimile No.: ____________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Brian Carlsen ___________________

By: /s/ Brian Carlsen _________________
Name:
Title:

Address for Notice: ___________________________

Telephone No.: ___________________________

Facsimile No.: ___________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: David Fisch ____________________

By: /s/ David Fisch __________________
Name:
Title:

Address for Notice: ____________________________

Telephone No.: ____________________________

Facsimile No.: ____________________________

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Deven McGraw ____________________

By: /s/ Deven McGraw ________________
Name:
Title:

Address for Notice: ____________________________

Telephone No.: ____________________________

Facsimile No.: ____________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Farid Vij___________________

By: /s/ Farid Vij ________________
Name:
Title:

Address for Notice: _________________________

Telephone No.: _________________________

Facsimile No.: _________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Hughes Ventures, LLC ________

By: /s/ James V. Buzzitta ________
Name: James V. Buzzitta
Title: Manager

Address for Notice: ________________________

Telephone No.: ________________________

Facsimile No.: ________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Intermountain Ventures Fund, LLC____

By: /s/ Nickolas Mark ____________
Name: Nickolas Mark
Title: Vice President of Managing Member

Address for Notice: ______________________

Telephone No.: ______________________

Facsimile No.: ______________________

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: John Wayne Horton________________

By: /s/ John Wayne Horton_____________
Name:
Title:

Address for Notice: ___________________________

Telephone No.: ___________________________

Facsimile No.: ___________________________

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Jordan Shlain__________________

By: /s/ Jordan Shlain________________
Name:
Title:

Address for Notice: ___________________________

Telephone No.: ___________________________

Facsimile No.: ___________________________

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Laurence Marton__________________

By: /s/ Laurence Marton________________
Name:
Title:

Address for Notice: _________________________

Telephone No.: _________________________

Facsimile No.: _________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Lincoln Nadauld__________________

By: /s/ Lincoln Nadauld________________
Name:
Title:

Address for Notice: __________________________

Telephone No.: __________________________

Facsimile No.: __________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Lisa Belliveau____________________

By: /s/ Lisa Belliveau ________________
Name:
Title:

Address for Notice: _________________________

Telephone No.: _________________________

Facsimile No.: _________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: MDC Capital Partners (Ventures) LP____

By: /s/ Howard Caro __________
Name: Howard Caro
Title: Authorized Signatory

Address for Notice: ____________________________

Telephone No.: ____________________________

Facsimile No.: ____________________________

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Nasha Fitter__________________

By: /s/ Nasha Fitter________________
Name:
Title:

Address for Notice: ___________________________

Telephone No.: ___________________________

Facsimile No.: ___________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Nikunj J. Parekh____________________

By: /s/ Nikun J. Parekh___________________
Name:
Title:

Address for Notice: ____________________________

Telephone No.: ____________________________

Facsimile No.: ____________________________

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Peeyush Rai______________________

By: /s/ Peeyush Rai ____________________
Name:
Title:

Address for Notice: ___________________________

Telephone No.: ___________________________

Facsimile No.: ___________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Prashant Palsokar____________________

By: /s/ Prashant Palsokar ________________
Name:
Title:

Address for Notice: ____________________________

Telephone No.: ____________________________

Facsimile No.: ____________________________

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Premal S. Shah____________________

By: /s/ Premal S. Shah ________________
Name:
Title:

Address for Notice: ________________________

Telephone No.: ________________________

Facsimile No.: ________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Priyoadarshi Sen_ __________________

By: /s/ Priyodarshi Sen__________________
Name:
Title:

Address for Notice: __________________________

Telephone No.: __________________________

Facsimile No.: __________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Sand Family Trust____________________

By: /s/ Adam Sand ________________
Name: Adam Sand
Title: Trustee

Address for Notice: ____________________________

Telephone No.: ____________________________

Facsimile No.: ____________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Schox Venture Capital, LP – A2__________

By: /s/ Brett Sagan________________________
Name: Brett Sagan
Title: Authorized Person

Address for Notice: ____________________________

Telephone No.: ____________________________

Facsimile No.: ____________________________

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Section 32 Fund 2, LP
By: Section 32 GP 2, Its General Partner___

By: /s/ William J. Maris____________________
Name: William J. Maris
Title: Managing Member

Address for Notice: ___________________________

Telephone No.: ___________________________

Facsimile No.: ___________________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: StellaTechnology Inc.______________

By: /s/ Lalo Valdez ________
Name: Lalo Valdez
Title: President & CEO

Address for Notice: ____________________

Telephone No.: ____________________

Facsimile No.: ____________________
Email Address:

[Signature Page to Registration Rights Agreement]

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: The 4100 Group, Inc.

By: /s/ Sue E. Jenkins
Name: Sue E. Jenkins
Title: General Counsel and Secretary

Address for Notice: ____________________

Telephone No.: ____________________

Facsimile No.: ____________________

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: The Ahuja Family Trust________________

By: /s/ Deepak Ahuja ____________
Name: Deepak Ahuja
Title: Trustee

Address for Notice: ___________________________

Telephone No.: ___________________________

Facsimile No.: ___________________________

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Verily Life Sciences LLC________________

By: /s/ Andrew Conrad ____________
Name: Andrew Conrad
Title: Chief Executive Officer

Address for Notice: ____________________________

Telephone No.: ____________________________

Facsimile No.: ____________________________

Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Wavemaker Three-Sixty Health A, LP______

By: /s/ John G. Nackel ____________
Name: John G. Nackel
Title: General Partner

Address for Notice: ______________________

Telephone No.: ______________________

Facsimile No.: ______________________
Email Address:

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement as of the date first written above.

HOLDER:

Name: Wavemaker Three-Sixty Health, LP______

By: /s/ John G. Nackel ____________
Name: John G. Nackel
Title: General Partner

Address for Notice: ____________________

Telephone No.: ____________________

Facsimile No.: ____________________
Email Address:

SNP BIO, INC.

2018 EQUITY INCENTIVE PLAN

1. Purpose.

The purpose of the Plan is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company by providing such persons with equity ownership opportunities and thereby better aligning the interests of such persons with those of the Company's stockholders. Capitalized terms used in the Plan are defined in Section 11 below.

2. Eligibility.

Service Providers are eligible to be granted Awards under the Plan, subject to the limitations described herein.

3. Administration and Delegation.

(a) Administration. The Plan will be administered by the Administrator. The Administrator shall have authority to determine which Service Providers will receive Awards, to grant Awards and to set all terms and conditions of Awards (including, but not limited to, vesting, exercise and forfeiture provisions). In addition, the Administrator shall have the authority to take all actions and make all determinations contemplated by the Plan and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Administrator may correct any defect or ambiguity, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem necessary or appropriate to carry the Plan and any Awards into effect, as determined by the Administrator. The Administrator shall make all determinations under the Plan in the Administrator's sole discretion and all such determinations shall be final and binding on all persons having or claiming any interest in the Plan or in any Award.

(b) Appointment of Committees. To the extent permitted by Applicable Laws, the Board may delegate any or all of its powers under the Plan to one or more Committees. The Board may abolish any Committee at any time and re-vest in itself any previously delegated authority.

4. Stock Available for Awards.

(a) Number of Shares. Subject to adjustment under Section 8 hereof, Awards may be made under the Plan covering up to 14,100,000 shares of Common Stock. If any Award expires or lapses or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at or below the original issuance price), in any case in a manner that results in any shares of Common Stock covered by such Award not being issued or being so reacquired by the Company, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock delivered (either by actual delivery or attestation) to the Company by a Participant to satisfy the applicable exercise or purchase price of an Award and/or to satisfy any applicable tax withholding obligation (including shares retained by the Company from the Award being exercised or purchased and/or creating the tax obligation) shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any

limitations under the Code. Shares of Common Stock issued under the Plan may consist in whole or in part of authorized but unissued shares, shares purchased on the open market or treasury shares.

(b) Substitute Awards. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Administrator may grant Awards in substitution for any options or other stock or stock-based awards granted prior to such merger or consolidation by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Administrator deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a) hereof, except as may be required by reason of Section 422 of the Code.

5. Stock Options.

(a) General. The Administrator may grant Options to any Service Provider, subject to the limitations on Incentive Stock Options described below. The Administrator shall determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to Applicable Laws, as it considers necessary or advisable.

(b) Incentive Stock Options. The Administrator may grant Options intended to qualify as Incentive Stock Options only to employees of the Company, any of the Company's present or future "parent corporations" or "subsidiary corporations" as defined in Sections 424(e) or (f) of the Code, respectively, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code. All Options intended to qualify as Incentive Stock Options shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. Neither the Company nor the Administrator shall have any liability to a Participant, or any other party, (i) if an Option (or any part thereof) which is intended to qualify as an Incentive Stock Option fails to qualify as an Incentive Stock Option or (ii) for any action or omission by the Administrator that causes an Option not to qualify as an Incentive Stock Option, including without limitation, the conversion of an Incentive Stock Option to a Non-Qualified Stock Option or the grant of an Option intended as an Incentive Stock Option that fails to satisfy the requirements under the Code applicable to an Incentive Stock Option. Any Option that is intended to qualify as an Incentive Stock Option, but fails to so qualify for any reason, including without limitation, the portion of any Option becoming exercisable in excess of the $100,000 limitation described in Treasury Regulation Section 1.422-4, shall be treated as a Non-Qualified Stock Option for all purposes.

(c) Exercise Price. The Administrator shall establish the exercise price of each Option and specify the exercise price in the applicable Award Agreement. The exercise price shall be not less than 100% of the Fair Market Value on the date the Option is granted. In the case of an Incentive Stock Option granted to an employee who, at the time of grant of the Option, owns (or is treated as owning under Section 424 of the Code) stock representing more than 10% of the voting power of all classes of stock of the Company (or a "parent corporation" or "subsidiary corporation" thereof within the meaning of Sections 424(e) or 424(f) of the Code, respectively), the per share exercise price shall be no less than 110% of the Fair Market Value on the date the Option is granted.

(d) Duration of Options. Each Option shall be exercisable at such times and subject to such terms and conditions as the Administrator may specify in the applicable Award Agreement, provided that the term of any Option shall not exceed ten years. In the case of an Incentive Stock Option granted to an employee who, at the time of grant of the Option, owns (or is treated as owning under Section 424 of the Code) stock representing more than 10% of the voting power of all classes of stock of the Company (or a "parent corporation" or "subsidiary corporation" thereof within the meaning of Sections 424(e) or 424(f) of the Code, respectively), the term of the Option shall not exceed five years.

(e) Exercise of Option; Notification of Disposition. Options may be exercised by delivery to the Company of a written notice of exercise, in a form approved by the Administrator (which may be an electronic form), signed by the person authorized to exercise the Option, together with payment in full (i) as specified in Section 5(f) hereof for the number of shares for which the Option is exercised and (ii) as specified in Section 9(e) hereof for any applicable withholding taxes. Unless otherwise determined by the Administrator, an Option may not be exercised for a fraction of a share of Common Stock. If an Option is designated as an Incentive Stock Option, the Participant shall give prompt notice to the Company of any disposition or other transfer of any shares of Common Stock acquired from the Option if such disposition or transfer is made (i) within two years from the grant date with respect to such Option or (ii) within one year after the transfer of such shares to the Participant (other than any such disposition made in connection with a Change in Control). Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by the Participant in such disposition or other transfer.

(f) Payment Upon Exercise. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for in cash, by wire transfer of immediately available funds or by check, payable to the order of the Company, or, subject to Section 10(h), any Company insider trading policy (including, without limitation, any blackout periods) and Applicable Laws, by:

(i) if the Company is a Publicly Listed Company, unless the Administrator otherwise determines, (A) delivery of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to pay the exercise price, or (B) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to pay the exercise price, provided in either case, that such amount is paid to the Company at such time as may be required by the Administrator;

(ii) to the extent permitted by the Administrator, delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their Fair Market Value, provided (A) such method of payment is then permitted under Applicable Laws, (B) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Company at any time, and (C) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(iii) to the extent permitted by the Administrator, surrendering shares of Common Stock then issuable upon exercise of the Option valued at their Fair Market Value on the date of exercise;

(iv) to the extent permitted by the Administrator, delivery of a promissory note of the Participant to the Company on terms determined by the Administrator;

(v) to the extent permitted by the Administrator, delivery of property of any other kind which constitutes good and valuable consideration as determined by the Administrator; or

(vi) to the extent permitted by the Administrator, any combination of the above permitted forms of payment (including cash or check).

(g) Early Exercise of Options. The Administrator may provide in the terms of an Award Agreement that the Service Provider may exercise an Option in whole or in part prior to the full vesting of the Option in exchange for unvested shares of Restricted Stock with respect to any unvested

portion of the Option so exercised. Shares of Restricted Stock acquired upon the exercise of any unvested portion of an Option shall be subject to such terms and conditions as the Administrator shall determine.

6. Restricted Stock; Restricted Stock Units.

(a) General. The Administrator may grant Restricted Stock, or the right to purchase Restricted Stock, to any Service Provider, subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price from the Participant (or to require forfeiture of such shares if issued at no cost) in the event that conditions specified by the Administrator in the applicable Award Agreement are not satisfied prior to the end of the applicable restriction period or periods established by the Administrator for such Award. In addition, the Administrator may grant to Service Providers Restricted Stock Units, which may be subject to vesting and forfeiture conditions during applicable restriction period or periods, as set forth in an applicable Award Agreement.

(b) Terms and Conditions for All Restricted Stock and Restricted Stock Unit Awards. The Administrator shall determine and set forth in the applicable Award Agreement the terms and conditions applicable to each Restricted Stock and Restricted Stock Unit Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, in each case, if any.

(c) Additional Provisions Relating to Restricted Stock.

(i) Dividends. Participants holding shares of Restricted Stock will be entitled to all ordinary cash dividends paid with respect to such shares to the extent such dividends have a record date that is on or after the date on which the Participant to whom such Restricted Shares are granted becomes the record holder of such Restricted Shares, unless otherwise provided by the Administrator in the applicable Award Agreement. In addition, unless otherwise provided by the Administrator, if any dividends or distributions are paid in shares, or consist of a dividend or distribution to holders of Common Stock of property other than an ordinary cash dividend, the shares or other property will be subject to the same restrictions on transferability and forfeitability as the shares of Restricted Stock with respect to which they were paid. Each dividend payment will be made as provided in the applicable Award Agreement, but in no event later than the end of the calendar year in which the dividends are paid to stockholders of that class of stock or, if later, the 15th day of the third month following the later of (A) the date the dividends are paid to stockholders of that class of stock, and (B) the date the dividends are no longer subject to forfeiture.

(ii) Stock Certificates. The Company may require that any stock certificates issued in respect of shares of Restricted Stock be deposited in escrow by the Participant, together with a stock power endorsed in blank, with the Company (or its designee).

(d) Additional Provisions Relating to Restricted Stock Units.

(i) Settlement. Upon the vesting of a Restricted Stock Unit, the Participant shall be entitled to receive from the Company one share of Common Stock or an amount of cash or other property equal to the Fair Market Value of one share of Common Stock on the settlement date, as the Administrator shall determine and as provided in the applicable Award Agreement. The Administrator may provide that settlement of Restricted Stock Units shall occur upon or as soon as reasonably practicable after the vesting of the Restricted Stock Units or shall instead be deferred, on a mandatory basis or at the election of the Participant, in a manner that complies with Section 409A.

(ii) Voting Rights. A Participant shall have no voting rights with respect to any Restricted Stock Units unless and until shares are delivered in settlement thereof.

(iii) Dividend Equivalents. To the extent provided by the Administrator, a grant of Restricted Stock Units may provide a Participant with the right to receive Dividend Equivalents. Dividend Equivalents may be paid currently or credited to an account for the Participant, may be settled in cash and/or shares of Common Stock and may be subject to the same restrictions on transfer and forfeitability as the Restricted Stock Units with respect to which the Dividend Equivalents are paid, as determined by the Administrator, subject, in each case, to such terms and conditions as the Administrator shall establish and set forth in the applicable Award Agreement.

7. Other Stock-Based Awards.

Other Stock-Based Awards may be granted hereunder to Participants, including, without limitation, Awards entitling Participants to receive shares of Common Stock to be delivered in the future. Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan, as stand-alone payments and/or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock, cash or other property, as the Administrator shall determine. Subject to the provisions of the Plan, the Administrator shall determine the terms and conditions of each Other Stock-Based Award, including any purchase price, transfer restrictions, vesting conditions and other terms and conditions applicable thereto, which shall be set forth in the applicable Award Agreement.

8. Adjustments for Changes in Common Stock and Certain Other Events.

(a) In the event that the Administrator determines that any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), reorganization, merger, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of assets of the Company, or exchange of Common Stock or other securities of the Company, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, or other similar corporate transaction or event, as determined by the Administrator, affects the Common Stock such that an adjustment is determined by the Administrator to be appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award, then the Administrator may, in such manner as it may deem equitable, adjust any or all of:

(i) the number and kind of shares of Common Stock (or other securities or property) with respect to which Awards may be granted or awarded (including, but not limited to, adjustments of the limitations in Section 4 hereof on the maximum number and kind of shares which may be issued);

(ii) the number and kind of shares of Common Stock (or other securities or property) subject to outstanding Awards;

(iii) the grant or exercise price with respect to any Award; and

(iv) the terms and conditions of any Awards (including, without limitation, any applicable financial or other performance "targets" specified in an Award Agreement).

(b) In the event of any transaction or event described in Section 8(a) hereof (including without limitation any Change in Control) or any unusual or nonrecurring transaction or event

affecting the Company or the financial statements or financial condition of the Company, or any change in any Applicable Laws or accounting principles, the Administrator, on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to or after the occurrence of such transaction or event and either automatically or upon the Participant's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to (i) prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award granted or issued under the Plan, (ii) to facilitate such transaction or event or (iii) give effect to such changes in Applicable Laws or accounting principles:

(i) To provide for the cancellation of any such Award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of such Award or realization of the Participant's rights had such Award been currently exercisable, payable and fully vested, as applicable; provided that, if the amount that could have been obtained upon the exercise or settlement of such Award or realization of the Participant's rights, in any case, is equal to or less than zero, then such Award may be terminated without payment;

(ii) To provide that such Award shall vest and, to the extent applicable, be exercisable as to all shares covered thereby, notwithstanding anything to the contrary in the Plan or the provisions of such Award;

(iii) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and applicable exercise or purchase price, in all cases, as determined by the Administrator;

(iv) To make adjustments in the number and type of shares of Common Stock (or other securities or property) subject to outstanding Awards, and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards which may be granted in the future;

(v) To replace such Award with other rights or property selected by the Administrator; and/or

(vi) To provide that the Award will terminate and cannot vest, be exercised or become payable after the applicable event.

(c) In connection with the occurrence of any Equity Restructuring, and notwithstanding anything to the contrary in this Section 8, the Administrator will equitably adjust each outstanding Award, which adjustments may include adjustments to the number and type of securities subject to each outstanding Award and/or the exercise price or grant price thereof, if applicable, the grant of new Awards to Participants, and/or the making of a cash payment to Participants, as the Administrator deems appropriate to reflect such Equity Restructuring. The adjustments provided under this Section 8(c) shall be nondiscretionary and shall be final and binding on the affected Participant and the Company; provided that whether an adjustment is equitable shall be determined by the Administrator.

(d) In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the shares of Common Stock or the share price of the Common Stock, including any Equity Restructuring, or if necessary to comply with Applicable Laws or

the Code, or for reasons of administrative convenience, the Administrator may, in its sole discretion, refuse to permit the exercise of any Award during a period of up to thirty days prior to the consummation of any such transaction.

(e) Except as expressly provided in the Plan or pursuant to action of the Administrator under the Plan, no Participant shall have any rights by reason of any subdivision or consolidation of shares of stock of any class, the payment of any dividend, any increase or decrease in the number of shares of stock of any class or any dissolution, liquidation, merger, or consolidation of the Company or any other corporation. Except as expressly provided in the Plan or pursuant to action of the Administrator under the Plan, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number of shares of Common Stock subject to an Award or the grant or exercise price of any Award. The existence of the Plan, any Award Agreements and the Awards granted hereunder shall not affect or restrict in any way the right or power of the Company to make or authorize (i) any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, (ii) any merger, consolidation dissolution or liquidation of the Company or sale of Company assets or (iii) any sale or issuance of securities, including without limitation, securities with rights superior to those of the Common Stock or which are convertible into or exchangeable for Common Stock. The Administrator may treat Participants and Awards (or portions thereof) differently under this Section 8.

9. General Provisions Applicable to Awards.

(a) Transferability of Awards. Except as the Administrator may otherwise determine or provide in an Award Agreement or otherwise, in any case in accordance with Applicable Laws, Awards, including any interest therein, may not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the life of the Participant, shall be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees.

(b) Documentation. Each Award shall be evidenced in an Award Agreement, which may be in such form (written, electronic or otherwise) as the Administrator shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Discretion. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award to a Participant need not be identical, and the Administrator need not treat Participants or Awards (or portions thereof) uniformly.

(d) Termination of Status. The Administrator shall determine the effect on an Award of the disability, death, retirement, authorized leave of absence or any other change or purported change in a Participant's Service Provider status and the extent to which, and the period during which, the Participant, the Participant's legal representative, conservator, guardian or Designated Beneficiary may exercise rights under the Award, if applicable.

(e) Withholding. Each Participant shall pay to the Company, or make provision satisfactory to the Administrator for payment of, any taxes required by law to be withheld in connection with Awards to such Participant no later than the date of the event creating the tax liability. Except as the Administrator may otherwise determine, all such payments shall be made in cash, by wire transfer of immediately available funds or by check, payable to the order of the Company. Notwithstanding the foregoing, Participants may satisfy such tax obligations, subject to Section 10(h), any Company insider

trading policy (including blackout periods) and Applicable Laws, to the extent permitted by the Administrator, (i) in whole or in part by delivery of shares of Common Stock, including shares of Common Stock retained from the Award creating the tax obligation, valued at their Fair Market Value, and (ii) if there is a public market for shares of Common Stock at the time the tax obligations are satisfied, unless the Administrator otherwise determines, (A) delivery (including, without limitation, telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to satisfy the tax obligations, or (B) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to satisfy the tax withholding; provided that such amount is paid to the Company at such time as may be required by the Administrator. The number of shares of Common Stock which may be so withheld or surrendered shall be limited to the number of shares of Common Stock which have a Fair Market Value on the date of withholding or repurchase no greater than the aggregate amount of such liabilities based on the minimum statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such supplemental taxable income. The Company may, to the extent permitted by Applicable Laws, deduct any such tax obligations from any payment of any kind otherwise due to a Participant.

(f) Amendment of Award. The Administrator may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or settlement, and converting an Incentive Stock Option to a Non-Qualified Stock Option. The Participant's consent to such action shall be required unless (i) the Administrator determines that the action, taking into account any related action, would not materially and adversely affect the Participant, or (ii) the change is permitted under Section 8 and 10(f) hereof.

(g) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Administrator deems necessary or appropriate to satisfy the requirements of any Applicable Laws. The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is determined by the Administrator to be necessary to the lawful issuance and sale of any securities hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such shares as to which such requisite authority shall not have been obtained.

(h) Acceleration. The Administrator may at any time provide that any Award shall become vested and/or exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be.

10. Miscellaneous.

(a) No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or any Award, except as expressly provided in an applicable Award Agreement.

(b) No Rights As Stockholder; Certificates. Subject to the provisions of the applicable Award Agreement, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to an Award until becoming the record holder of such shares. Notwithstanding any other provision of the Plan, unless otherwise determined by the Administrator or required by any Applicable Laws, the Company shall not be required to deliver to any Participant certificates evidencing shares of Common Stock issued in connection with any Award and instead such shares of Common Stock may be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator). The Company may place legends on stock certificates issued under the Plan deemed necessary or appropriate by the Administrator in order to comply with Applicable Laws.

(c) Effective Date and Term of Plan. The Plan shall become effective on the date on which it is adopted by the Board. No Awards shall be granted under the Plan after the completion of ten years from the earlier of (i) the date on which the Plan was adopted by the Board or (ii) the date the Plan was approved by the Company's stockholders, but Awards previously granted may extend beyond that date in accordance with the terms of the Plan.

(d) Amendment of Plan. The Administrator may amend, suspend or terminate the Plan or any portion thereof at any time; provided that no amendment of the Plan shall materially and adversely affect (as determined by the Administrator) any Award outstanding at the time of such amendment without the consent of the affected Participant. Awards outstanding under the Plan at the time of any suspension or termination of the Plan shall continue to be governed in accordance with the terms of the Plan and the applicable Award Agreement, as in effect prior to such suspension or termination. The Board shall obtain stockholder approval of any Plan amendment to the extent necessary to comply with Applicable Laws.

(e) Provisions for Foreign Participants. The Administrator may modify Awards granted to Participants who are foreign nationals or employed outside the United States or establish subplans or procedures under the Plan to address differences in laws, rules, regulations or customs of such foreign jurisdictions with respect to tax, securities, currency, employee benefit or other matters.

(f) Section 409A.

(i) General. The Company intends that all Awards be structured in compliance with, or to satisfy an exemption from, Section 409A, such that no adverse tax consequences, interest, or penalties under Section 409A apply in connection with any Awards. Notwithstanding anything herein or in any Award Agreement to the contrary, the Administrator may, without a Participant's prior consent, amend this Plan and/or Awards, adopt policies and procedures, or take any other actions (including amendments, policies, procedures and actions with retroactive effect) as are necessary or appropriate to preserve the intended tax treatment of Awards under the Plan, including without limitation, any such actions intended to (A) exempt this Plan and/or any Award from the application of Section 409A, and/or (B) comply with the requirements of Section 409A, including without limitation any such regulations, guidance, compliance programs and other interpretative authority that may be issued after the date of grant of any Award. The Company makes no representations or warranties as to the tax treatment of any Award under Section 409A or otherwise. The Company shall have no obligation under this Section 10(f) or otherwise to take any action (whether or not described herein) to avoid the imposition of taxes, penalties or interest under Section 409A with respect to any Award and shall have no liability to any Participant or any other person if any Award, compensation or other benefits under the Plan are determined to constitute non-compliant, "nonqualified deferred compensation" subject to the imposition of taxes, penalties and/or interest under Section 409A.

(ii) Separation from Service. With respect to any Award that constitutes "nonqualified deferred compensation" under Section 409A, any payment or settlement of such Award that is to be made upon a termination of a Participant's Service Provider relationship shall, to the extent necessary to avoid the imposition of taxes under Section 409A, be made only upon the Participant's "separation from service" (within the meaning of Section 409A), whether such "separation from service" occurs upon or subsequent to the termination of the Participant's Service Provider relationship. For purposes of any such provision of this Plan or any Award Agreement relating to any such payments or benefits, references to a "termination," "termination of employment" or like terms shall mean "separation from service."

(iii) Payments to Specified Employees. Notwithstanding any contrary provision in the Plan or any Award Agreement, any payment(s) of "nonqualified deferred compensation" that are otherwise required to be made under an Award to a "specified employee" (as defined under Section 409A and determined by the Administrator) as a result of his or her "separation from service" shall, to the extent necessary to avoid the imposition of taxes under Code Section 409A(a)(2)(B)(i), be delayed until the expiration of the six-month period immediately following such "separation from service" (or, if earlier, until the date of death of the specified employee) and shall instead be paid (in a manner set forth in the Award agreement) on the day that immediately follows the end of such six-month period or as soon as administratively practicable thereafter (without interest). Any payments of "nonqualified deferred compensation" under such Award that are, by their terms, payable more than six months following the Participant's "separation from service" shall be paid at the time or times such payments are otherwise scheduled to be made.

(g) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, other employee or agent of the Company will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan or any Award, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as an Administrator, director, officer, other employee or agent of the Company. The Company

will indemnify and hold harmless each director, officer, other employee and agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be granted or delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Administrator's approval) arising out of any act or omission to act concerning this Plan unless arising out of such person's own fraud or bad faith.

(h) Lock-Up Period. The Company may, at the request of any representative of the underwriters or otherwise, in connection with any registration of the offering of any securities of the Company under the Securities Act, prohibit Participants from, directly or indirectly, selling or otherwise transferring any shares of Common Stock or other securities of the Company during a period of up to one hundred eighty days following the effective date of a registration statement of the Company filed under the Securities Act.

(i) Right of First Refusal.

(i) Before any shares of Common Stock held by a Participant or any permitted transferee (each, a "Holder") may be sold, pledged, assigned, hypothecated, transferred, or otherwise disposed of (each, a "Transfer"), the Company or its assignee(s) shall have a right of first refusal to purchase the shares of Common Stock proposed to be Transferred on the terms and conditions set forth in this Section 10(i) (the "Right of First Refusal"). In the event that the Company's charter, bylaws and/or a stockholders' agreement applicable to the shares of Common Stock contain a right of first refusal with respect to the shares of Common Stock, such right of first refusal shall apply to the shares of Common Stock to the extent such provisions are more restrictive than the Right of First Refusal set forth in this Section 10(i) and the Right of First Refusal set forth in this Section 10(i) shall not in any way restrict the operation of the Company's charter, bylaws or the operation of any applicable stockholders' agreement.

(ii) In the event any Holder desires to Transfer any shares of Common Stock, the Holder shall deliver to the Company a written notice (the "Notice") stating: (A) the Holder's bona fide intention to sell or otherwise Transfer such shares of Common Stock; (B) the name of each proposed purchaser or other transferee ("Proposed Transferee"); (C) the number of shares of Common Stock to be Transferred to each Proposed Transferee; and (D) the price for which the Holder proposes to Transfer the shares of Common Stock (the "Offered Price"), and the Holder shall offer such shares of Common Stock at the Offered Price to the Company or its assignee(s).

(iii) Within twenty-five days after receipt of the Notice, the Company and/or its assignee(s) may elect in writing to purchase all, but not less than all, of the shares of Common Stock proposed to be Transferred to any one or more of the Proposed Transferees by delivery of a written exercise notice to the Holder (a "Company Notice"). The purchase price ("Purchase Price") for the shares of Common Stock repurchased under this Section 10(i) shall be the Offered Price.

(iv) Payment of the Purchase Price shall be made, at the option of the Company or its assignee(s), in cash (by check or wire transfer), by cancellation of all or a portion of any outstanding indebtedness of the Holder to the Company (or, in the case of repurchase by an assignee, to the assignee), or by any combination thereof, within five days after delivery of the Company Notice or in the manner and at the times mutually agreed to by the Company and the Holder. Should the Offered Price specified in the Notice be payable in property other than cash, the Company or its assignee shall have the right to pay the purchase price in the form of cash equal in amount to the value of such property, as determined by the Administrator.

(v) If all or a portion of the shares of Common Stock proposed in the Notice to be Transferred are not purchased by the Company and/or its assignee(s) as provided in this Section 10(i), then the Holder may sell or otherwise Transfer such shares of Common Stock to that Proposed Transferee at the Offered Price or at a higher price; provided that such sale or other Transfer is consummated within sixty days after the date of the Notice; and provided, further, that any such sale or other Transfer is effected in accordance with any Applicable Laws and the Proposed Transferee agrees in writing that the provisions of this Plan and the applicable Award Agreement and any other applicable agreements governing the shares of Common Stock to be Transferred shall continue to apply to the shares of Common Stock in the hands of such Proposed Transferee. If the shares of Common Stock described in the Notice are not Transferred to the Proposed Transferee within such sixty-day period, a new Notice shall be given to the Company, and the Company and/or its assignees shall again be offered the Right of First Refusal, as provided herein, before any shares of Common Stock held by the Holder may be sold or otherwise Transferred.

(vi) Anything to the contrary contained in this Section 10(i) notwithstanding and to the extent permitted by the Administrator, the Transfer of any or all of the shares of Common Stock during a Participant's lifetime or upon a Participant's death by will or intestacy to the Participant's Immediate Family or a trust for the benefit of the Participant's Immediate Family shall be exempt from the Right of First Refusal. As used herein, "Immediate Family" shall mean spouse, lineal descendant or antecedent, father, mother, brother or sister or stepchild (whether or not adopted). In such case, the transferee or other recipient shall receive and hold the shares of Common Stock so Transferred subject to the provisions of this Plan (including the Right of First Refusal), the applicable Award Agreement and any other applicable agreements governing the shares of Common Stock to be Transferred, and there shall be no further Transfer of such shares of Common Stock except in accordance with the terms of this Section 10(i) (or otherwise as expressly provided under the Plan).

(vii) The Right of First Refusal shall terminate as to all shares of Common Stock if the Company becomes a Publicly Listed Company upon such occurrence.

(j) Data Privacy. As a condition of receipt of any Award, each Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this paragraph by and among, as applicable, the Company and its subsidiaries and affiliates for the exclusive purpose of implementing, administering and managing the Participant's participation in the Plan. The Company and its subsidiaries and affiliates may hold certain personal information about a Participant, including but not limited to, the Participant's name, home address and telephone number, date of birth, social security or insurance number or other identification number, salary, nationality, job title(s), any shares of stock held in the Company or any of its subsidiaries and affiliates, details of all Awards, in each case, for the purpose of implementing, managing and administering the Plan and Awards (the "Data"). The Company and its subsidiaries and affiliates may transfer the Data amongst themselves as necessary for the purpose of implementation, administration and management of a Participant's participation in the Plan, and the Company and its subsidiaries and affiliates may each further transfer the Data to any third parties assisting the Company in the implementation, administration and management of the Plan. These recipients may be located in the Participant's country, or elsewhere, and the Participant's country may have different data privacy laws and protections than the recipients' country. Through acceptance of an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing the Participant's participation in the Plan, including any requisite transfer of such Data as may be required to a broker or other third party with whom the Company or the Participant may elect to deposit any shares of Common Stock. The Data

related to a Participant will be held only as long as is necessary to implement, administer, and manage the Participant's participation in the Plan. A Participant may, at any time, view the Data held by the Company with respect to such Participant, request additional information about the storage and processing of the Data with respect to such Participant, recommend any necessary corrections to the Data with respect to the Participant or refuse or withdraw the consents herein in writing, in any case without cost, by contacting his or her local human resources representative. The Company may cancel Participant's ability to participate in the Plan and, in the Administrator's discretion, the Participant may forfeit any outstanding Awards if the Participant refuses or withdraws his or her consents as described herein. For more information on the consequences of refusal to consent or withdrawal of consent, Participants may contact their local human resources representative.

(k) Severability. In the event any portion of the Plan or any action taken pursuant thereto shall be held illegal or invalid for any reason, the illegality or invalidity shall not affect the remaining parts of the Plan, and the Plan shall be construed and enforced as if the illegal or invalid provisions had not been included, and the illegal or invalid action shall be null and void.

(l) Governing Documents. In the event of any contradiction between the Plan and any Award Agreement or any other written agreement between a Participant and the Company or any Subsidiary of the Company that has been approved by the Administrator, the terms of the Plan shall govern, unless it is expressly specified in such Award Agreement or other written document that a specific provision of the Plan shall not apply.

(m) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, disregarding choice-of-law principles of the law of any state that would require the application of the laws of a jurisdiction other than such state.

(n) Submission to Jurisdiction; Waiver of Jury Trial. By accepting an Award, each Participant irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the courts of the State of Delaware and of the United States of America, in each case located in the State of Delaware, for any action arising out of or relating to the Plan (and agrees not to commence any litigation relating thereto except in such courts), and further agrees that service of any process, summons, notice or document by U.S. registered mail to the address contained in the records of the Company shall be effective service of process for any litigation brought against it in any such court. By accepting an Award, each Participant irrevocably and unconditionally waives any objection to the laying of venue of any litigation arising out of Plan or Award hereunder in the courts of the State of Delaware or the United States of America, in each case located in the State of Delaware, and further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such litigation brought in any such court has been brought in an inconvenient forum. By accepting an Award, each Participant irrevocably and unconditionally waives, to the fullest extent permitted by applicable law, any and all rights to trial by jury in connection with any litigation arising out of or relating to the Plan or any Award hereunder.

(o) Restrictions on Shares; Claw-Back Provisions. Awards and shares of Common Stock acquired in respect of Awards shall be subject to such terms and conditions as the Administrator shall determine, including, without limitation, restrictions on the transferability of shares of Common Stock, the right of the Company to repurchase shares of Common Stock, the right of the Company to require that shares of Common Stock be transferred in the event of certain transactions, tag-along rights, bring-along rights, redemption and co-sale rights and voting requirements. Such terms and conditions may be additional to those contained in the Plan and may, as determined by the Administrator, be contained in the applicable Award Agreement or in an exercise notice, stockholders' agreement or in such other agreement as the Administrator shall determine, in each case in a form determined by the

Administrator. The issuance of such shares of Common Stock shall be conditioned on the Participant's consent to such terms and conditions and the Participant's entering into such agreement or agreements. All Awards (including any proceeds, gains or other economic benefit actually or constructively received by Participant upon any receipt or exercise of any Award or upon the receipt or resale of any shares of Common Stock underlying the Award) shall be subject to the provisions of any claw-back policy implemented by the Company, including, without limitation, any claw-back policy adopted to comply with the requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder, to the extent set forth in such claw-back policy and/or in the applicable Award Agreement. A Participant shall, as a condition to receiving an Award, agree to execute such further instruments and to take such further action as the Company requests to carry out the purposes and intent of the Plan and any Award, including, without limitation, restrictions on the transferability of shares of Common Stock, the right of the Company to repurchase shares of Common Stock, the right of the Company to require that shares of Common Stock be transferred in the event of certain transactions, tag-along rights, bring-along rights, redemption and co-sale rights and voting requirements in accordance with Section 10(o) of the Plan.

(p) Titles and Headings. The titles and headings of the Sections in the Plan are for convenience of reference only and, in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control.

(q) Conformity to Securities Laws. Participant acknowledges that the Plan is intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any and all regulations and rules promulgated by the Securities and Exchange Commission thereunder, and state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan and all Awards granted hereunder shall be administered only in such a manner as to conform to such laws, rules and regulations. To the extent permitted by Applicable Laws, the Plan and all Award Agreements shall be deemed amended to the extent necessary to conform to such laws, rules and regulations.

11. Definitions. As used in the Plan, the following words and phrases shall have the following meanings:

(a) "Administrator" means the Board or a Committee to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.

(b) "Applicable Laws" means the requirements relating to the administration of equity incentive plans under U.S. federal and state securities, tax and other applicable laws, rules and regulations, the applicable rules of any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws and rules of any foreign country or other jurisdiction where Awards are granted or issued under the Plan.

(c) "Award" means, individually or collectively, a grant under the Plan of Options, Restricted Stock, Restricted Stock Units or Other Stock-Based Awards.

(d) "Award Agreement" means a written agreement evidencing an Award, which agreements may be in electronic medium and shall contain such terms and conditions with respect to an Award as the Administrator shall determine, consistent with and subject to the terms and conditions of the Plan.

(e) "Board" means the Board of Directors of the Company.

(f) "Cause," with respect to a Participant, means "Cause" (or any term of similar effect) as defined in such Participant's employment agreement with the Company if such an agreement exists and contains a definition of Cause (or term of similar effect), or, if no such agreement exists or such agreement does not contain a definition of Cause (or term of similar effect), then Cause shall include, but not be limited to: (i) the Participant's unauthorized use or disclosure of confidential information or trade secrets of the Company or any material breach of a written agreement between the Participant and the Company, including without limitation a material breach of any employment, confidentiality, non-compete, non-solicit or similar agreement; (ii) the Participant's commission of, indictment for or the entry of a plea of guilty or nolo contendere by the Participant to, a felony under the laws of the United States or any state thereof or any crime involving dishonesty or moral turpitude (or any similar crime in any jurisdiction outside the United States); (iii) the Participant's gross negligence or willful misconduct or the Participant's willful or repeated failure or refusal to substantially perform assigned duties; (iv) any act of fraud, embezzlement, material misappropriation or dishonesty committed by the Participant against the Company; or (v) any acts, omissions or statements by a Participant which the Company reasonably determines to be materially detrimental or damaging to the reputation, operations, prospects or business relations of the Company.

(g) "Change in Control" means (i) a merger or consolidation of the Company with or into any other corporation or other entity or person, (ii) a sale, lease, exchange or other transfer in one transaction or a series of related transactions of all or substantially all of the Company's assets, or (iii) any other transaction, including the sale by the Company of new shares of its capital stock or a transfer of existing shares of capital stock of the Company, the result of which is that a third party that is not an affiliate of the Company or its stockholders (or a group of third parties not affiliated with the Company or its stockholders) immediately prior to such transaction acquires or holds capital stock of the Company representing a majority of the Company's outstanding voting power immediately following such transaction; provided that the following events shall not constitute a "Change in Control": (A) a transaction (other than a sale of all or substantially all of the Company's assets) in which the holders of the voting securities of the Company immediately prior to the merger or consolidation hold, directly or indirectly, at least a majority of the voting securities in the successor corporation or its parent immediately after the merger or consolidation; (B) a sale, lease, exchange or other transaction in one transaction or a series of related transactions of all or substantially all of the Company's assets to an affiliate of the Company; (C) an initial public offering of any of the Company's securities or any other transaction or series of related transactions principally for bona fide equity financing purposes; (D) a reincorporation of the Company solely to change its jurisdiction; (E) a transaction undertaken for the primary purpose of creating a holding company that will be owned in substantially the same proportion by the persons who held the Company's securities immediately before such transaction; or (F) a transaction or series of related transactions principally for bona fide equity financing purposes in which cash is received by the Company or any successor or indebtedness of the Company is cancelled or converted, or a combination thereof. Notwithstanding the foregoing, if a Change in Control would give rise to a payment or settlement event with respect to any Award that constitutes "nonqualified deferred compensation," the transaction or event constituting the Change in Control must also constitute a "change in control event" (as defined in Treasury Regulation §1.409A-3(i)(5)) in order to give rise to the payment or settlement event for such Award, to the extent required by Section 409A.

(h) "Code" means the Internal Revenue Code of 1986, as amended, and the regulations issued thereunder.

(i) "Committee" means one or more committees or subcommittees of the Board, which may be comprised of one or more directors and/or executive officers of the Company, in either case, to the extent permitted in accordance with Applicable Laws.

(j) "Common Stock" means the common stock of the Company.

(k) "Company" means SNP Bio, Inc., a Delaware corporation, or any successor thereto. Except where the context otherwise requires, the term "Company" includes any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a significant interest, as determined by the Administrator.

(l) "Consultant" means any person, including any advisor, engaged by the Company or a parent or subsidiary of the Company to render services to such entity.

(m) "Designated Beneficiary" means the beneficiary or beneficiaries designated, in a manner determined by the Administrator, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death or incapacity In the absence of an effective designation by a Participant, "Designated Beneficiary" shall mean the Participant's estate.

(n) "Director" means a member of the Board.

(o) "Disability" means a permanent and total disability within the meaning of Section 22(e)(3) of the Code, as it may be amended from time to time.

(p) "Dividend Equivalents" means a right granted to a Participant pursuant to Section 6(d)(3) hereof to receive the equivalent value (in cash or shares of Common Stock) of dividends paid on shares of Common Stock.

(q) "Employee" means any person, including officers and Directors, employed by the Company (within the meaning of Section 3401(c) of the Code) or any parent or subsidiary of the Company.

(r) "Equity Restructuring" means, as determined by the Administrator, a non-reciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off or recapitalization through a large, nonrecurring cash dividend, that affects the shares of Common Stock (or other securities of the Company) or the share price of Common Stock (or other securities of the Company) and causes a change in the per share value of the Common Stock underlying outstanding Awards.

(s) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

(t) "Fair Market Value" means, as of any date, the value of Stock determined as follows: (i) if the Common Stock is listed on any established stock exchange, its Fair Market Value shall be the closing sales price for such Common Stock as quoted on such exchange for such date, or if no sale occurred on such date, the first market trading day immediately prior to such date during which a sale occurred, as reported in The Wall Street Journal or such other source as the Administrator deems reliable; (ii) if the Common Stock is not traded on a stock exchange but is quoted on a national market or other quotation system, the last sales price on such date, or if no sales occurred on such date, then on the date immediately prior to such date on which sales prices are reported, as reported in The Wall Street Journal or such other source as the Administrator deems reliable; or (iii) in the absence of an established market for the Common Stock, the Fair Market Value thereof shall be determined by the Administrator.

(u) "Good Reason" shall mean (a) a change in the Participant's position with the Company (or its subsidiary employing the Participant) that materially reduces the Participant's authority, duties or responsibilities, (b) a material diminution in the Participant's level of base compensation, except in connection with a general reduction in the base compensation of the Company's personnel with similar status and responsibilities or (c) a relocation of the Participant's place of employment by more than 50

miles, provided that such change, reduction or relocation is effected by the Company (or its subsidiary employing the Participant) without the Participant's consent. Notwithstanding the foregoing, Good Reason shall only exist if Participant shall have provided the Company with written notice within sixty (60) days of the initial occurrence of any of the foregoing events or conditions, and the Company or any successor or affiliate fails to eliminate the conditions constituting Good Reason within thirty (30) days after receipt of written notice of such event or condition from Participant. Participant's resignation from employment with the Company for "Good Reason" must occur within six (6) months following the initial occurrence of one of the foregoing events or conditions. Notwithstanding the foregoing, if Participant is a party to a written employment or consulting agreement with the Company (or its subsidiary) in which the term "good reason" is defined, then "Good Reason" shall be as such term is defined in the applicable written employment or consulting agreement.

(v) "Incentive Stock Option" means an "incentive stock option" as defined in Section 422 of the Code.

(w) "Non-Qualified Stock Option" means an Option that is not intended to be or otherwise does not qualify as an Incentive Stock Option.

(x) "Option" means an option to purchase Common Stock.

(y) "Other Stock-Based Awards" means other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property.

(z) "Participant" means a Service Provider who has been granted an Award under the Plan.

(aa) "Plan" means this 2018 Equity Incentive Plan.

(bb) "Publicly Listed Company" means that the Company or its successor (i) is required to file periodic reports pursuant to Section 12 of the Exchange Act and (ii) the Common Stock is listed on one or more National Securities Exchanges (within the meaning of the Exchange Act) or is quoted on NASDAQ or a successor quotation system.

(cc) "Restricted Stock" means Common Stock awarded to a Participant pursuant to Section 6 hereof that is subject to certain vesting conditions and other restrictions.

(dd) "Restricted Stock Unit" means an unfunded, unsecured right to receive, on the applicable settlement date, one share of Common Stock or an amount in cash or other consideration determined by the Administrator equal to the value thereof as of such payment date, which right may be subject to certain vesting conditions and other restrictions.

(ee) "Section 409A" means Section 409A of the Code and all regulations, guidance, compliance programs and other interpretative authority thereunder.

(ff) "Securities Act" means the Securities Act of 1933, as amended from time to time.

(gg) "Service Provider" means an Employee, Consultant or Director.

(hh) "Termination of Service" means the date the Participant ceases to be a Service Provider.

SNP BIO, INC.

2018 EQUITY INCENTIVE PLAN

CALIFORNIA SUPPLEMENT

The Administrator has adopted this supplement for purposes of satisfying the requirements of Section 25102(o) of the California Corporations Code and the regulations issued thereunder ("Section 25102(o)"). Notwithstanding anything to the contrary contained in the Plan and except as otherwise determined by the Administrator, the provisions set forth in this supplement shall apply to all Awards granted under the Plan to a Participant who is a resident of the State of California on the date of grant (a "California Participant") and which are intended to be exempt from registration in California pursuant to Section 25102(o). This supplement shall not apply to Awards granted to California Participants or after the date on which the Company becomes a Publicly Listed Company. Definitions in the Plan are applicable to this supplement.

1. Limitation on Securities Issuable under the Plan. The amount of securities issued pursuant to the Plan shall not exceed the amounts permitted under section 260.140.45 of the California Code of Regulations to the extent applicable.

2. Additional Limitations On Options.

(a) Maximum Duration of Options. No Options granted to California Participants will be granted for a term in excess of 10 years.

(b) Minimum Exercise Period Following Termination. Unless a California Participant's Service Provider relationship is terminated for Cause, in the event of termination of such Participant's Service Provider relationship, to the extent required by Applicable Laws, he or she shall have the right to exercise an Option, to the extent that he or she was otherwise entitled to exercise such Option on the date employment terminated, as follows: (i) at least six months from the date of termination, if termination was caused by such Participant's death or Disability and (ii) at least 30 days from the date of termination, if termination was caused other than by such Participant's death or Disability.

3. Additional Limitations For Restricted Stock Awards, Restricted Stock Units and Other Stock-Based Awards. The terms of all Awards granted to California Participants shall comply, to the extent applicable, with Section 260.140.41 and Section 260.140.42 of the California Code of Regulations.

4. Adjustments. The Administrator will make such adjustments to an Award held by a California Participant as may be required by Section 260.140.41 or Section 260.140.42 of the California Code of Regulations.

5. Additional Requirement To Provide Information To California Participants. To the extent required by Section 260.140.46 of the California Code of Regulations, the Company shall provide to each California Participant and to each California Participant who acquires Common Stock pursuant to the Plan, not less frequently than annually, copies of annual financial statements (which need not be audited). The Company shall not be required to provide such statements to key persons whose duties in connection with the Company assure their access to equivalent information. In addition, this information requirement shall not apply to the Plan to the extent that it complies with all conditions of Rule 701 of the Securities Act ("Rule 701") as determined by the Administrator; provided that for purposes of

determining such compliance, any registered domestic partner shall be considered a "family member" as that term is defined in Rule 701.

6. Stockholder Approval; Additional Limitations On Timing Of Awards. The Plan will be submitted for the approval of the Company's stockholders within twelve (12) months after the date of the Board's adoption of the Plan. Awards may be granted or awarded prior to such stockholder approval; provided that no Award granted to a California Participant shall become exercisable, vested or realizable, as applicable to such Award, unless the Plan has been approved by the Company's stockholders within twelve months before or after the date the Plan was adopted by the Administrator; and provided, further, that if such approval has not been obtained at the end of said twelve-month period, all Awards previously granted or awarded under the Plan to California Participants shall thereupon be canceled and become null and void.

AMENDMENT NO. 1
TO THE
STRATIFY GENOMICS INC. 2018 EQUITY INCENTIVE PLAN

THIS AMENDMENT NO. 1 TO THE STRATIFY GENOMICS INC. 2018 EQUITY INCENTIVE PLAN (this "Amendment"), dated as of , 2019, is made and adopted by STRATIFY GENOMICS INC., a Delaware corporation (the "Company"). Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Plan (as defined below).

RECITALS

WHEREAS, the Company has adopted the Stratify Genomics Inc. 2018 Equity Incentive Plan (the "Plan");

WHEREAS, the Company desires to amend the Plan as set forth below;

WHEREAS, pursuant to Section 10(d) of the Plan, the Plan may be amended by the Board of Directors of the Company; and

WHEREAS, the Board of Directors of the Company has approved this Amendment pursuant to resolutions adopted on , 2019, and the stockholders of the Company have approved this Amendment pursuant to resolutions adopted on , 2019.

NOW, THEREFORE, in consideration of the foregoing, the Company hereby amends the Plan as follows:

1. The first sentence of Section 4 of the Plan is hereby amended to read as follows:

   "Subject to adjustment under Section 8 hereof, Awards may be made under the Plan covering up to 9,230,000 shares of Common Stock."

2. This Amendment shall be and is hereby incorporated in and forms a part of the Plan. All other terms and provisions of the Plan shall remain unchanged except as specifically modified herein. The Plan, as amended by this Amendment, is hereby ratified and confirmed.

[REMAINDER OF PAGE LEFT INTENTIONALLY BLANK]

I hereby certify that the foregoing Amendment was duly adopted by the Board of Directors of Stratify Genomics Inc. on , 2019, and duly approved by the stockholders of Stratify Genomics Inc. on , 2019.

By: /s/ Martyn Gross
Name: Martyn Gross
Title: President

AMENDMENT NO. 2 TO THE
STRATIFY GENOMICS INC. 2018 EQUITY INCENTIVE PLAN

THIS AMENDMENT NO. 2 TO THE STRATIFY GENOMICS INC. 2018 EQUITY INCENTIVE PLAN (this "Plan Amendment No. 2"), dated as of May 15, 2020, is made and adopted by STRATIFY GENOMICS INC., a Delaware corporation (the "Company"). Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Plan (as defined below).

RECITALS

WHEREAS, the Company has previously adopted the Stratify Genomics Inc. 2018 Equity Incentive Plan (as subsequently amended, the "Plan");

WHEREAS, the Company previously amended the Plan pursuant to that certain Amendment No. 1 to the Corporation's 2018 Equity Incentive Plan, which, among other things, decreased the total number of shares issuable under the 2018 Equity Incentive Plan to 9,230,000 shares;

WHEREAS, the Company now desires to amend the Plan to increase the available shares that are issuable under the Plan as set forth below;

WHEREAS, pursuant to Section 10(d) of the Plan, the Plan may be amended by the Board of Directors of the Company; and

WHEREAS, the Board of Directors of the Company has approved this Plan Amendment No. 2 pursuant to resolutions adopted on May 15, 2020 and has submitted this Plan Amendment No. 2 to the stockholders of the Company for their approval.

NOW, THEREFORE, in consideration of the foregoing, the Company hereby amends the Plan as follows:

1. The first sentence of Section 4 of the Plan is hereby amended to read as follows:

   Subject to adjustment under Section 8 hereof, Awards may be made under the Plan covering up to 11 million (11,000,000) shares of Common Stock."

2. This Plan Amendment No. 2 shall be and is hereby incorporated in and forms a part of the Plan. All other terms and provisions of the Plan shall remain unchanged except as specifically modified herein. The Plan, as amended by this Plan Amendment No. 2, is hereby ratified and confirmed.

[REMAINDER OF PAGE LEFT INTENTIONALLY BLANK]

I hereby certify that the foregoing Amendment No. 2 to the Stratify Genomics Inc. 2018 Equity Incentive Plan was duly adopted by the Board of Directors of Stratify Genomics Inc. on May 15, 2020, and has been submitted for approval by the stockholders of Stratify Genomics Inc.

By: /s/ Dalaura Kader
Name: Dalaura Kader
Title: President

Exhibit 21.1

LIST OF SUBSIDIARIES OF INVITAE CORPORATION

Subsidiary	Jurisdiction
ArcherDX, LLC	Delaware
ArcherDX Clinical Services, Inc.	Colorado
Ciitizen, LLC	Delaware
Genelex India Private Limited	India
Genetic Solutions LLC, d/b/a Genelex	Pennsylvania
Genosity, LLC	Delaware
Good Start Genetics, Inc.	Delaware
Invitae Australia PTY LTD	Australia
Invitae Canada Inc.	British Colombia, Canada
Invitae Israel Inc Ltd.	Israel
Invitae Japan, KK	Japan
Invitae Latvia SIA	Latvia
Invitae Medical Genetics Brasil Ltda.	Brazil
Invitae Netherlands, B.V.	Netherlands
Invitae (Singapore) Pte. Ltd.	Singapore
Medneon LLC	Delaware
Ommdom Inc.	Delaware
Orbicule BVBA d/b/a Diploid	Belgium
Prompt Genomics, LLC	Delaware
Reference Genomics, LLC d/b/a One Codex	Delaware
YouScript, LLC	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statements on Form S-3 (Nos. 333-220053, 333-220054 and 333-226756) of Invitae Corporation and the related prospectuses
- Registration Statements on Form S-3ASR (Nos. 333-230053, 333-233109, 333-233110, 333-234768 333-237268, 333-237758, 333-237759, 333-253653, 333-253655, 333-255765, 333-256683 and 333-259550) of Invitae Corporation and the related prospectuses
- Registration Statement on Form S-4 (No. 333-220447) of Invitae Corporation, including any post-effective amendments thereto on Form S-3 or Form S-8
- Registration Statement on Form S-4 (No. 333-240137) of Invitae Corporation, including any post-effective amendments thereto on Form S-8
- Registration Statement on Form S-8 (No. 333-202066) pertaining to the 2015 Stock Incentive Plan, the Employee Stock Purchase Plan, and the 2010 Stock Incentive Plan of Invitae Corporation
- Registration Statements on Form S-8 (Nos. 333-216761, 333-223455 ,333-229972, 333-236799 and 333-253615) pertaining to the 2015 Stock Incentive Plan and the Employee Stock Purchase Plan of Invitae Corporation
- Registration Statement on Form S-8 (Nos. 333-232208, 333-237073, 333-240360, 333-249894, 333-255770, 333-258654 and 333-259512) pertaining to the 2015 Stock Incentive Plan of Invitae Corporation
- Registration Statement on Form S-8 (Nos. 333-261920) pertaining to the Stratify Genomics Inc. 2018 Incentive Plan

of our reports dated March 1, 2022, with respect to the consolidated financial statements of Invitae Corporation and the effectiveness of internal control over financial reporting of Invitae Corporation included in this Annual Report (Form 10-K) of Invitae Corporation for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Redwood City, California
March 1, 2022

Exhibit 31.1

PRINCIPAL EXECUTIVE OFFICER'S CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sean E. George, certify that:

1. I have reviewed this annual report on Form 10-K of Invitae Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2022

/s/ Sean E. George, Ph.D.

Sean E. George, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER'S CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Yafei (Roxi) Wen, certify that:

1. I have reviewed this annual report on Form 10-K of Invitae Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2022

/s/ Yafei (Roxi) Wen

Yafei (Roxi) Wen
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report of Invitae Corporation (the “Company”) on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer’s knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2022

/s/ Sean E. George, Ph.D.
Sean E. George, Ph.D.
Chief Executive Officer and Director

(Principal Executive Officer)

Exhibit 32.2

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report of Invitae Corporation (the “Company”) on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer’s knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2022

/s/ Yafei (Roxi) Wen

Yafei (Roxi) Wen
Chief Financial Officer
(Principal Financial Officer)