

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  

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**Form 10-K**

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

For the fiscal year ended December 31, 2022

☐ **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**

**Invitae Corporation**

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

Delaware  
(State or other jurisdiction of  
incorporation or organization)

**27-1701898**  
(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. ☒

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

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

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

As of June 30, 2022, the aggregate market value of common stock held by non-affiliates of the Registrant was approximately \$569.8 million, 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 24, 2023 was 246,235,501.

**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 of this Annual Report on Form 10-K 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 2023 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 of our strategic realignment efforts;
- the expected costs and benefits of our strategic realignment, including anticipated annualized cash savings, and our ability to achieve positive operating cash flow;
- 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;
- our expectations regarding our platform and future offerings;
- 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;
- our ability to obtain and maintain adequate reimbursement for our tests;
- regulatory, political and other 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 to service and repay our debt;
- our future financial performance;
- our beliefs regarding our future growth and the drivers of such growth;
- 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;
- the impact of macroeconomic conditions, including inflation and recession, on our business; 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 Part I, Item 1A. “Risk Factors” in this Annual Report on Form 10-K. 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. 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. 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 Annual Report and, in particular, the following principal risks and all of the other specific factors described in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K 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.
- Our strategic realignment and the associated headcount reduction have and are expected to significantly change our business, result in significant expense, may not result in anticipated savings, and will disrupt our business.
- 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 services, and our failure to generate sufficient demand for our tests and other services would have a negative impact on our business and our ability to attain profitability.
- The global macroeconomic environment could negatively impact our business, our financial position and our results of operations.
- 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.
- 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 for our tests, our commercial success will be negatively affected.
- 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.
- Impairment in the value of our goodwill or other intangible assets has and may in the future have a material adverse effect on our operating results and financial condition.
- We have a large amount of debt, servicing our debt requires a significant amount of cash, we may not have sufficient cash flow from our business to service our debt, and we may need to refinance all or a significant portion of our debt.
- If the U.S. 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.
- 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.

## 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. We offer genetic testing across multiple clinical areas, including hereditary cancer, precision oncology, women's health, rare diseases and pharmacogenomics. 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. We also utilize digital health solutions to improve ease-of-use and to deliver actionable information about risk, prevention, treatment, and monitoring. As of December 31, 2022, we have served over 3.6 million patients, and over 2.2 million of those patients have made their information available for data sharing. We believe the depth of our genetic data, along with our approach to combine genetic testing information with third-party patient data, produce an enriched dataset that could lead to valuable insights and benefits to the lives of patients and their families and to the healthcare ecosystem, including providers, biopharma partners, patient advocacy groups and more. Our access and scale enables genomic information to speed the discovery and development of new personalized medical therapies — all while making clinical genetic testing and new solutions 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.

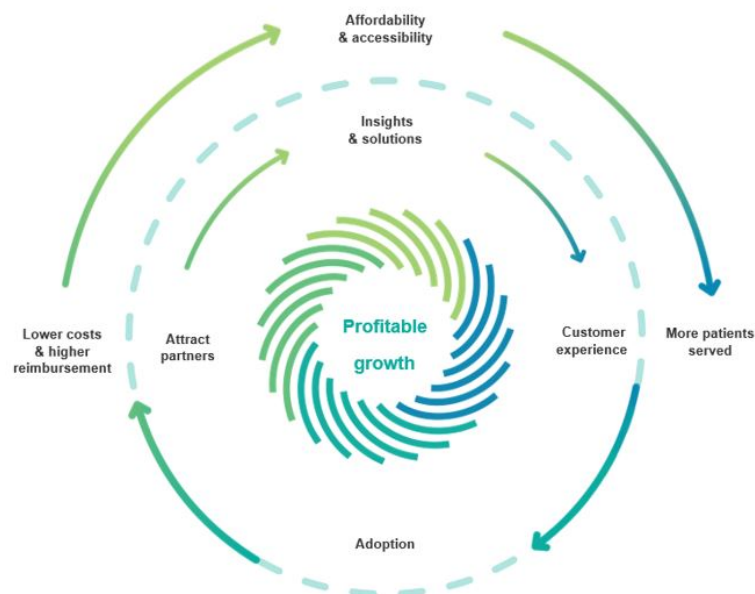
#### Mission and strategy

Invitae's mission is to bring comprehensive genetic information into mainstream medical practice to improve the quality of healthcare for billions of people.

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, profitable growth centers on seven 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:



Those key drivers include:

- **Customer experience:** We see customer experience for patients, providers, and partners as integral to our long-term growth strategy and as an under-utilized catalyst to move genetics into mainstream medicine. Our view is that providing great service and enabling "ease-of-use", such as efficient ordering, comprehensive choices, and reliable turnaround time, are especially important for physicians.
- **Adoption:** As we improve customer experience, we expect more physicians would be open and more willing to increase genetic information in their practice. This is particularly true in fostering adoption among non-genetic experts, who are often the first contact for patients in a health journey. This work will be in parallel with our efforts in producing research supporting guideline expansion and broader advocacy for the benefits of genetic testing.
- **Attract partners:** As we continue to gain adoption and expand our reach, our value proposition to potential partners should increase. These include patient advocacy groups, biopharma partners that utilize our data, testing, network, and services, as well as health systems that intend to implement comprehensive precision medicine.
- **Insights and solutions:** In parallel with bringing new tools and products to the market, our unique capability to combine phenotypic and genotypic data, through both our genetic testing and third-party patient data, we believe produces a rich dataset that is highly attractive to biopharma partners, patient advocacy groups and more. Our services allow our partners to be more precise and move faster with their efforts, such as identifying and recruiting patients, enabling Investigational New Drug (IND) filings, structuring clinical trials, and eventually bringing new therapies to market.
- **Lower cost and higher reimbursement:** As our network continues to scale, we expect to lower our costs and increase our margin, while continuing our pursuit of low prices to drive accessibility and affordability of genetic information. Our ability to sustainably lower our prices is also expected to be balanced by our success in improving reimbursements and cash collection. Through the generation of scientific evidence and proactive engagement with stakeholders, we intend to pursue better payment and additional coverage.
- **Affordability and accessibility:** As we progress, we can continue to drive down prices, yielding more affordability and accessibility of our products for more patients.
- **More patients served:** All of these efforts should compound upon each other, expanding our reach and increasing the value of each offering, ultimately serving more patients.

Ultimately, we anticipate more solutions to further improve customer experiences, which in turn feed more answers for patients, foster greater adoption, and bring on more partners to create a flywheel effect.

### **Business overview**

We are focused on making comprehensive, high-quality medical genetic information more accessible and instrumental to the healthcare ecosystem and stakeholders, including patients, healthcare providers, payers, biopharma partners, patient advocacy groups and more. Medical genetics is central to health outcomes and we are working to bring it to the mainstream by enhancing the customer experience, lowering costs, removing barriers to adoption, and expanding insights and solutions. Ultimately, we expect the utility of the accumulated data will compound, enabling improved individual and population health and advancing the benefits of molecular medicine around the globe.

As we grow, we expect that our business will expand and evolve in three stages:

- 1) **One patient, one test:** We first launched in November 2013 with an offering of approximately 200 genes, growing the test menu over time to include more than 20,000 genes. In 2022, we processed billable volume of 1,290,000 units and generated revenue of \$516.3 million compared to 1,169,000 units and \$460.4 million 2021 billable volume and revenue, respectively.
- 2) **One patient, multiple insights:** We utilize digital health solutions to deliver actionable information about risk, prevention, treatment, and monitoring. With integration, connectivity, and refined go-to-market strategies, we are shifting to a scenario where each patient test provides many opportunities to deliver solutions — for them, for their families and for others in the ecosystem. Our comprehensive portfolio is expected to enable precision medicine, and provide multiple insights for patients as they engage with us across different stages in life and through different health needs. As of December 31,

2022, we have served over 3.6 million patients, and information from over 2.2 million of those patients is available for data sharing.

- 3) **Many patients, many solutions:** Each patient engagement generates data and insights. Aggregating these into solutions for key stakeholders including patients, providers, policymakers, biopharma partners, advocacy groups and others is where we expect the next phase of transformation will occur. We are focusing our efforts on partnering with these stakeholders to advance the development and utility of our platform. Our real-world data is patient-owned and controlled; and our goal is to enable and build a data and patient network through which individuals and partners can access, aggregate, and customize genetic information to further research and create better outcomes. We expect this to allow for the collective insights from many patients to provide multiple solutions for multiple use cases and customer types.

In addition to investing in informatics solutions and infrastructure to support our data and patient network development, we have been expanding our strategic partnerships, which as of December 31, 2022 numbered more than 100 leading biopharmaceutical companies supporting improved patient diagnosis, clinical trial recruitment and other research-related initiatives.

In addition, 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.

### **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 Corporation ("Ambry Genetics"), a subsidiary of Realm IDx, Inc. ("Realm IDx"); Athena Diagnostics, Inc. ("Athena Diagnostics") and Blueprint Genetics, subsidiaries of Quest Diagnostics Incorporated ("Quest Diagnostics"); Baylor-Miraca Genetics Laboratories LLC ("Baylor-Miraca Genetics Laboratories"); Caris Life Sciences, Inc. ("Caris Life Sciences"); Centogene AG; Color Health, Inc. ("Color Health"); Connective Tissue Gene Test LLC ("Connective Tissue Gene Test"), a subsidiary of Health Network Laboratories, L.P. ("Health Network Laboratories"); Cooper Surgical, Inc. ("Cooper Surgical"); Emory Genetics Laboratory, a subsidiary of Eurofins Scientific; Exact Sciences Corporation ("Exact Sciences"); Foundation Medicine, Inc. ("Foundation Medicine"), a subsidiary of Roche Holding AG; Fulgent Genetics, Inc. ("Fulgent Genetics"); GeneDx Holdings Corp ("GeneDx Holdings"); Guardant Health, Inc. ("Guardant Health"); Integrated Genetics, Sequenom Inc. ("Sequenom"), Correlagen Diagnostics, Inc. ("Correlagen Diagnostics"), and MNG Laboratories, subsidiaries of Laboratory Corporation of America Holdings ("Labcorp"); Myriad Genetics, Inc. ("Myriad Genetics"); Natera, Inc. ("Natera"); NeoGenomics, Inc. ("NeoGenomics"); Perkin Elmer, Inc. ("Perkin Elmer"); and Tempus Labs, Inc. ("Tempus Labs") as well as other commercial and academic laboratories.

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. ("Illumina") 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:

- comprehensive content;
- quality;
- reliability;
- accessibility of results;
- turnaround time of testing results;
- price and quality of tests;
- coverage and reimbursement arrangements with third-party payers;
- ease-of-use and 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 2024 and every three years thereafter (or annually for “advanced diagnostic laboratory tests”), private payer payment rates and volumes for their tests. We do not have 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 2024. 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 were limited to 10% per test per year in each of the years 2018 through 2020. Rates were held at 2020 levels during 2021 and 2022 and will continue to be held at such levels in 2023. Then, where applicable based upon median private payer rates reported in 2017 or 2024, payment rates may be reduced by up to 15% per test per year in each of 2024 through 2026 (with a second round of private payer rate reporting in 2024 to establish rates for 2025 through 2027).

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 national Medicare 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 national Medicare 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, North Carolina 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 California, North Carolina, and 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 those states. 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 laboratory holds the required out-of-state laboratory licenses for Maryland, New York, Pennsylvania, and Rhode Island. Our Washington, North Carolina and New Jersey laboratories hold the required out-of-state laboratory licenses in California, Maryland, New York, Pennsylvania, and Rhode Island.

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 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.

### ***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 tests we may offer in the future that FDA 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 order, 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 order 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 are 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 the safety and effectiveness of a medical device to obtain FDA 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.

### ***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;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of “off-label” uses of cleared or approved products;
- 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. 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 grant certain rights to individuals with respect to their PHI, including the right to access and amend certain records containing their PHI, request restrictions on the use or disclosure of their PHI, and request an accounting of disclosures of their 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 include requirements for implementing workforce training, implementing policies, 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 the event of a breach of unsecured PHI, a covered entity must notify any affected individual, the Secretary of the U.S. Department of Health and Human Services and, under certain circumstances, the media. A business associate must notify the relevant covered entity of any breach of unsecured PHI.

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 \$1.9 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. 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 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. 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 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 FTC has become more aggressive in its enforcement actions against not only companies, but individual executives as well. To the extent that individual executives become subject to an FTC consent decree, or that an executive subject to a consent decree joins our company, it could impact our operations.

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, and especially, data that the FTC considers sensitive, such as geolocation 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.

### ***State Consumer Privacy Legislation***

The California Consumer Privacy Act, or CCPA, is a comprehensive consumer privacy law that took effect on January 1, 2020 and was further amended as of January 1, 2023. The CCPA regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of natural persons who reside in California. Among other things, the CCPA confers to California residents the rights of data transparency, access, deletion, correction, and the ability to opt-out of or limit the use of their personal data for certain purposes. The CCPA also requires a business to implement reasonable security procedures to safeguard personal information against unauthorized access, use, or disclosure.

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.

Several states have passed consumer privacy legislation that is substantially similar to the CCPA and will take effect in 2023. The Colorado Privacy Act will take effect on July 1, 2023; the Connecticut Personal Data Privacy Act will take effect on July 1, 2023; the Utah Consumer Privacy Act will take effect on December 31, 2023, and the Virginia Consumer Data Protection Act came into effect on January 1, 2023. Each of these state laws provides substantially the same rights to residents of each respective state as does the CCPA for California residents. Unlike the CCPA, however, each of these other state laws excludes information collected from employees or business-to-business contacts. Each of the laws also do not apply to PHI under HIPAA and also generally exempt HIPAA-regulated entities from their reach. The state laws are enforced by their respective state's Attorney Generals, and none of them 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 proscriptive than those in the U.S., while other jurisdictions may have laws less restrictive or proscriptive 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 themselves 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 of 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. Canada is considering a series of significant amendments to PIPEDA, the implementation of which would be to make PIPEDA more like GDPR. If the amendments to PIPEDA were to come into effect, they could have an impact on our operations in Canada.

## *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 went 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 approximately \$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 the civil monetary penalty 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 May 9, 2022, whose associated violations occurred after November 2, 2015, the penalties range from \$12,537 to 25,076 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, among other things, 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, certain other providers including 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 \$185,009 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 \$27,750 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, 2021 and 2022 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, Integrated DNA Technologies Inc. ("IDT"), Roche Holdings Ltd., QIAGEN N.V. ("QIAGEN") 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 as described in Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual 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. 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 online 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 revenue trends**

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, 2022, 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 higher demand for our tests from patients who have met their annual insurance deductible. Revenue in the fourth quarter of fiscal year 2022 declined as we exited product offerings and geographies related to our strategic realignment. The continued impact of exiting product offerings and geographies coupled with changes in our product and payer mix might cause these historical trends to be different than future trends 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. We had approximately 1,700 employees as of December 31, 2022, of which approximately 61% were women and 39% men. Our management team as of December 31, 2022 was 29% women and 71% men.

#### *Diversity, Equity and Inclusion, or DEI*

Our DEI mission is to attract, 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. As of December 31, 2022, approximately 56% of our workforce was White, 21% Asian, 9% Hispanic, 5% Black or African American, 4% two or more races (not Hispanic or Latino) and 5% not self-identified based on our payroll system and individual self-identification. On our management team,

21% are people who identify as non-White. With the addition of a board member on January 26, 2023, our board of directors is now 50% racially diverse with 38% female representation and an average age of 58.

#### *Our culture and mission*

Our team is driven to make a difference for the patients. We aim to be a highly functioning and collaborative team, well equipped to attract, develop and retain diverse talent while driving culture, engagement, and change management in support of business objectives. Our People & Culture business partners are embedded within leadership teams to help support our talent strategy and team development throughout our organization. We provide employees with opportunities to grow and advance, supported by flexible work hours, flexible paid time off (non-accrual), the ability to work remotely for many roles, and the satisfaction of doing meaningful work.

#### *Our total rewards philosophy*

We offer a competitive total rewards package, which includes base compensation, incentive compensation, equity, healthcare coverage, 401(k) (with a partial match), an employee stock purchase plan, and a broad range of other benefits including family leave and parental leave for new parents. Our health vendor provides fertility and adoption benefits for our U.S. employees and most of our global employees. Additionally, we have an employer-sponsored genetic testing program, which provides employees and their covered dependents access to our genetic testing at no cost.

#### *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, which is responsible for ensuring our COVID-19 policies and practices meet all necessary standards and regulations. Our response has evolved as the situation has evolved. We monitor, update and align our corporate policies to meet state and federal occupational health and safety rules. We work to ensure employees follow guidance regarding COVID-19 protocols including testing, quarantine requirements, exposure control measures, contact tracing, and masking.

#### **Information about our executive officers**

The names of our executive officers and other corporate officers, and their ages as of February 28, 2023, are as follows:

<b>Name</b>	<b>Age</b>	<b>Position</b>
<b>Executive officers</b>		
Kenneth D. Knight	62	Chief Executive Officer and Director
Yafei (Roxi) Wen	50	Chief Financial Officer
Thomas R. Brida	52	General Counsel, Chief Compliance Officer and Secretary
Robert L. Nussbaum, M.D.	73	Chief Medical Officer
Robert F. Werner	49	Chief Accounting Officer

*Kenneth D. Knight* has served as a director and our Chief Executive Officer since July 2022. Mr. Knight also served as our Chief Operating Officer from June 2020 to July 2022. Prior to joining Invitae, 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 an M.B.A. from the Massachusetts Institute of Technology.

*Yafei (Roxi) Wen* has served as our Chief Financial officer since June 2021. Prior to joining Invitae, from February 2019 to June 2021, she served as the Chief Financial Officer at Mozilla Corporation, an open-source software company, 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, a touch screen systems and components company, from April 2014 to February 2019, and General Electric Critical Power, an electronics power technology company, from 2008 to 2013, following her experience driving capital market and business finance efforts at Medtronic, a leading medical technology company, from 2002 to 2008. Roxi is a CFA charterholder and has an M.B.A. from the University of Minnesota.

*Thomas R. Brida* has served as our General Counsel since January 2017, our Chief Compliance Officer since February 2019, and our Secretary since May 2019. 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.

*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.

*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 B.S. 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](http://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](http://www.invitae.com). All reports that we file are also available at [www.sec.gov](http://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, 2022, 2021 and 2020, our net losses were \$3.1 billion, \$379.0 million and \$602.2 million, respectively. At December 31, 2022, our accumulated deficit was \$4.8 billion. We expect to continue to incur significant losses as we invest in our business. We incurred research and development expenses of \$402.1 million, \$416.1 million and \$240.6 million and selling and marketing expenses of \$218.9 million, \$225.9 million and \$168.3 million in 2022, 2021 and 2020, respectively. Since 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; 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 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 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.

***Our strategic realignment and the associated headcount reduction have and are expected to significantly change our business, result in significant expense, may not result in anticipated savings, and will disrupt our business.***

On July 18, 2022, we initiated a strategic realignment of our operations and began implementing programs to reduce operating costs and drive future growth aligned with our core genetic testing and data platform and patient network. This realignment involves a significant reduction in our workforce as well as other steps to streamline our operations, including exiting our distributed products business and significantly decreasing our global footprint outside of the United States to less than a dozen countries or territories. Management currently expects that the strategic realignment will be completed in 2023 and estimates that the total costs incurred may be up to \$170 million for associated employee severance and benefits, losses on asset disposals, and other restructuring costs including the write-off of prepaid assets related to the exit of certain product offerings, professional service fees and contract exit costs. Actual costs may be higher than we expect. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our realignment efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. For example, our divestiture activities may divert management's attention from our core business operations, result in significant write-offs and other charges, and have an adverse effect on existing relationships with partners, customers, patients and third-party payers. We have also terminated early, changed the scope of, or may not be able to perform under certain contracts as a result of our realignment efforts, and we could incur significant liability if we do not successfully negotiate wind-down provisions or new terms. For example, we have informed certain contractual counterparties that we will not be able to perform under our companion diagnostic development agreements. Any of these or other events could adversely affect our financial condition and results of operations. In addition, we may not be able to retain qualified personnel, which may negatively affect our infrastructure and operations or result in a loss of employees and reduced productivity among remaining employees. For example, our turnaround times in returning test results increased recently. Further, the realignment may yield unintended consequences, such as attrition beyond our intended workforce reduction, reduced employee morale, loss of customers or partners, and other adverse effects on our business.

If our management is unable to successfully manage this transition and realignment activities, our expenses may be more than expected and may vary significant from period to period and we may be unable to implement our business strategy. As a result, our future financial performance, operations, and prospects would be negatively affected.

***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. In July 2022, we initiated a strategic realignment of our operations and began implementing cost reduction programs that will ultimately reduce our workforce by approximately 1,000 employees. This reduction in workforce has and will continue to result in the loss of institutional knowledge and expertise and the reallocation of and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Further, the realignment has and may continue to yield unintended consequences, such as attrition beyond our intended workforce reduction and reduced employee morale. 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, and remains depressed, as it has in the recent past, or if we do not have enough shares authorized to grant equity awards to new and existing employees, we may not be able to recruit and retain 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 and evolves, 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 services, and our failure to generate sufficient demand for our tests and other 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 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 infrastructure growth will be in advance of demand for our tests and other services. Many of our current and future expense levels are fixed. Because the timing and amount of revenue from our 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 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.

***The global macroeconomic environment could negatively impact our business, our financial position and our results of operations.***

Adverse macroeconomic developments, including inflation, slowing growth, rising interest rates, or recession, may adversely affect our business and financial condition. These developments have caused, and could in the future cause, disruptions and volatility in global financial markets and increased rates of default and bankruptcy, and negatively affect business and consumer spending. Adverse economic conditions have and may continue to increase the costs of operating our business, including vendor, supplier and workforce expenses, and may limit our access to capital or may significantly increase our cost of capital. Management continues to evaluate the impact of macroeconomic events, including inflation, on our business and our future plans and intends to take appropriate measures to help alleviate their impact, but there can be no assurance that these efforts will be successful. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. A severe or prolonged economic downturn, such as the global financial crisis, could also reduce our ability to raise additional capital when needed on acceptable terms, if at all. Presently, we have customers who have been adversely affected by Russia's invasion of Ukraine, and we have experienced some disruption in our engineering productivity as we have sought to assist contractors in both Ukraine and Russia who have been dislocated or who have chosen to flee Russia. Likewise, the capital and credit markets have been and may continue to be adversely affected by the invasion, the possibility of a wider European or global conflict, and global sanctions imposed in response to the invasion. We cannot predict the future trajectory of these risks, including how the macroeconomic environment will evolve or how it will continue to impact us.

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 or otherwise, 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.

***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 COVID-19 pandemic. Global health concerns relating to COVID-19 have negatively affected the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty. As discussed in our prior and current Form 10-K and 10-Q filings, our operations have been and will continue to be impacted by the COVID-19 pandemic and its related economic challenges. 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.

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.

***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, and cost-effective, and/or whether the patient has received prior authorization.

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 copayment 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 Realm IDx; Athena Diagnostics and Blueprint Genetics, subsidiaries of Quest Diagnostics; Baylor-Miraca Genetics Laboratories; Caris Life Sciences; Centogene AG; Color Health; Connective Tissue Gene Test, a subsidiary of Health Network Laboratories; Cooper Surgical; Emory Genetics Laboratory, a subsidiary of Eurofins Scientific; Exact Sciences; Foundation Medicine, a subsidiary of Roche Holding AG; Fulgent Genetics; GeneDx Holdings; Guardant Health; Integrated Genetics, Sequenom, Correlagen Diagnostics, and MNG Laboratories, subsidiaries of Labcorp; Myriad Genetics; Natera; NeoGenomics; Perkin Elmer; and Tempus Labs; as well as other commercial and academic laboratories;
- a few large, established general testing companies with large market share and significant channel power, such as Labcorp and Quest Diagnostics;
- 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, 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 2021 acquisition of Ciitizen Corporation ("Ciitizen"). Ciitizen competes with companies in the patient data platform business, including, among others, PicnicHealth, All Stripes Research Inc., Seqster PDM, Inc., Apple Inc. ("Apple"), and Flatiron Health, Inc.

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 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.

***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, ransomware fraud, spikes in customer usage and denial of service issues. There continues to be a significant level of in ransomware and cyber security attacks related to the ongoing conflict between Russia and Ukraine, 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.

In addition to data security risks, we face privacy risks. Should we actually violate, or be perceived to have violated, any privacy commitments 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 and liability and penalties under federal, state, foreign, or multinational laws that regulate the privacy, security, or breach of personal information, such as but not limited to HIPAA, HITECH, the FTC Act, state UDAP data security and data breach notification laws, the GDPR and the UK Data Protection Act of 2018.

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 in May 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. Among other requirements, the GDPR imposes strict rules 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. Maximum penalties for violations of the GDPR are capped at 20.0 million 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, in June 2018, California adopted the California Consumer Privacy Act of 2018, or the CCPA. The CCPA, is a comprehensive consumer privacy law that took effect in January 2020 and was further amended as of January 1, 2023. The CCPA regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of natural persons who reside in California. 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.

Virginia, Connecticut, Colorado, and Utah have recently enacted similar privacy acts, and dozens of other states in the United States are currently considering similar consumer data privacy laws, which could impact our operations if enacted. 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 for 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 research and development activities related to our Personalized Cancer Monitoring ("PCM") service for cancer monitoring. The demand for this service is unproven, and we may not be successful in achieving market awareness and demand for these services through our sales and marketing 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 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 may 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 has and may in the future 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 has and may in the future result in an impairment of goodwill or intangible assets and, in turn, a charge to net income. These charges in the three months ended June 30, 2022 and any future charges related to intangible assets have, and may in the future have, a material adverse effect on our results of operations or financial condition.

During the three months ended June 30, 2022, as a result of a significant, sustained decline in our stock price and related market capitalization and lower than expected financial performance, we performed an impairment assessment of goodwill, in-process research and development ("IPR&D") intangible assets, and long-lived assets, including definite-lived intangibles.

For our goodwill, we measured the fair value of the reporting unit utilizing the discounted cash flow method under the income approach. This approach relies on significant unobservable inputs including, but not limited to, management's forecasts of projected revenue associated with future cash flows, discount rates, and control premium. Based on this analysis, we recognized a non-cash, pre-tax goodwill impairment charge of \$2.3 billion during the three months ended June 30, 2022, which is included in goodwill and IPR&D impairment expense in the consolidated statements of operations.

We also identified indicators of impairment related to the IPR&D intangible asset initially recognized as part of the acquisition of Singular Bio, Inc. ("Singular Bio") that it was more likely than not that the asset is impaired. We identified conditions during the three months ended June 30, 2022 such as alternative technologies and uncertainties around the desired outcome of our in-development asset and other economic factors that raised issues with the realizability of our asset. As a result of our evaluation, we recognized a non-cash, pre-tax impairment charge of \$30.0 million during the three months ended June 30, 2022 related to the IPR&D intangible asset, which is included in goodwill and IPR&D impairment expense in the consolidated statements of operations.

***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, IDT, QIAGEN, 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.

***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, California, 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 provide our services, or develop new services. 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 recent changes in our leadership may adversely affect our business.***

In July 2022, in connection with our strategic realignment, we announced the appointment of Kenneth D. Knight, who had served as our Chief Operating Officer since 2020, as our Chief Executive Officer. We also announced that Dr. Sean E. George, who co-founded our company and served as our Chief Executive Officer since 2017, would support our company through a transition period as a consultant. These changes in our executive management, and any future changes, as well as the effects of our business realignment, could disrupt our business, and could impact our ability to preserve our culture, which could negatively affect our ability to recruit and retain personnel. If we are not successful in managing the transition of Mr. Knight into his new role, it could be viewed negatively by our customers, employees or investors and could have an adverse impact on our business. Further, these changes also increase our dependency on other members of our executive management team. If we lose the services of any member of the executive management team or any key personnel, we may not be able to secure a suitable or qualified replacement, which could disrupt our business and could be particularly disruptive considering our strategic realignment.

***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.

***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 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 evaluate 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.

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. Acquisitions by us have, and may in the future, 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. In addition, as part of our strategic realignment, we have and may continue to divest assets acquired in previous acquisitions at substantial discounts to the price we paid, or without realizing the benefits we intended at the time of the acquisition. 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. In addition, in connection with our strategic realignment, we have recently divested or sublicensed certain product offerings, technologies and assets that we had acquired in prior years.

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.

***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, 2022, we have substantial deferred tax assets consisting of federal and state net operating losses and tax credit carryforwards. At December 31, 2022, our total gross deferred tax assets were \$795.5 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. 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% stockholders” 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 our indebtedness

***We have a large amount of debt, servicing our debt requires a significant amount of cash, we may not have sufficient cash flow from our business to service our debt, and we may need to refinance all or a significant portion of our debt.***

In September 2019, we issued \$350.0 million aggregate principal amount of our convertible senior notes due 2024 in a private placement, and in April 2021 we issued \$1,150.0 million 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 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, including paying off the principal when due, and make necessary capital expenditures. The conversion prices of our convertible notes are significantly higher than the prevailing market prices for our common stock, and our stock price would have to increase significantly in order for holdings to convert our notes prior to maturity. If we are unable to generate cash flow necessary to service or repay our debt at maturity, 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, and the terms of any such refinancing may be less favorable to us than the terms of our current indebtedness. 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.

**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 "Regulation—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 individualized enforcement action, more generally as outlined in final guidance or 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.

***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 any disease or impairment of, or the assessment of health of, human beings. CLIA regulations establish specific requirements and 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 are also required to maintain certain in-state and out-of-state laboratory licenses and approvals to conduct testing. For more information about our federal (CLIA) and state laboratory licenses and approvals, please see Part I, Item 1. under the headings "Regulation—Clinical Laboratory Improvement Amendments of 1988, or CLIA" and "Regulation—State laboratory licensure requirements," which are incorporated by reference herein. 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.

***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 and HITECH, which set forth comprehensive federal standards with respect to the privacy and security of protected health information, breach notification requirements, and requirements for the use of certain standardized electronic transactions;
- 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 and other, similar state consumer privacy laws, which, among other things, regulate how subject businesses may collect, use, and disclose the personal information of consumers in the regulated state, afford rights to consumers that they may exercise against businesses that collect their information, and require implementation of reasonable security measures to safeguard personal information of 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 federal Physician Payments Sunshine Act, which requires reporting of certain payments and other transfers of value made by applicable manufacturers, directly or indirectly, to or on behalf of various healthcare professionals (including doctors, physician assistants, and nurse practitioners) and teaching hospitals, and requires reporting of certain ownership and investment interests held by physicians and their immediate family members as well as similar state laws that require reporting of information in addition to what is required under the federal Physician Payments Sunshine Act;
- 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 operations 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. In October 2021, we 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 have produced documents and information in response 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 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 2024 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 do not have "advanced diagnostic laboratory test" status for our tests, but in the event that we obtain 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 "Regulation—Reimbursement" for a description of how public and private payers 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. 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.

***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 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.***

Our AMP chemistry is the foundation of our PCM service. One of our competitors, Natera, Inc., or Natera, has filed complaints against ArcherDX, LLC ("ArcherDX"), Invitae and Genosity, Inc. ("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, 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, on August 2, 2022, Senator Thom Tillis (R-NC) introduced a bill entitled The Patent Eligibility Restoration Act of 2022 that would overrule current U.S. Supreme Court precedent concerning the scope of patentable subject matter. If the proposed bill were to be 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.

As an example, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system will likely be introduced by the end of 2023, which would significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

***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.

## **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;
- effects of our strategic realignment and workforce reduction and our ability to achieve the intended benefits of these activities;
- costs associated with our strategic realignment;

- 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 substantial leverage and market perceptions regarding the same;
- the level of short interest in our stock, and the effect of short sellers on the price of our stock;
- 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 the NYSE ranged from \$2.36 to \$11.65 between February 1, 2022 through January 31, 2023. 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 such as the current conflict in Ukraine, 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, 2022, we had outstanding 245.6 million shares of our common stock, options to purchase 2.4 million shares of our common stock (of which 1.4 million were exercisable as of that date) and outstanding restricted stock units, or RSUs, representing 11.9 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 8.8 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 shares of our common stock in an aggregate amount not to exceed \$400 million. In addition, as of December 31, 2022, 5.5 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, 2023, 9.8 million and 2.5 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 October 2026 and we may renew the lease for an additional ten years.

Following our strategic realignment, in December 2022, we entered into an agreement to sublease 41,630 square feet of office space located in a multi-tenant building in Boulder, Colorado. This sublease agreement expires on January 31, 2025.

We also lease approximately 573,000 square feet of additional office and laboratory space domestically in California, Colorado, Massachusetts, New Jersey, New York, North Carolina, Texas and Washington, and internationally in Australia, Belgium, Israel and Japan. As part of our strategic realignment announced in July 2022, we began cost reduction initiatives including office and laboratory space consolidation and a reduction in our international footprint. Under this strategic realignment, we decided to cease use of certain leased premises and actively began looking to sublease certain facilities.

We believe that our facilities are adequate to meet the needs for our business in the near term.

**ITEM 3. Legal Proceedings**

For a discussion of legal matters as of December 31, 2022, 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 NYSE under the symbol "NVTA" since February 12, 2015. Prior to that time, there was no public market for our common stock.

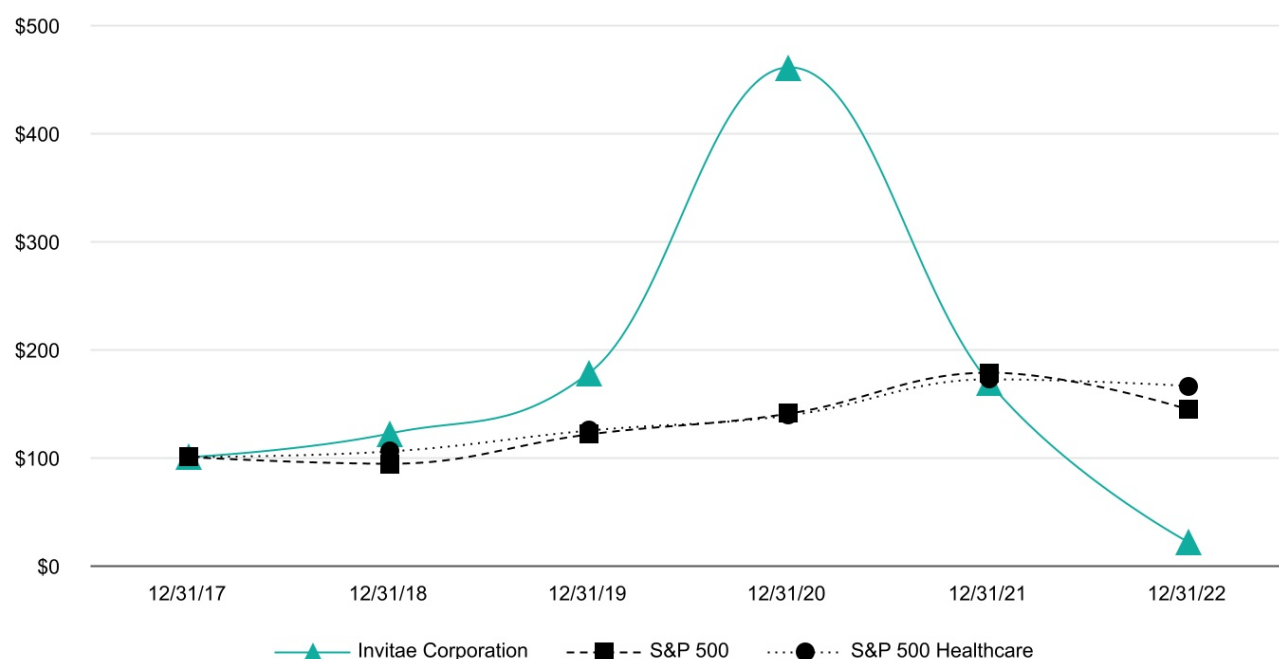
As of February 24, 2023, there were 276 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

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.

Comparison of Historical Cumulative Total Return Among Invitae Corporation, the S&P 500 Index and the S&P 500 Healthcare Index (\*)



(\*) The above graph shows the cumulative total stockholder return of an investment of \$100 in cash on December 31, 2017 through December 31, 2022 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.

	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022
Invitae Corporation	\$ 100.00	\$ 121.81	\$ 177.64	\$ 460.46	\$ 168.17	\$ 20.48
S&P 500	\$ 100.00	\$ 93.76	\$ 120.84	\$ 140.49	\$ 178.27	\$ 143.61
S&P 500 Healthcare Index	\$ 100.00	\$ 104.69	\$ 124.25	\$ 138.45	\$ 171.90	\$ 165.80

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 are focused on making comprehensive and high-quality, medical genetic testing information more accessible and instrumental to the healthcare ecosystem and stakeholders, including patients, healthcare providers, payers, biopharma partners, patient advocacy groups, and more. We offer genetic testing across multiple clinical areas, including hereditary cancer, precision oncology, women's health, rare diseases and pharmacogenomics. Medical genetics is central to health outcomes and we are working to bring it to the mainstream by enhancing the customer experience, lowering the costs, removing barriers to adoption, and expanding insights and solutions. Ultimately, we expect the utility of the accumulated data will compound, enabling improved individual and population health and advancing the benefits of molecular medicine around the globe.

Historically, a component of our strategy was to augment internal growth with complementary transactions. We did not complete any acquisitions in fiscal year 2022 but did have dispositions related to our strategic realignment. In 2021, we completed the acquisitions of Reference Genomics, Inc. d/b/a One Codex, or One Codex, Genosity, Medneon LLC, or Medneon, Citiizen, and Stratify Genomics Inc., or Stratify. See Note 4, "Business combinations and dispositions" and Note 5, "Goodwill and intangible assets" in the Notes to Consolidated Financial statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information on our recent acquisitions and dispositions.

For the years ended December 31, 2022, 2021 and 2020, our revenue was \$516.3 million, \$460.4 million and \$279.6 million, respectively, and we incurred net losses of \$3.1 billion, \$379.0 million and \$602.2 million, respectively. At December 31, 2022, our accumulated deficit was \$4.8 billion.

In 2022, 2021 and 2020, we generated 1,290,000, 1,169,000 and 659,000 billable units, respectively. We calculate volume using billable units, which are billable events that include individual test reports released and individual reactions shipped related to our precision oncology products. We refer to the set of reagents needed to perform a next generation sequencing ("NGS") test for our research use only ("RUO") product as a "reaction." As part of the strategic realignment, we discontinued the sale of and sublicensed to others our distributed precision oncology products, which includes our RUO kit and IVD product offerings. For the year ended December 31, 2022, approximately 53% of the billable volume generated were billable to patients and institutional customers (e.g., hospitals, clinics, medical centers, biopharmaceutical partners), 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, or at times due to other situations, 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 a 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 believe that the keys to long-term profitable growth are:

- **Consistently improve the client experience:** efficient ordering; comprehensive choices; reliable turnaround time; easy-to use;
- **Lower costs and higher reimbursement:** align our cost structure with our streamlined product portfolio and implement operational discipline; reduce the costs associated with performing our genetic tests; achieve broad reimbursement coverage for our tests from third-party payers and increase the amount we receive from other types of payers; focus our efforts on testing categories that are more regularly reimbursed to avoid the process of appeals and slow or non-existing payment;
- **Advance insights and solutions:** optimize the amount of genetic content we offer and is used by providers across the range of healthcare platforms; deliver actionable insights through digital health solutions; develop our data services;
- **Improve affordability and accessibility and serve more patients:** provide affordable pricing for genetic analysis and interpretation; partner to reach underserved populations; expand call points;
- **Drive adoption:** increase physician and patient utilization of our platform for ordering and delivery of results; and

- **Attract new partners:** increasing the number of strategic partners working with us to add value for all our customer segments.

## Strategic realignment

On July 18, 2022, we initiated a strategic realignment of our operations and began implementing cost reduction programs in order to accelerate our path to positive operating cash flow. We are in the process of realigning and sharpening our focus on the portfolio of businesses that we believe can generate margins and deliver returns to fuel future investment. In the testing business, we have shifted operational and commercial efforts to accelerate positive cash flow by maintaining robust support of the higher-margin, higher-growth testing opportunities among hereditary cancer, precision oncology, women's health, rare disease and pharmacogenomics. We also plan to continue our expansion and integration of key digital health-based technologies and services in order to create a differentiated model in genetic health. Longer-term, we remain committed to our data platform and patient network. We believe that we hold significant growth potential and intend to continue to prioritize the tools, partnerships and applications that support the development of this platform as the catalyst for the future of healthcare.

The strategic realignment included a reduction in workforce of approximately 1,000 positions, lab and office space consolidation, portfolio optimization, decrease in other operating expenses, as well as a reduced international footprint. Management currently expects the strategic realignment will be completed in 2023 and estimates that the total costs incurred may be up to \$170 million for associated employee severance and benefits, asset impairments and losses on asset disposals, and other restructuring costs related to the realignment, which excludes the gain on sale of the RUO kit assets. This reflects the best estimate of management, which may be revised in subsequent periods as the strategic realignment progresses. With the major initiatives in our strategic realignment largely complete as of December 31, 2022, we anticipate annualized cash savings of approximately \$326 million, which is expected to be fully realized by the end of fiscal year 2023. We may not realize, in full or in part, the anticipated annualized cash savings due to unforeseen difficulties or delays in implementing further decreases in other operating expenses.

We expect to continue to incur operating losses for the near term as we execute on the strategic realignment of our operations. If we are unable to achieve these objectives and successfully grow revenue and manage our costs, we may not be able to achieve positive operating cash flow in the near term or at all.

## Russia and Ukraine Conflict

During the first quarter of 2022, Russia commenced a military invasion of Ukraine, and the ensuing conflict has created disruption in the region and around the world. We have suspended operations in Russia, which has not and is not expected to have a material impact on our operating results. We serve customers globally across a broad geographic base. Neither Russia nor Ukraine has comprised or is expected to comprise a material portion of our total revenue, net loss, or net assets. We continue to closely monitor the ongoing conflict and related sanctions, which could impact our financial results in the future. Other impacts due to this evolving situation are currently unknown and could potentially subject our business to adverse consequences should the situation escalate beyond its current scope. For additional information about the conflict between Russia and Ukraine and its potential effect on our business and results of operations, see risk factors "—The global macroeconomic environment could negatively impact our business, our financial position and our results of operations" and "—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" under the heading "Risks related to our business and strategy" in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K.

## Impact of COVID-19

While we expect COVID-19 may continue to impact our business, we have experienced limited disruption since 2020. 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. Substantially all of the Company's offices have re-opened in a hybrid working model, subject to operating restrictions which adhere to healthcare guidelines to protect public health and the health and safety of employees. We continue to monitor, update and align our corporate policies to meet state and federal occupational health and safety rules. 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.

As a result of government-imposed restrictions, many announced healthcare guidelines resulted in 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, continued 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 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.

Although many government-imposed restrictions have been reduced or eliminated, the future impact of the COVID-19 pandemic continues to be highly uncertain. 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.

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.

### **Adverse macroeconomic conditions**

Adverse macroeconomic developments, including inflation, slowing growth, rising interest rates, or recession, may adversely affect our business and financial condition. These developments have caused, and could in the future cause, disruptions and volatility in global financial markets and increased rates of default and bankruptcy, and negatively affect business and consumer spending. Adverse economic conditions may also increase the costs of operating our business, including vendor, supplier and workforce expenses, and may limit our access to capital or may significantly increase our cost of capital. Management continues to evaluate the impact of macroeconomic events, including inflation, on our business and our future plans and intends to take appropriate measures to help alleviate their impact, but there can be no assurance that these efforts will be successful.

### **Factors affecting our performance**

#### ***Number of billable units***

Our test revenue is tied to the number of tests which we bill patients, third-party payers that pay on behalf of patients, and institutions (e.g., hospitals, clinics, medical centers, biopharmaceutical partners). We refer to the set of reagents needed to perform an NGS test for our RUO product 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 insurance companies and institutions. 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. As a result of the strategic realignment, we terminated early or changed the scope of certain collaborations as part of our pharma development services, and are in the process of supporting wind-down activities for certain companion diagnostic development agreements to conclude existing contracts.



### ***Success obtaining and maintaining reimbursement***

Our ability to increase volume and revenue will depend in part on our success in 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 332 million lives, including Medicare, all 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.

### ***Ability to optimize our genetic content in meeting market needs and create new pathways to test***

We intend to continue to reduce the average cost per test, optimize our test menus and content, and offer the tests at affordable prices in order to meet customer and patient needs. In addition, we have and intend to 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. We also continue to collaborate with strategic partners and identify new market and channel opportunities.

### ***Realignment of our business and timing of expenses***

As part of the strategic realignment of our operations announced in July 2022, we initiated a comprehensive plan focused on supporting business lines and geographies that we believe can generate sustainable margins, provide the best return to fuel future investment and accelerate the Company's path to positive cash flow. We believe the plan further helps ensure we remain at the forefront of innovation and advancements in genomics by allocating resources towards our core genetic testing and data and patient network platform that have the potential to improve healthcare outcomes.

We conducted an assessment of our product portfolio as well as the associated research and development and commercial spending. Our plan shifts the focus to programs relevant to the core testing business to drive profitable growth. We also performed an extensive review of internal and external costs and how those expenses align with the business structure. Additional savings are expected to be generated through the ongoing digitization of workflows, elimination of duplication and streamlined processes across the core platforms and rationalization of technology and external services.

As we refocus our operations on our core genomic testing platform, we also plan to continue to invest in our genetic testing and data business to drive long-term profitable growth. 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 also expect to incur software development costs as we seek to further digitize and automate our laboratory processes and our genetic interpretation and report sign-out procedures, scale our customer service capabilities to improve our clients' experience, and expand the functionality of our website. We will continue to incur costs related to marketing and branding as we expand our initiatives beyond our current customer base and focus on providing access to customers through our website. 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 insurance companies and institutions that include pricing provisions under which such tests are billed.

Pharma development service revenue is 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. Subsequent to the strategic realignment, pharma development service revenue is generated from personalized cancer monitoring services and sample processing activities. Revenue is recognized as services are provided using the input method based on our assessment of performance completed to date toward completion of a contract.

## **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 contracted reimbursement coverage from third-party payers and increase the amount we receive from other types of payers, improve payer collections, and grow our relationships with biopharma partners.

As a result of the strategic realignment, we exited certain product lines including our distributed precision oncology products and terminated early or changed the scope of certain collaborations as part of our pharma development services. We are in the process of supporting wind-down activities for certain companion diagnostic development agreements to conclude existing contracts.

### ***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 an increase in billable volume. We also expect amortization of acquired intangible assets, which is not dependent on billed volume, to remain consistent with 2022 expenses. 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 other cost reductions achieved through automation, supply chain and logistics initiatives, process standardization, 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 related to our operational activities: 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. Operating expense categories also include goodwill and IPR&D impairment, restructuring and other costs, gain on sale of RUO kit assets, and change in fair value of contingent consideration, which are discussed further below.

### ***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 decrease as we streamline our product portfolio, shift investments, including the exit of certain business lines and commercial geographies, and reduce labor costs through a reduction in workforce. We expect to make investments to reduce costs and streamline our technology to provide patients access to testing aligned to scale with our long-term profitable growth targets.

During October 2020 through our acquisition of ArcherDX, we recognized \$512.4 million of IPR&D technology for two assets representing a therapy selection IVD and PCM technologies, both using an income approach. During the year ended December 31, 2022, the IVD and PCM products were fully developed resulting in the reclassification of the related IPR&D intangibles to developed technology intangibles, which are finite-lived and amortizable.

#### *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 decrease as a result of a reduction in workforce, targeted sales force expansion and lower marketing spending as we implement a more efficient sales and marketing approach to support our core genetic testing platform.

#### *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 decrease as a result of our strategic realignment including a reduction in workforce, consolidation of underutilized facilities, digitization of workflows, elimination of duplication and streamlined processes, and rationalization of technology and external services spending.

#### *Goodwill and IPR&D impairment*

Goodwill and IPR&D impairment expenses include the impairment loss recognized on goodwill and the IPR&D indefinite-lived intangible asset initially recognized as part of the acquisition of Singular Bio. Goodwill and indefinite-lived intangible assets are assessed for impairment on an annual basis and whenever events and circumstances indicate that these assets may be impaired. We compare the fair value of our reporting unit to its carrying value, including goodwill. 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.

#### *Restructuring and other costs*

Restructuring and other costs includes employee severance and benefits, assets impairments and losses on asset disposals and other costs. Employee separation costs are comprised of severance, other termination benefit costs, and stock-based compensation expense for the acceleration of RSUs related to workforce reductions. Employee separation costs include one-time termination benefits that are recognized as a liability at estimated fair value, at the time of communication to employees, unless future service is required, in which case the costs are recognized ratably over the future service period. Ongoing termination benefits are recognized as a liability at estimated fair value when the amount of such benefits is probable and reasonably estimable. Asset impairments and losses on asset disposals include operating lease impairments, losses on disposals of property and equipment and leasehold improvements associated with exiting lines of business, consolidating lab and office space, and reducing our international footprint. Other restructuring costs include the write-off of prepayments made to certain vendors for which we will no longer benefit from those goods or services, legal and professional fees, and contract exit costs.

#### *Gain on sale of RUO kit assets*

The gain on the sale of the RUO kit assets consists of the consideration received including up front consideration subject to a hold-back to satisfy indemnification obligations that may arise.

#### *Change in fair value of contingent consideration*

Changes in fair value of contingent consideration are adjustments to contingent consideration related to business combinations. We did not complete any acquisitions in fiscal year 2022, which has reduced our contingent liability balance as of December 31, 2022 and the associated change in fair value of contingent consideration for the year ended December 31, 2022. We expect future fair value changes to fluctuate from period to period due to fair value adjustments that are dependent on many factors, including no new acquisitions in 2022, 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 zero as of as of June 30, 2021, 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. In April 2022, an agreement was entered into with previous ArcherDX stockholders to extend the date of achievement of the ArcherDX final milestone to March 31, 2023. We currently do not believe that this milestone will be achieved within this timeframe. As such, no liability was recorded as of December 31, 2022 or 2021.

#### ***Other income (expense), net***

Other income (expense), net, primarily consists of adjustments to the fair value of our acquisition-related liabilities and interest income. Acquisition-related liabilities include stock payable liabilities arising from business combinations, and we expect the adjustments to fluctuate from period to period primarily 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 the Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information.

#### ***Income tax benefit***

Since we generally establish a full valuation allowance against our deferred tax assets, our income tax benefit primarily consists of changes in our deferred tax realization assessments as a result of taxable temporary differences assumed in connection with our acquisitions and changes in the expected timing of the reversal of taxable temporary differences.

#### **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 our 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 or as 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 insurance companies and institutions 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 price 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 generated test revenue through the sale of our distributed precision oncology products, which is comprised primarily of sales of our RUO kit and IVD product offerings for therapy selection. We recognized revenue on these sales once shipment had occurred. Product sales were recorded net of discounts and other deductions. Billing terms were generally net 30 days. As part of the strategic realignment, we exited these product offerings in fiscal year 2022. See Note 4, "Business combinations and dispositions" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information on the disposition of the RUO kit assets. See Note 5, "Goodwill and intangible assets" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information on the exit of the IVD product offering.

Shipping and handling fees billed to customers are recorded as revenue in 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 collaboration agreements and genome network contracts as well as pharma development services provided to biopharmaceutical companies related to companion diagnostic development.

We 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.

Contracts for companion diagnostic development consisted primarily of milestone-based payments along with annual fees and marked-up pass-through costs. The arrangements were 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 were required to pay for the proportion of services provided under milestones that were in progress. We recognized revenue in an amount that reflected the consideration which we expect to receive in exchange for those goods or services. We recognized revenue as services are provided based on the progress made toward achieving the performance obligation, utilizing input methods, including labor hours expended and tests processed, that measure our progress toward the achievement of the milestone.

### **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.

Factors that may indicate potential impairment and trigger an interim impairment test include, but are not limited to, current economic, market and geopolitical conditions, including a significant, sustained decline in our stock price and market capitalization compared to the net book value, an adverse change in legal factors, business climate or operational performance of the business, or significant changes in the ability of a particular asset (or group of assets) to generate positive cash flows for our strategic business objectives. During the three months ended June 30, 2022, as a result of significant, sustained decline in our stock price and related market capitalization and lower than expected financial performance, we performed an impairment assessment of goodwill, IPR&D intangibles, and long-lived assets, including definite-lived intangibles.

In the quarter ended June 30, 2022, the Company completed a quantitative impairment test for goodwill. In performing the goodwill impairment test, we estimated the fair value of the reporting unit by utilizing the discounted cash flow method under the income approach. The determination of the fair value of the reporting unit requires significant estimates and assumptions, including significant unobservable inputs. The key inputs to this valuation approach include, but were not limited to, management's forecast of projected revenues associated with future cash flows, discount rates, and control premiums.

When performing our income approach for the reporting unit, we incorporate the use of projected financial information and a discount rate that is developed using market participant-based assumptions. The cash flow projections are based on an 11-year financial forecast developed by management that includes projections of billable units, revenue by test type and mix, rate changes, capital spending trends, investments in working capital to support future revenue and projected cash flow sources and needs, among others. The selected discount rate then considers the risk and nature of the reporting unit's cash flows and rates of return market participants would require to invest capital in the reporting unit.

Based on this analysis, we recognized a goodwill impairment charge of \$2.3 billion during the quarter ended June 30, 2022, which was included in goodwill and IPR&D impairment expense in the consolidated statements of operations. This charge fully impaired the goodwill balance as of June 30, 2022.

We also identified indicators of impairment related to the IPR&D intangible asset initially recognized as part of the acquisition of Singular Bio that is more likely than not that the asset is impaired. The Company identified conditions during the quarter ended June 30, 2022 such as alternative technologies and uncertainties around the desired outcome of our in-development asset and other economic factors that raised issues with the realizability of our asset. As a result of our evaluation, we recognized an impairment charge of \$30.0 million during the quarter ended June 30, 2022. The impairment charges are recorded in goodwill and IPR&D impairment expense in the consolidated statements of operations. This charge fully impaired the indefinite-lived intangible asset balance as of June 30, 2022. We did not record any goodwill or intangible asset impairment losses during the years ended December 31, 2021 and 2020, respectively.

#### ***Impairment assessment of long-lived assets***

A recoverability test was performed for the long-lived assets, including definite-lived intangibles, using the undiscounted cash flows approach, which included significant unobservable inputs including management's forecasts of projected revenue associated with future cash flows and residual value. The cash flow estimates reflected the Company's assumptions about its use of the long-lived assets and eventual disposition of the asset group. We determined that our long-lived assets held and used, including intangible assets that are subject to amortization, did not have identifiable cash flows that are largely independent of the cash flows of other assets and liabilities and of other asset groups, because the assets are highly interrelated and interdependent. Therefore, the Company evaluated its long-lived assets for impairment on an entity-wide level. As a result of the recoverability test, we concluded that the carrying value of long-lived assets was recoverable at June 30, 2022. No impairment was recorded except for operating lease impairments, which are discussed under the heading "Leases" within Note 8, "Commitments and contingencies" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report on Form 10-K. We also recorded losses on disposal of assets pursuant to the strategic realignment, which are discussed within Note 11, "Restructuring and other costs" in the Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report on Form 10-K.

#### ***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:

*Fair value of common stock*—The fair value of each share of common stock is based on the closing price of our common stock on the date of grant as reported on the NYSE.

*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, 2022, we recorded a full valuation allowance on our net deferred tax assets because we expect that it is more likely than not that our net 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, 2022 compared to the year ended December 31, 2021 is presented below. 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 can be found under Part II, Item 7. in our Annual Report on Form 10-K for the year ended December 31, 2021.

### Comparison of the Years Ended December 31, 2022 and 2021

	Year Ended December 31,			
	2022	2021	Dollar Change	% Change
Revenue:				
Test revenue	\$ 500,560	\$ 444,072	\$ 56,488	13%
Other revenue	15,743	16,377	(634)	(4)%
Total revenue	516,303	460,449	55,854	12%
Operating expenses:				
Cost of revenue	417,256	348,669	68,587	20%
Research and development	402,088	416,087	(13,999)	(3)%
Selling and marketing	218,881	225,910	(7,029)	(3)%
General and administrative	192,314	248,070	(55,756)	(22)%
Goodwill and IPR&D impairment	2,313,047	—	2,313,047	100%
Restructuring and other costs	140,331	—	140,331	100%
Gain on sale of RUO kit assets	(47,354)	—	(47,354)	100%
Change in fair value of contingent consideration	(1,850)	(386,646)	384,796	100%
Total operating expenses	3,634,713	852,090	2,782,623	NM
Loss from operations	(3,118,410)	(391,641)	(2,726,769)	NM
Other income (expense), net:				
Change in fair value of acquisition-related liabilities	15,906	25,196	(9,290)	(37)%
Other income, net	8,054	482	7,572	NM
Total other income, net	23,960	25,678	(1,718)	(7)%
Interest expense	(56,747)	(49,900)	(6,847)	(14)%
Net loss before taxes	(3,151,197)	(415,863)	(2,735,334)	NM
Income tax benefit	44,904	36,857	8,047	22%
Net loss	\$ (3,106,293)	\$ (379,006)	\$ (2,727,287)	NM

NM - Not Meaningful

### Revenue

The increase in revenue of \$55.9 million for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to increased billable volume and higher average revenue per billable unit. Billable volume increased to 1,290,000 during the year ended December 31, 2022 compared to 1,169,000 in the same period in 2021, an increase of 10%, due to growth in the business. Average revenue per unit increased to \$388 during the year ended December 31, 2022 compared to \$380 in the same period in 2021 primarily due to changes in payer and product mix.

### Cost of revenue

The increase in the cost of revenue of \$68.6 million for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to increased billable volume. For the year ended December 31, 2022, the number of units billed increased to 1,290,000 from approximately 1,169,000 for the same period in 2021. Cost per unit was \$323 in 2022 compared to \$298 in 2021. The increase in cost per unit is primarily attributable to an increase in amortization of acquired intangible assets of \$50.6 million, an increase in inventory and prepaid asset write downs of \$18.2 million principally related to the exit of certain product offerings and geographies, and an increase in shipping costs of \$6.4 million related to higher volumes and passed through increases in fuel prices. These increases were partially offset by lower lab materials costs of \$5.2 million primarily due to a decrease in the volume and change in mix of materials, and a decrease in other costs of \$1.4 million.

### *Research and development*

The decrease in research and development expense of \$14.0 million for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to decreases in lab-related expenses of \$37.7 million as a result of lower costs related to external development projects and lab supplies and services, decreases in personnel-related expenses of \$19.5 million primarily due to the reduction in workforce related to our strategic realignment, and decreases in information technology costs of \$3.7 million due to lower network and cloud computing expenses. These decreases were partially offset by increases in acquisition-related compensation expenses of \$40.3 million primarily due to a full year of stock-based compensation in 2022 as compared to a partial year of expense in 2021 related to several acquisitions in the comparative period, and increases in professional fees of \$6.6 million due to higher contract labor.

### *Selling and marketing*

The decrease in selling and marketing expenses of \$7.0 million for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to decreases in marketing expenses of \$10.5 million as a result of lower costs related to brand initiatives and advertising, decreases in other expenses of \$1.9 million, and decreases in professional fees of \$1.7 million due to lower contract labor. These decreases were offset by increases in personnel-related expenses of \$2.7 million driven by headcount growth in 2022 prior to our strategic realignment, increases in travel-related expenses of \$2.4 million due to more in-person travel as a result of reduced COVID-19 restrictions, and increases in information technology costs of \$2.0 million due to higher spending on software licenses.

### *General and administrative*

The decrease in general and administrative expenses of \$55.8 million for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to decreases in acquisition-related compensation expense of \$49.1 million as a result of several acquisitions in the comparative period, decreases in legal fees of \$9.7 million for litigation-related expenses in the comparative period, and decreases in personnel-related costs of \$7.1 million primarily due to the reduction in workforce related to our strategic realignment. These decreases were partially offset by increases in other corporate expenses of \$6.3 million in 2022 prior to our strategic realignment, and increases in facilities-related expenses of \$3.8 million due to lease expenses and higher security and building support costs.

### *Goodwill and IPR&D impairment*

We completed an interim impairment test for goodwill and the IPR&D indefinite-lived intangible asset as of June 30, 2022, and as a result recorded a non-cash impairment charge of \$2.3 billion. See Critical accounting policies and estimates above and Note 5, "Goodwill and intangible assets" in Notes to the Consolidated Financial Statements in Part II, Item 8. "Consolidated Financial Statements" of this Annual Report on Form 10-K for further information.

### *Restructuring and other costs*

During the year ended December 31, 2022, we incurred restructuring and other costs of \$140.3 million. Restructuring and other costs were comprised of \$65.5 million in employee severance and benefits, \$60.5 million in asset impairments and losses on asset disposals, and \$14.3 million in other restructuring expenses. We did not have similar expenses for the year ended December 31, 2021. See Note 11, "Restructuring and other costs" in Notes to the Consolidated Financial Statements in Part II, Item 8. "Consolidated Financial Statements" of this Annual Report on Form 10-K for further information.

### *Gain on sale of RUO kit assets*

During the year ended December 31, 2022, we completed the sale and transfer to IDT of select assets and liabilities related to the RUO kit product offering, which represents the RUO distributed target enrichment kit and data analysis platform of ArcherDX. After adjustments, the sale resulted in a gain of approximately \$47.4 million for the year ended December 31, 2022. We did not have a similar gain for the year ended December 31, 2021. See Note 4, "Business combinations and dispositions" in Notes to the Consolidated Financial Statements in Part II, Item 8. "Consolidated Financial Statements" of this Annual Report on Form 10-K for further information.

### *Change in fair value of contingent consideration*

The change in fair value of contingent consideration represented income of \$1.9 million and \$386.6 million for the years ended December 31, 2022 and 2021, respectively. The year ended December 31, 2022 includes fair value adjustments to reduce our contingent consideration liability related to the acquisition of Genelex Solutions, LLC

("Genelex") and the achievement of certain product milestones related to gross revenues received by us for a pharmacogenetic product reimbursed through certain payers during the earn-out period. The adjustment to decrease our contingent consideration liability primarily related to the probability of achieving gross revenue reimbursements during the earn-out period. The year ended December 31, 2021 includes fair value adjustments to reduce our contingent consideration liability primarily related to our acquisition of ArcherDX and the remaining development milestones resulting from a decrease in the value of our common stock. The prior year adjustments to decrease our contingent consideration were due to our determination that our outstanding milestone for FDA clearance or approval of a therapy selection IVD will not be achieved in the timeframe prescribed in the acquisition agreement.

#### *Change in fair value of acquisition-related liabilities*

The decrease in change in fair value of acquisition-related liabilities of \$9.3 million for the year ended December 31, 2022 compared to the same period in 2021 was due to a decrease in fair value adjustments related to our stock payable as a result of the decrease in the price of our common stock and settlement of acquisition-related hold-backs.

#### *Other income, net*

The increase in other income, net of \$7.6 million for the year ended December 31, 2022 compared to the same period in 2021 was due to an increase in interest income earned on our marketable securities investments.

#### *Interest expense*

The increase in interest expense of \$6.8 million for the year ended December 31, 2022 compared to the same period in 2021 was principally due to increased debt outstanding during 2022 as compared to the prior year.

#### *Income tax benefit*

The increase in income tax benefit of \$8.0 million for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to the release of federal and state valuation allowances as a result of the reclassification of the IVD and PCM in-process research and development intangibles from indefinite-lived intangibles to developed technology, which enabled the associated deferred tax liability to serve as a source of income to existing finite-lived deferred tax assets for which a valuation allowance had previously been established. There was no similar income tax benefit for the year ended December 31, 2021.

### **Liquidity and capital resources**

#### ***Liquidity and capital expenditures***

We have generally incurred net losses since our inception. For the years ended December 31, 2022, 2021 and 2020, our net losses were \$3.1 billion, \$379.0 million and \$602.2 million, respectively, and we expect to incur additional losses in the future. At December 31, 2022, we had an accumulated deficit of \$4.8 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 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 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 2022, we issued 2.4 million shares of common stock at an average price of \$3.99 per share in an "at the market" offering for aggregate proceeds of \$10.0 million and net proceeds of \$9.7 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 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 note purchase agreement we entered into in November 2018. In April 2021, we issued \$1,150.0 million of aggregate principal amount of convertible senior notes due 2028, which bear cash interest at a rate of 1.5% per year. Our business may not generate cash flow from operations in the future sufficient to service our debt, including paying off the principal when due, and make necessary

capital expenditures. 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. 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, which could adversely affect our liquidity. 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 or to repay outstanding notes when they mature.

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 agreement to borrow \$135.0 million. The private placement and credit agreement closed concurrently with the merger in October 2020. The terms of this credit agreement restrict our ability to incur certain indebtedness, pay dividends, make acquisitions and take other actions. On February 7, 2023, we made a \$53.7 million payment which reduced the principal balance of the 2020 Term Loan by \$50.0 million and included a \$3.0 million prepayment fee, with the remainder attributable to interest. On February 28, 2023, we repaid the remaining principal balance outstanding of \$85.0 million plus outstanding interest of \$1.9 million and a prepayment fee of \$5.1 million. See Note 16, "Subsequent events" in Notes to the Consolidated Financial Statements in Part II, Item 8. "Consolidated Financial Statements" of this Annual Report on Form 10-K for further information.

At December 31, 2022 and 2021, we had \$557.1 million and \$1.1 billion, respectively, of cash, cash equivalents, restricted cash and marketable securities.

Our primary uses of cash are to fund our operations. 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 \$10.0 to \$15.0 million for 2023.

We have incurred substantial losses since inception, and we expect to continue to incur losses in the near future. We believe our existing cash, cash equivalents and marketable securities as of December 31, 2022 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 expect to raise additional funding to finance operations and service debt obligations prior to achieving profitability or should we make additional acquisitions. We regularly consider fundraising opportunities and expect to determine the timing, nature and size of future financings based upon various factors, including market conditions, debt maturities and our operating plans. We may in the future elect to finance operations by selling equity or debt securities or borrowing money. 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,		
	2022	2021	2020
Cash used in operating activities	\$ (492,961)	\$ (559,815)	\$ (298,502)
Cash used in investing activities	(174,803)	(204,080)	(400,583)
Cash provided by financing activities	1,758	1,565,940	672,993
Net (decrease) increase in cash, cash equivalents and restricted cash	\$ (666,006)	\$ 802,045	\$ (26,092)

### **Cash flows from operating activities**

For the year ended December 31, 2022, cash used in operating activities was \$493.0 million and principally resulted from our net loss of \$3.1 billion, a \$47.4 million gain on the sale of the RUO kit assets, a \$44.9 million income tax benefit, non-cash charges for remeasurements of liabilities in connection with business combinations of \$17.8 million, and \$1.5 million of amortization of premiums on investment securities. These were partially offset by non-cash

charges of \$2.3 billion for goodwill and IPR&D impairments, \$199.3 million for stock-based compensation, \$142.1 million for depreciation and amortization, \$60.5 million related to impairments and losses on disposals of long-lived assets related to our strategic realignment, \$15.6 million for amortization of debt discount and issuance costs related to our outstanding debt, \$10.2 million of non-cash lease expense, \$8.4 million of post-combination deferred compensation expense, and \$1.0 million of other adjustments. The net effect on cash for changes in net operating assets was a decrease of cash of \$25.3 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, 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, \$3.5 million of non-cash lease expense, and \$1.5 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, \$1.2 million of amortization premiums on investment securities, and \$0.2 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.

#### ***Cash flows from investing activities***

For the year ended December 31, 2022, cash used in investing activities of \$174.8 million was primarily due to net purchases and maturities of marketable securities of \$166.0 million and cash used for purchases of property and equipment of \$53.3 million, partially offset by proceeds from the sale of the RUO kit assets of \$44.5 million.

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.

#### ***Cash flows from financing activities***

For the year ended December 31, 2022, cash provided by financing activities of \$1.8 million primarily consisted of cash received from net proceeds from the sale of common stock of \$9.7 million and issuances of common stock of \$8.1 million. These were partially offset by cash used to settle acquisition obligations of \$10.6 million and finance lease principal payments of \$5.4 million.

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.

### Contractual obligations

The following table summarizes our contractual obligations, including interest, as of December 31, 2022 (in thousands):

Contractual obligations:	2023	2024 and 2025	2026 and 2027	2028 and beyond	Total
Operating leases	\$ 23,691	\$ 45,773	\$ 39,852	\$ 91,177	\$ 200,493
Finance leases	5,595	3,839	—	—	9,434
Convertible senior notes	—	349,996	—	1,150,000	1,499,996
2020 Term Loan	—	135,000	—	—	135,000
Purchase commitments	19,756	12,909	750	—	33,415
Total	\$ 49,042	\$ 547,517	\$ 40,602	\$ 1,241,177	\$ 1,878,338

Operating lease maturity amounts included in the table above do not include sublease income expected to be received under our sublease with IDT. Under the sublease agreement, we expect to receive sublease income for fiscal years ending December 31, 2023, 2024 and 2025 of \$0.9 million, \$0.9 million and \$0.1 million, respectively.

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 in Part II, Item 8. of this Annual Report 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 \$557.1 million at December 31, 2022, 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, 2022, 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. As of December 31, 2022, a hypothetical 100 basis point increase in interest rates would have an estimated \$1.4 million impact per year on our financial position and results of operations, based on the 2020 Term Loan principal outstanding through maturity. By February 28, 2023, we paid the principal balance outstanding plus interest and prepayment fees. As of December 31, 2022, the fair value of the 2020 Term Loan was \$130.0 million. For additional information about the 2020 Term Loan, see Note 8, "Commitments and contingencies" and Note 16, "Subsequent events" in Notes to Consolidated Financial Statements in Part II, Item 8. of this Annual Report.

Although our convertible senior notes are based on a fixed rate, changes in interest rates could impact the fair value we disclose. As of December 31, 2022, the fair market value of the convertible senior notes due 2024 and due 2028 was \$261.6 million and \$576.7 million, 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

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## 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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 28, 2023 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, 2022, the Company recognized test revenue billed to insurance carriers of \$310.3 million. As discussed in Note 2 to the consolidated financial statements, the Company often provides price concessions for tests billed to insurance carriers, and therefore the transaction price for patient insurance-billed tests is considered variable consideration. Revenue for tests billed to insurance carriers was recognized based on an estimate of the consideration to which the Company expects to be entitled at an amount for which it is probable that a reversal of cumulative revenue recognized will not occur.

Auditing the measurement of the Company's test revenue billed to insurance carriers was complex due to the significant judgment required to determine the amount of consideration to which the Company expects to be entitled. In particular, the estimate of test revenue billed to insurance carriers was based on assumptions in payer behavior such as 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. For example, we tested controls over management's review of the significant assumptions and inputs used in the estimate of the amount to which the Company expects to be entitled. We also tested controls over the completeness and accuracy of the current and historical data used in the Company's revenue models.

Our audit procedures over the Company's test revenue billed to insurance carriers included, among other things, assessing the revenue models and testing the significant assumptions and inputs 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 the Company's contracted rates, government and private insurance payer collection trends, and other relevant factors. We assessed the completeness and accuracy of the historical cash collections used in the Company's revenue models. We also assessed the completeness and accuracy of adjustments to estimates of future cash collections resulting from significant contract amendments and changes in collection trends.

### ***Impairment of long-lived assets***

*Description of the Matter* At December 31, 2022, the Company's property and equipment, net, intangible assets, net, and operating lease assets (collectively, long-lived assets) were \$108.7 million, \$1,012.5 million, and \$106.6 million, respectively. As discussed in Note 2 to the consolidated financial statements, long-lived assets are assessed for recoverability whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. When indicators of impairment exist, the Company compares the estimated future undiscounted net cash flows to the carrying amount of the asset group. If the carrying amount of the asset group exceeds the estimated future undiscounted cash flows, an impairment is measured based on the difference between the carrying amount of the asset group and its fair value.

Auditing the Company's recoverability test for long-lived assets was challenging due to subjective estimates and assumptions used by the Company to determine the undiscounted cash flows associated with the asset group. The estimate of undiscounted cash flows was subject to higher estimation uncertainty due to management's judgments over significant assumptions, including revenue growth and revenue multiples. Changes in these significant assumptions could have a significant effect on the undiscounted cash flows and resulting recoverability of the asset group.

*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 impairment assessment for long-lived assets. For example, we tested controls over management's review of the significant inputs and assumptions in the determination of undiscounted cash flows, specifically as it relates to revenue growth and revenue multiples.

Our audit procedures over the Company's impairment assessment for long-lived assets included, among others, assessing the reasonableness of significant assumptions, specifically revenue growth and revenue multiples, and assessing the completeness and accuracy of the underlying data used by the Company in its analyses. We evaluated whether the significant assumptions were reasonable by comparing them to the past performance of the Company, current industry data and current market forecasts, and whether such assumptions were consistent with evidence obtained in other areas of the audit. We also involved our valuation specialists to assist us in evaluating the reasonableness of the Company's valuation methodologies and assumptions, including the revenue multiples as compared to industry and market data.

/s/ Ernst & Young LLP

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

San Mateo, California

February 28, 2023

**INVITAE CORPORATION**

**Consolidated Balance Sheets**

(in thousands, except par value data)

	December 31,	
	2022	2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 257,489	\$ 923,250
Marketable securities	289,611	122,121
Accounts receivable	96,148	66,227
Inventory	30,386	33,516
Prepaid expenses and other current assets	19,496	33,691
Total current assets	693,130	1,178,805
Property and equipment, net	108,723	114,714
Operating lease assets	106,563	121,169
Restricted cash	10,030	10,275
Intangible assets, net	1,012,549	1,187,994
Goodwill	—	2,283,059
Other assets	23,121	23,551
Total assets	<u>\$ 1,954,116</u>	<u>\$ 4,919,567</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 13,984	\$ 21,127
Accrued liabilities	74,388	106,453
Operating lease obligations	14,600	12,359
Finance lease obligations	5,121	4,156
Total current liabilities	108,093	144,095
Operating lease obligations, net of current portion	134,386	124,369
Finance lease obligations, net of current portion	3,780	5,683
Debt	122,333	113,391
Convertible senior notes, net	1,470,783	1,464,138
Deferred tax liability	8,130	51,696
Other long-term liabilities	4,775	37,797
Total liabilities	1,852,280	1,941,169
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value: 20,000 shares authorized; nil shares issued and outstanding as of December 31, 2022 and 2021, respectively	—	—
Common stock, \$0.0001 par value: 600,000 and 400,000 shares authorized; 245,562 and 228,116 shares issued and outstanding as of December 31, 2022 and 2021, respectively	25	23
Accumulated other comprehensive loss	(80)	(7)
Additional paid-in capital	4,931,032	4,701,230
Accumulated deficit	(4,829,141)	(1,722,848)
Total stockholders' equity	101,836	2,978,398
Total liabilities and stockholders' equity	<u>\$ 1,954,116</u>	<u>\$ 4,919,567</u>

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,		
	2022	2021	2020
Revenue:			
Test revenue	\$ 500,560	\$ 444,072	\$ 272,310
Other revenue	15,743	16,377	7,288
Total revenue	516,303	460,449	279,598
Operating expenses:			
Cost of revenue	417,256	348,669	198,275
Research and development	402,088	416,087	240,605
Selling and marketing	218,881	225,910	168,317
General and administrative	192,314	248,070	270,029
Goodwill and IPR&D impairment	2,313,047	—	—
Restructuring and other costs	140,331	—	—
Gain on sale of RUO kit assets	(47,354)	—	—
Change in fair value of contingent consideration	(1,850)	(386,646)	54,544
Total operating expenses	3,634,713	852,090	931,770
Loss from operations	(3,118,410)	(391,641)	(652,172)
Other income (expense), net:			
Change in fair value of acquisition-related liabilities	15,906	25,196	(37,527)
Other income, net	8,054	482	5,195
Total other income (expense), net	23,960	25,678	(32,332)
Interest expense	(56,747)	(49,900)	(29,766)
Net loss before taxes	(3,151,197)	(415,863)	(714,270)
Income tax benefit	44,904	36,857	112,100
Net loss	\$ (3,106,293)	\$ (379,006)	\$ (602,170)
Net loss per share, basic and diluted	\$ (13.18)	\$ (1.80)	\$ (4.47)
Shares used in computing net loss per share, basic and diluted	235,676	210,946	134,587

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

**INVITAE CORPORATION**

**Consolidated Statements of Comprehensive Loss**

(in thousands)

	Year Ended December 31,		
	2022	2021	2020
Net loss	\$ (3,106,293)	\$ (379,006)	\$ (602,170)
Other comprehensive (loss) income:			
Unrealized (loss) income on available-for-sale marketable securities, net of tax	(73)	(8)	10
Comprehensive loss	<u>\$ (3,106,366)</u>	<u>\$ (379,014)</u>	<u>\$ (602,160)</u>

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

**INVITAE CORPORATION**

**Consolidated Statements of Stockholders' Equity**

(in thousands)

	Year Ended December 31,		
	2022	2021	2020
<b>Common stock:</b>			
Balance, beginning of period	\$ 23	\$ 19	\$ 10
Common stock issued	2	4	9
Balance, end of period	25	23	19
<b>Accumulated other comprehensive (loss) income:</b>			
Balance, beginning of period	(7)	1	(9)
Unrealized (loss) income on available-for-sale marketable securities, net of tax	(73)	(8)	10
Balance, end of period	(80)	(7)	1
<b>Additional paid-in capital:</b>			
Balance, beginning of period	4,701,230	3,337,120	1,138,316
Common stock issued in private placement, net	—	—	263,628
Common stock issued in connection with public offering, net	9,658	434,263	263,685
Common stock issued on exercise of stock options, net	643	8,984	10,730
Common stock issued pursuant to exercises of warrants	—	1,242	974
Common stock issued pursuant to employee stock purchase plan	7,513	13,550	8,871
Common stock and equity awards issued pursuant to acquisitions	15,027	805,124	1,524,227
Warrants issued pursuant to loan agreement	—	—	27,000
Stock-based compensation expense	196,961	176,435	110,076
Reclassification of equity component of convertible senior notes	—	(75,488)	—
Reclassification of stock payable liabilities	—	—	(10,387)
Balance, end of period	4,931,032	4,701,230	3,337,120
<b>Accumulated deficit:</b>			
Balance, beginning of period	(1,722,848)	(1,360,847)	(758,677)
Cumulative effect of accounting change	—	17,005	—
Net loss	(3,106,293)	(379,006)	(602,170)
Balance, end of period	(4,829,141)	(1,722,848)	(1,360,847)
<b>Total stockholders' equity</b>	<b>\$ 101,836</b>	<b>\$ 2,978,398</b>	<b>\$ 1,976,293</b>

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

**INVITAE CORPORATION**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	Year Ended December 31,		
	2022	2021	2020
<b>Cash flows from operating activities:</b>			
Net loss	\$ (3,106,293)	\$ (379,006)	\$ (602,170)
Adjustments to reconcile net loss to net cash used in operating activities:			
Goodwill and IPR&D impairment	2,313,047	—	—
Impairments and losses on disposals of long-lived assets	60,507	—	—
Gain on sale of RUO kit assets	(47,354)	—	—
Depreciation and amortization	142,071	80,472	39,050
Stock-based compensation	199,304	180,075	158,747
Amortization of debt discount and issuance costs	15,587	14,226	17,204
Remeasurements of liabilities associated with business combinations	(17,756)	(411,842)	92,348
Benefit from income taxes	(44,904)	(36,857)	(112,100)
Post-combination expense for acceleration of unvested equity and deferred stock compensation	8,428	9,530	91,021
Amortization of premiums and discounts on investment securities	(1,515)	6,221	1,236
Non-cash lease expense	10,240	3,496	777
Other	1,018	1,487	(588)
Changes in operating assets and liabilities, net of businesses acquired:			
Accounts receivable	(29,921)	(16,696)	(2,814)
Inventory	3,130	(1,486)	(7,832)
Prepaid expenses and other current assets	14,195	(14,563)	(2,010)
Other assets	3,124	(3,274)	895
Accounts payable	(2,465)	(9,258)	10,186
Accrued expenses and other long-term liabilities	(13,404)	17,660	17,548
Net cash used in operating activities	(492,961)	(559,815)	(298,502)
<b>Cash flows from investing activities:</b>			
Purchases of marketable securities	(892,361)	(325,957)	(280,258)
Proceeds from sales of marketable securities	—	—	12,832
Proceeds from maturities of marketable securities	726,313	425,293	277,487
Acquisition of businesses, net of cash acquired	—	(247,396)	(383,753)
Proceeds from sale of RUO kit assets	44,554	—	—
Purchases of property and equipment	(53,309)	(54,720)	(22,865)
Other	—	(1,300)	(4,026)
Net cash used in investing activities	(174,803)	(204,080)	(400,583)
<b>Cash flows from financing activities:</b>			
Proceeds from public offerings of common stock, net	9,658	434,263	263,688
Proceeds from issuance of common stock	8,157	23,767	284,203
Proceeds from issuance of convertible senior notes, net	—	1,116,427	—
Proceeds from issuance of debt, net	—	—	129,214
Finance lease principal payments	(5,410)	(3,759)	(2,655)
Settlement of acquisition obligations	(10,647)	(4,758)	(1,457)
Net cash provided by financing activities	1,758	1,565,940	672,993
<b>Net (decrease) increase in cash, cash equivalents and restricted cash</b>	<b>(666,006)</b>	<b>802,045</b>	<b>(26,092)</b>
<b>Cash, cash equivalents and restricted cash at beginning of period</b>	<b>933,525</b>	<b>131,480</b>	<b>157,572</b>
<b>Cash, cash equivalents and restricted cash at end of period</b>	<b>\$ 267,519</b>	<b>\$ 933,525</b>	<b>\$ 131,480</b>
<b>Supplemental cash flow information:</b>			
Interest paid	\$ 40,504	\$ 31,400	\$ 12,130
<b>Supplemental cash flow information of non-cash investing and financing activities:</b>			
Consideration receivable for sale of RUO kit assets	\$ 3,000	\$ —	\$ —
Equipment acquired through finance leases	\$ 4,472	\$ 8,224	\$ 4,463
Purchases of property and equipment in accounts payable and accrued liabilities	\$ 820	\$ 13,222	\$ 1,869
Warrants issued pursuant to debt agreement	\$ —	\$ —	\$ 27,000
Common stock issued for acquisition of businesses	\$ 6,600	\$ 802,073	\$ 1,157,958
Consideration payable for acquisition of businesses	\$ —	\$ 46,649	\$ 940,829
Operating lease assets obtained in exchange for lease obligations, net	\$ 4,495	\$ 88,777	\$ 14,058

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, precision oncology, women's health, rare diseases and pharmacogenomics. To augment our portfolio and realize our mission, we have previously acquired multiple assets and businesses that further expanded our test menu and suite of digital health and data offerings and accelerated our entry into key genomics markets. We are building a platform to harness genetics to diagnose more patients correctly and earlier, while enabling our partners to bring therapies to market faster. Invitae operates in one segment.

#### *Strategic realignment*

On July 18, 2022, the Company initiated a strategic realignment of our operations and began implementing cost reduction programs to prioritize its core genetic testing and digital health and data platforms, which was approved by the board of directors of the Company on July 16, 2022. See Note 11, "Restructuring and other costs" for additional information regarding our strategic realignment.

#### 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 impairment assessment of goodwill and intangible assets;
- the recoverability of long-lived assets;
- 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.

##### *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, restricted cash, 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 in the consolidated statements of operations. Our revenue and accounts receivable from significant customers as a percentage of our total revenue and total accounts receivable was as follows:

	Revenue			Accounts receivable	
	Year Ended December 31,			December 31,	
	2022	2021	2020	2022	2021
Medicare	14 %	15 %	19 %	16 %	*

\* less than 10%

### **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,	
	2022	2021
Cash and cash equivalents	\$ 257,489	\$ 923,250
Restricted cash	10,030	10,275
Total cash, cash equivalents and restricted cash	\$ 267,519	\$ 933,525

### **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 income (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 at each balance sheet date 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 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 12 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.

### **In-process research and development**

Intangible assets related to 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.

### **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 of our operating right-of-use assets 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.

During the year ended December 31, 2022, we recognized losses on disposal of property and equipment of \$19.1 million, which are recorded in restructuring and other costs in the consolidated statements of operations. See Note 5, "Goodwill and intangible assets" under the heading "Impairment assessment" and Note 6, "Balance sheet components" under the heading "Property and equipment, net" for additional information. We did not incur any losses on disposal of property and equipment during the years ended December 31, 2021 and 2020, respectively.

### **Fair value of financial instruments**

Our financial instruments consist principally of cash and cash equivalents, marketable securities, accounts payable, accrued liabilities, finance lease liabilities, 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 our finance lease liabilities approximates 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 insurance companies and institution customers 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 generated test revenue through the sale of our distributed precision oncology products, which is comprised primarily of sales of our RUO kit and IVD product offerings for therapy selection. We recognized revenue on these sales once shipment had occurred. Product sales were recorded net of discounts and other deductions. Billing terms were generally net 30 days. As part of the strategic realignment, we exited these product offerings in fiscal year 2022. See Note 4, "Business combinations and dispositions" for additional information on the disposition of

the RUO kit assets. See Note 5, "Goodwill and intangible assets" for additional information on the exit of the IVD product offering.

Shipping and handling fees billed to customers are recorded as revenue in 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 collaboration agreements and genome network contracts as well as pharma development services provided to biopharmaceutical companies related to companion diagnostic development.

We 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.

Contracts for companion diagnostic development consisted primarily of milestone-based payments along with annual fees and marked-up pass-through costs. The arrangements were 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 were required to pay for the proportion of services provided under milestones that were in progress. We recognized revenue in an amount that reflected the consideration which we expect to receive in exchange for those goods or services. We recognized revenue as services are provided based on the progress made toward achieving the performance obligation, utilizing input methods, including labor hours expended and tests processed, that measure our progress toward the achievement of the milestone.

#### **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.

#### **Advertising**

Advertising expenses are expensed as incurred. We incurred advertising expenses of \$5.9 million, \$20.2 million and \$11.4 million during the years ended December 31, 2022, 2021 and 2020, respectively.

#### **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.

### ***Restructuring and other costs***

Restructuring and other costs are comprised of employee severance and benefits, asset impairments and losses on asset disposals, and other costs primarily related to implementing our strategic realignment. Employee separation costs are comprised of severance, other termination benefit costs, and stock-based compensation expense for the acceleration of stock awards related to workforce reductions. We recognize costs and liabilities associated with exit and disposal activities in accordance with ASC 420, *Exit and Disposal Cost Obligations*, and other costs and liabilities associated with postemployment nonretirement benefits in accordance with ASC 712, *Postemployment Nonretirement Benefits*. Liabilities are based on the estimate of fair value in the period the liabilities are incurred, with subsequent changes to the liability recognized as adjustments in the period of change. We recognize losses on asset disposals in accordance with ASC 360, *Impairment or Disposal of Long-Lived Assets*. Restructuring and other costs are recognized as an operating expense within the consolidated statements of operations and the related liabilities are recorded within accrued liabilities in the consolidated balance sheets.

### ***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.

### ***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 Accounting Standards Updates ("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 606, *Revenue from Contracts with Customers*. At the acquisition date, an acquirer should account for the related revenue contracts in accordance with ASC 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 are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, and should be applied prospectively to all business combinations occurring after the date of adoption. Early adoption is permitted. We are currently evaluating the impact this guidance will have on our consolidated financial statements.

#### 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, with early adoption 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 Note 8, "Commitments and contingencies" for additional information about our convertible senior notes.

### 3. Revenue, accounts receivable and deferred revenue

During the year ended December 31, 2022, the Company changed its presentation of disaggregated revenue from revenue by services and products to clinical category of our product offerings to better align with our operations. The change had no impact on the timing of revenue recognition and had no effect on our reported results of operations. Presentation of disaggregated revenue by services and products in prior periods have been modified to conform to the current period presentation.

Test revenue is generated from sales of diagnostic tests and precision oncology products to two groups of customers: patients, consideration for which may be paid directly by the patients or by the patients' insurance carriers, and institutions (e.g., hospitals, clinics, medical centers and biopharmaceutical partners). Amounts billed and collected, and the timing of collections, vary based on the type of customer and the corresponding payer, including the patients' insurance carriers that are paying on behalf of the customer. Data and service revenue consists principally of revenue recognized for the performance of activities as outlined in biopharmaceutical development contracts and other collaboration and genome network agreements.

The following tables present revenue disaggregated by customer and product offering by disease category (in thousands):

	Patient		Institution	Year Ended December 31, 2022
	Insurance	Direct		
Product:				
Oncology	\$ 208,239	\$ 10,327	\$ 89,922	\$ 308,488
Women's health	70,571	18,082	7,127	95,780
Rare diseases	31,527	10,044	24,462	66,033
Data/services	—	—	46,002	46,002
Total revenue	<u>\$ 310,337</u>	<u>\$ 38,453</u>	<u>\$ 167,513</u>	<u>\$ 516,303</u>

	Patient		Institution	Year End December 31,
	Insurance	Direct		
Product:				
Oncology	\$ 200,456	\$ 11,341	\$ 70,439	\$ 282
Women's health	52,759	21,316	8,696	82
Rare diseases	23,701	9,011	24,504	57
Data/services	—	—	38,226	38
Total revenue	<u>\$ 276,916</u>	<u>\$ 41,668</u>	<u>\$ 141,865</u>	<u>\$ 460</u>

	Patient		Institution	Year End December 31,
	Insurance	Direct		
Product:				
Oncology	\$ 142,552	\$ 6,479	\$ 25,868	\$ 174
Women's health	25,050	12,684	6,404	44
Rare diseases	13,424	4,809	16,320	34
Data/services	—	—	26,008	26
Total revenue	\$ 181,026	\$ 23,972	\$ 74,600	\$ 279

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. In subsequent periods, we update our estimate of the amounts recognized for previously delivered tests resulting in the following increases to revenue and decreases to our net loss from operations and basic and diluted net loss per share (in millions, except per share data):

	Year Ended December 31,		
	2022	2021	2020
Revenue	\$ 2.8	\$ 13.5	\$ 4.4
Loss from operations	\$ (2.8)	\$ (13.5)	\$ (4.4)
Net loss per share, basic and diluted	\$ (0.01)	\$ (0.06)	\$ (0.03)

The increase in revenue from previously delivered tests for the years ended December 31, 2022, 2021 and 2020 was primarily due to higher average revenue per test across all test categories when compared to initial estimates.

#### Impact of COVID-19

We expect the COVID-19 pandemic may continue to impact our business. 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 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 customers for test and data and service activities, and the estimated amounts to be collected from patients' insurance carriers for test services.

We record a contract asset for services delivered under certain biopharmaceutical contracts, which are unbilled as of the end of the period. The contract receivable was \$1.3 million and \$4.3 million as of December 31, 2022 and 2021, respectively, and was included in prepaid expenses and other current assets in 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 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 \$4.7 million and \$2.9 million from deferred revenue for the years ended December 31, 2022 and 2021, respectively. The current contract liability was \$4.8 million and \$9.4 million as of December 31, 2022 and 2021, respectively, which was included in accrued liabilities in the consolidated balance sheets. The long-term contract liability was \$0.1 million and \$0.7 million as of December 31, 2022 and 2021, respectively, and was included in other long-term liabilities in the consolidated balance sheets.



### *Refund liability*

As part of our strategic realignment, we terminated early or changed the scope of several companion diagnostic development contracts with milestones in progress. Upon termination, we recorded a refund liability related to the remaining outstanding performance-based milestones. The refund liability was \$4.7 million and \$1.2 million as of December 31, 2022 and 2021, respectively, which was included in accrued liabilities in the consolidated balance sheets.

### *Performance obligations*

Test and other revenue are generally recognized upon completion of our performance obligation when or as control of the promised good or service is transferred to the customer, typically a test report or upon shipment of our precision oncology products or other contractually defined milestone(s). The Company has applied the practical expedient in relation to information about our remaining performance obligations, as we have a right to consideration from a customer in an amount that corresponds directly with the value to the customer of the Company's performance completed to date. Most remaining performance obligations are primarily related to PCM services included in test revenue in our consolidated statement of operations and are generally satisfied over one to six months.

## **4. Business combinations and dispositions**

### ***Genelex and YouScript***

In April 2020, we acquired 100% of the equity interest of Genelex and 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 were 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 and were included in other long-term liabilities in the consolidated balance sheets, with the \$15.4 million change in fair value year over year recorded in other income (expense), net in the consolidated statement of operations. In April 2022, the amounts held back to satisfy indemnification obligations for YouScript were released in full to the former shareholders.

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, 2022 and 2021, the fair value of this contingent consideration was immaterial and \$1.9 million, respectively.

### ***ArcherDX***

In October 2020, we acquired ArcherDX, a genomics analysis company. 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. 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 with the exception of the volatility of our common stock. Significant changes in any of these inputs may result in a significant change in fair value, which is estimated at each reporting date. 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"). With respect to the ArcherDX Final Milestone, the liability was reduced to zero 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. In April 2022, an agreement was entered into with the previous ArcherDX stockholders to extend the date for achievement of the ArcherDX Final Milestone to March 31, 2023. We currently do not believe that this milestone will be achieved within this timeframe. As such, no liability was recorded as of December 31, 2022.

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 vested upon the achievement of the contingent consideration milestones discussed above and were subject to the employees' continued service with us, unless terminated without cause in which case vesting was only dependent on milestone achievement. As the number of shares that were expected to be issued are fixed, the awards are equity-classified. During the year ended December 31, 2022, we recorded stock-based compensation expense of zero related to the ArcherDX milestones. 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 would not be achieved within the specified timeframe prescribed in the acquisition agreement.

#### *Disposition of RUO kit assets*

In December 2022, we completed a transaction with IDT for net cash proceeds of \$44.5 million. The transaction value includes total cash consideration of \$48.1 million, subject to certain adjustments, including \$3.0 million of up front consideration subject to a hold-back to satisfy indemnification obligations that may arise. The disposition is part of our strategic realignment whereby we sold to IDT select assets and liabilities related to the RUO kit product offering, which represents the RUO distributed target enrichment kit and data analysis platform of ArcherDX. The transaction also includes certain licensed rights to our AMP technology. Assets sold primarily include property and equipment and inventory with a carrying value of zero. After adjustments, the sale resulted in a gain of approximately \$47.4 million during the three months ended December 31, 2022, and is included in gain on sale of RUO kit assets in our consolidated statements of operations. As of December 31, 2022, the \$3.0 million of up front consideration subject to a hold-back is included within other assets in our consolidated balance sheets.

Additionally, we entered into an agreement to sublease office space in Boulder, Colorado. See Note 8, "Commitments and contingencies" under the heading "Leases" for additional information regarding the sublease.

#### **One Codex**

In February 2021, we acquired 100% of the equity interest of 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 were subject to a hold-back to satisfy indemnification obligations that may have arisen 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. In February 2022, the amounts held back to satisfy indemnification obligations were released in full to the former stockholders.

#### *Disposition of One Codex intangible assets*

In September 2022, we sold our equity interest in One Codex and certain related assets for an immaterial amount of cash proceeds, as part of our strategic realignment. The disposition of One Codex was considered to be an

asset sale as substantially all of the fair value was concentrated in the developed technology and certain customer relationships. The carrying value of assets sold include developed technology of \$19.4 million and customer relationships of \$0.4 million. The sale resulted in a loss of approximately \$19.8 million during the three months ended September 30, 2022, which is included in restructuring and other costs in our consolidated statements of operations. See Note 5, "Goodwill and intangible assets" and Note 11, "Restructuring and other costs" for additional information.

### **Genosity**

In April 2021, we acquired 100% of the fully diluted equity of 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 \$1.7 million and \$0.8 million in stock-based compensation expense for the years ended December 31, 2022 and 2021, respectively.

Pursuant to the terms of the acquisition, we agreed 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 and the difference of \$3.8 million was recorded in general and administrative expense in the consolidated statements of operations.

### **Ciitizen**

In September 2021, we acquired 100% of the equity of 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, 2022 and 2021, the value of the stock payable liability was \$0.4 million and \$12.1 million, respectively, which was recorded in other long-term liabilities in the consolidated balance sheets with the fair value change of \$9.7 million and \$10.6 million for the years ended December 31, 2022 and 2021, respectively, recorded as income in other income (expense), net in the consolidated statements of operations. In September 2022, the amounts held back to satisfy indemnification obligations were partially released to the former stockholders. The remaining amounts held back to satisfy indemnification obligations are expected to be released in September 2023. In connection with this transaction, we granted RSUs having a value of up to \$246.9 million to certain continuing employees. During the years ended December 31, 2022 and 2021, we recorded stock-based compensation expense of \$87.2 million and \$24.4 million, respectively, primarily in research and development expense. Additionally, during the year ended December 31, 2022, we recorded \$29.0 million of stock-based compensation expense related to the acceleration of RSUs for employees who were terminated as part of our strategic realignment, which is included in restructuring and other costs in the consolidated statements of operations. See Note 10, "Stock incentive plans" for additional information.

## **5. Goodwill and intangible assets**

### **Goodwill**

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

Balance as of December 31, 2021	\$ 2,283,059
Impairment	(2,283,059)
Balance as of December 31, 2022	\$ —

## Intangible assets

The following table presents details of our acquired intangible assets as of December 31, 2022 (in thousands):

December 31, 2022						
	Cost	Accumulated Amortization	Asset Disposals	Net	Weighted-Average Useful Life (In Years)	Weighted-Average Estimated Remaining Useful Life (in Years)
Customer relationships	\$ 41,515	\$ (17,675)	\$ (359)	\$ 23,481	10.8	6.8
Developed technology	1,174,506	(183,133)	(19,426)	971,947	10.8	9.3
Non-compete agreement	286	(286)	—	—	—	—
Trade name	21,085	(3,964)	—	17,121	12.0	9.8
Patent assets and licenses	495	(156)	(339)	—	—	—
Right to develop new technology	19,359	(2,474)	(16,885)	—	—	—
	<u>\$ 1,257,246</u>	<u>\$ (207,688)</u>	<u>\$ (37,009)</u>	<u>\$ 1,012,549</u>	10.8	9.2

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

December 31, 2021						
	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)	—	—	—	
Trade name	21,085	(2,207)	18,878	12.0	10.8	
Patent assets and licenses	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	
	<u>\$ 1,287,234</u>	<u>\$ (99,240)</u>	<u>\$ 1,187,994</u>	10.4	9.2	

Acquisition-related intangibles included in the above tables 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. During the year ended December 31, 2022, the IVD and PCM products were fully developed resulting in the reclassification of \$512.4 million of the related IPR&D intangibles to developed technology intangibles, which are finite-lived and amortizable. Amortization expense was \$108.4 million, \$58.8 million, and \$26.6 million for the years ended December 31, 2022, 2021 and 2020, respectively. Amortization expense is recorded in cost of revenue, research and development, and selling and marketing expense.

In August 2022, in conjunction with the strategic realignment, management decided to exit the IVD product offering and we wrote-off the related intangible asset of \$16.9 million. Management also decided to exit the in-vitro fertilization product offering, and as a result we wrote-off the associated intangible asset of \$0.3 million. These charges are included in restructuring and other costs in the consolidated statements of operations. See Note 11, "Restructuring and other costs" for additional information.

See Note 4, "Business combinations and dispositions" for additional information on the sale of our interest in One Codex and the related disposition of developed technology and customer relationships during the three months ended September 30, 2022.

The following table summarizes our estimated future amortization expense of intangible assets with finite lives as of December 31, 2022 (in thousands):

2023	\$	114,440
2024		114,162
2025		112,408
2026		112,374
2027		111,708
Thereafter		447,457
Total estimated future amortization expense	\$	<u>1,012,549</u>

In December 2021, we acquired 100% of the equity interest of Stratify, 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, 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 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.

### **Impairment assessment**

Goodwill and indefinite-lived intangible assets are assessed for impairment on an annual basis and whenever events and circumstances indicate that these assets may be impaired. We evaluate the fair value of long-lived assets, which include property and equipment and finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amounts of the asset may not be fully recoverable. In testing for goodwill impairment, we have the option of first performing a qualitative assessment to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. If we elect to bypass the qualitative assessment, or if a qualitative assessment indicates it is more likely than not that the carrying value exceeds its fair value, we perform a quantitative goodwill impairment test to compare to the fair value of our reporting unit to its carrying value, including goodwill. 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. Factors that may indicate potential impairment and trigger an impairment test include, but are not limited to, current economic, market and geopolitical conditions, including a significant, sustained decline in our stock price and market capitalization compared to the net book value, an adverse change in legal factors, business climate or operational performance of the business, or significant changes in the ability of a particular asset (or group of assets) to generate positive cash flows for our strategic business objectives.

During the three months ended June 30, 2022, as a result of the significant, sustained decline in our stock price and related market capitalization and lower than expected financial performance, we performed an impairment assessment of goodwill, IPR&D intangible assets, and long-lived assets, including definite-lived intangibles.

For our goodwill, we measured the fair value of the reporting unit utilizing the discounted cash flow method under the income approach. This approach relies on significant unobservable inputs including, but not limited to, management's forecasts of projected revenue associated with future cash flows, discount rates, and control premium. Based on this analysis, we recognized a non-cash, pre-tax goodwill impairment charge of \$2.3 billion during the three months ended June 30, 2022, which was included in goodwill and IPR&D impairment expense in the consolidated statements of operations. The goodwill was fully impaired as of June 30, 2022.

We also identified indicators of impairment related to the IPR&D intangible asset initially recognized as part of the acquisition of Singular Bio that it was more likely than not that the asset is impaired. The Company identified conditions during the period ended June 30, 2022 such as alternative technologies and uncertainties around the desired outcome of our in-development asset and other economic factors that raised issues with the realizability of our asset. As a result of our evaluation, we recognized a non-cash, pre-tax impairment charge of \$30.0 million during the three months ended June 30, 2022 related to the IPR&D intangible asset. The impairment charges are recorded in

Goodwill and IPR&D impairment expense in the consolidated statements of operations. The indefinite-lived intangible asset was fully impaired as of June 30, 2022. Additionally, we recognized a loss on disposal of property and equipment of \$4.8 million during the three months ended June 30, 2022 related to specific equipment that is no longer being utilized on this project and has no alternative future use. The loss on disposal is recorded in restructuring and other costs in the consolidated statements of operations.

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.

A recoverability test was performed for the long-lived assets, including definite-lived intangibles, using the undiscounted cash flows approach, which included significant unobservable inputs including management's forecasts of projected revenue associated with future cash flows, and residual value. The cash flow estimates reflected the Company's assumptions about its use of the long-lived assets and eventual disposition of the asset group. We determined that our long-lived assets held and used, including intangible assets that are subject to amortization, did not have identifiable cash flows that are largely independent of the cash flows of other assets and liabilities and of other asset groups, because the assets are highly interrelated and interdependent. Therefore, the Company evaluated its long-lived assets for impairment on an entity-wide level. As a result of a recoverability test, we concluded that the carrying value of long-lived assets was recoverable at June 30, 2022. No impairment was recorded except for operating lease impairments, which are discussed under the heading "Leases" within Note 8, "Commitments and contingencies." We also recorded losses on disposal of assets pursuant to the strategic realignment, which are discussed in Note 11, "Restructuring and other costs."

## 6. Balance sheet components

### *Inventory*

Inventory consisted of the following (in thousands):

	December 31,	
	2022	2021
Raw materials	\$ 29,992	\$ 27,178
Work in progress	382	5,342
Finished goods	12	996
Total inventory	<u>\$ 30,386</u>	<u>\$ 33,516</u>

As part of the Company's strategic realignment, management decided to exit certain product offerings. During the year ended December 31, 2022, the Company wrote-off the remaining inventory related to these product offerings of \$14.3 million, which is included in cost of revenue in the consolidated statements of operations.

### *Property and equipment, net*

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

	December 31,	
	2022	2021
Leasehold improvements	\$ 74,108	\$ 31,159
Laboratory equipment	63,562	61,317
Computer equipment	13,712	15,452
Furniture and fixtures	1,428	2,130
Construction-in-progress	23,490	52,039
Other	2,996	925
Total property and equipment, gross	<u>179,296</u>	<u>163,022</u>
Accumulated depreciation and amortization	<u>(70,573)</u>	<u>(48,308)</u>
Total property and equipment, net	<u>\$ 108,723</u>	<u>\$ 114,714</u>

Depreciation expense was \$28.8 million, \$18.1 million and \$10.5 million for the years ended December 31, 2022, 2021 and 2020, respectively. Depreciation expense for the year ended December 31, 2022 includes accelerated depreciation of \$6.1 million from a change in the estimated useful lives of property and equipment related to the exit of certain product offerings.

As part of our strategic realignment, the Company decided to exit certain business lines, consolidate lab and office space, and reduce our international footprint. During the year ended December 31, 2022, we recognized losses on disposal of property and equipment of \$19.1 million, which is included in restructuring and other costs in our consolidated statement of operations. See Note 11, "Restructuring and other costs" for additional information.

See Note 5, "Goodwill and intangible assets" for additional information on the impairment assessment including long-lived assets and the related loss on disposal recognized during the three months ended June 30, 2022.

### **Accrued liabilities**

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued compensation and related expenses	\$ 25,315	\$ 35,877
Accrued expenses	23,628	32,136
Compensation and other liabilities associated with business combinations	5,335	11,622
Deferred revenue	4,814	9,431
Accrued interest	6,646	6,646
Accrued royalties	3,177	3,669
Other accrued liabilities	5,473	7,072
Total accrued liabilities	<u>\$ 74,388</u>	<u>\$ 106,453</u>

### **Other long-term liabilities**

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

	December 31,	
	2022	2021
Compensation and other liabilities associated with business combinations, non-current	\$ 769	\$ 27,919
Deferred revenue, non-current	50	663
Other	3,956	9,215
Total other long-term liabilities	<u>\$ 4,775</u>	<u>\$ 37,797</u>

## **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 financial instruments that were measured at fair value on a recurring basis (in thousands):

December 31, 2022							
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
<b>Financial assets:</b>							
Money market funds	\$ 158,931	\$ —	\$ —	\$ 158,931	\$ 158,931	\$ —	\$ —
U.S. Treasury notes	193,685	1	(123)	193,563	193,563	—	—
U.S. government agency securities	96,006	55	(13)	96,048	—	96,048	—
Total financial assets	<u>\$ 448,622</u>	<u>\$ 56</u>	<u>\$ (136)</u>	<u>\$ 448,542</u>	<u>\$ 352,494</u>	<u>\$ 96,048</u>	<u>\$ —</u>
<b>Financial liabilities:</b>							
Stock payable liability				\$ 744	\$ —	\$ —	\$ 744
Contingent consideration				25	—	—	25
Total financial liabilities				<u>\$ 769</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 769</u>
<b>December 31, 2022</b>							
<b>Reported as:</b>							
Cash equivalents						\$ 148,901	
Restricted cash							10,030
Marketable securities							289,611
Total cash equivalents, restricted cash, and marketable securities						<u>\$ 448,542</u>	
Other long-term liabilities						\$ 769	
<b>December 31, 2021</b>							
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
<b>Financial assets:</b>							
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	<u>\$ 1,036,118</u>	<u>\$ —</u>	<u>\$ (7)</u>	<u>\$ 1,036,111</u>	<u>\$ 1,025,171</u>	<u>\$ 10,940</u>	<u>\$ —</u>
<b>Financial liabilities:</b>							
Stock payable liability				\$ 20,925	\$ —	\$ —	\$ 20
Contingent consideration				1,875	—	—	1
Total financial liabilities				<u>\$ 22,800</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 22</u>
<b>December 31, 2021</b>							
<b>Reported as:</b>							
Cash equivalents						\$ 903	
Restricted cash							10
Marketable securities							122
Total cash equivalents, restricted cash, and marketable securities						<u>\$ 1,036</u>	
Other long-term liabilities						\$ 22	



The following tables include a rollforward of the stock payable liability and contingent consideration classified within Level 3 of the fair value hierarchy (in thousands):

	Stock Payable Liability	Contingent Consideration
Fair value at December 31, 2021	\$ 20,925	\$ 1,875
Change in fair value	(15,906)	(1,850)
Settlements	(4,275)	—
Fair value at December 31, 2022	\$ 744	\$ 25

	Stock Payable Liability	Contingent Consideration
Fair value at December 31, 2020	\$ 39,237	\$ 796,639
Additions	31,522	—
Change in fair value	(25,196)	(386,646)
Settlements	(24,638)	(408,118)
Fair value at December 31, 2021	\$ 20,925	\$ 1,875

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented. 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. At December 31, 2022, the remaining contractual maturities of available-for-sale securities ranged from one to five months. Interest income generated from our investments was \$6.8 million, \$6.9 million and \$4.0 million during the years ended December 31, 2022, 2021 and 2020, respectively.

The total fair value of investments with unrealized losses at December 31, 2022 was \$200.3 million. None of the available-for-sale securities held as of December 31, 2022 have been in an unrealized loss position for more than one year. The Company evaluates investments that are in an unrealized loss position for impairment as a result of credit loss. It was determined that no credit losses exist as of December 31, 2022, because the change in market value of those securities has resulted from fluctuations in market interest rates since the time of purchase, rather than a deterioration of the credit worthiness of the issuers. 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. We intend to hold our marketable securities to maturity and it is unlikely that they would be sold before their cost bases are recovered. The cost of securities sold is based on the specific identification method.

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 years ended December 31, 2022, 2021 and 2020, the change in fair value related to stock payable liabilities recorded to other income (expense), net was income of \$15.9 million and \$25.2 million and expense of \$37.5 million, respectively.

## 8. Commitments and contingencies

### Leases

The Company has entered into various non-cancellable operating lease agreements for office and laboratory space domestically and internationally. The Company's current leases have remaining terms ranging from approximately 1 to 12 years, some of which include options to extend the leases. The renewal options were not included in the calculation of the operating lease assets and the operating lease liabilities as they are not reasonably

certain of being exercised. The security deposits for our operating leases are included in restricted cash in our consolidated balance sheets.

In 2015, we entered into a non-cancelable operating lease agreement for our headquarters and main production facility in San Francisco, California, which commenced in 2016 with an initial lease term extending through 2026. In 2020, we entered into a non-cancelable operating lease agreement for additional office and laboratory space in San Francisco, California, which commenced in 2021 and has an initial lease term extending through 2031. In 2021, we entered into a non-cancelable operating lease agreement for a new laboratory and production facility in Morrisville, North Carolina, which commenced in the same year with an initial lease term extending through 2035.

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 in our consolidated balance sheets. Finance lease assets are recorded within other assets in our consolidated balance sheets.

As part of the strategic realignment, we began cost reduction initiatives including lab and office space consolidation and a reduction in our international footprint. Under this plan, we decided to cease use of certain leased premises and actively began looking to sublease certain facilities, including the related leasehold improvements. We determined that the changes in the intended use of these locations represented an indicator of impairment and performed a test of recoverability on September 30, 2022. For operating leases where the carrying values of right-of-use assets were lower than the undiscounted cash flows expected through sublease, we impaired the right-of-use assets to their fair value. The fair value was determined by utilizing the discounted cash flow method under the income approach. The key inputs to this valuation were expected sublease rental income ranging from \$0.1 million to \$2.8 million and discount rates ranging from 5.00% to 8.50%. This fair value measurement is based on significant inputs not observable in the market and, therefore, represents a Level 3 measurement. During the three months ended September 30, 2022, we recognized an impairment charge of \$4.4 million related to the right-of-use assets and \$2.3 million for the related leasehold improvements, which are included in restructuring and other costs in our consolidated statements of operations.

In connection with the disposition of the RUO kit assets in December 2022, we entered into an agreement to sublease a portion of our offices in Boulder, Colorado. The sublease term is concurrent with the term of the master lease extending through January 31, 2025, unless earlier terminated and with no option to extend the sublease. Per the sublease agreement, the amount of sublease payments to us will equal the amount of the master lease payments resulting in no adjustments to the right-of-use asset and related lease liability. Sublease income for the year ended December 31, 2022 was immaterial. There was no sublease income for the years ended December 31, 2021 and 2020, respectively. See Note 4, "Business combinations and dispositions" for additional information regarding the disposition of the RUO kit assets.

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

	Year Ended December 31,	
	2022	2021
Weighted-average remaining lease term:		
Operating leases	8.9 years	9.0 years
Finance leases	1.8 years	2.4 years
Weighted-average discount rate:		
Operating leases	6.7 %	7.0 %
Finance leases	7.3 %	7.2 %
Cash payments included in the measurement of lease liabilities (in millions):		
Operating leases	\$ 22.4	\$ 18.3
Finance leases	\$ 6.2	\$ 2.9

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

	Year Ended December 31,		
	2022	2021	2020
Operating lease costs	\$ 24,671	\$ 21,151	\$ 11,329
Finance lease costs:			
Amortization of right-of-use assets	4,778	3,488	2,084
Interest on lease liabilities	840	496	—
Total lease costs	\$ 30,289	\$ 25,135	\$ 13,413

Future payments under operating and finance leases as of December 31, 2022 are as follows (in thousands):

	Operating leases	Finance leases
2023	\$ 23,691	\$ 5,595
2024	28,308	3,344
2025	17,465	495
2026	23,989	—
2027	15,863	—
Thereafter	91,177	—
Future non-cancelable minimum lease payments	200,493	9,434
Less: interest	(51,507)	(533)
Total lease liabilities	148,986	8,901
Less: current portion	(14,600)	(5,121)
Lease obligations, net of current portion	\$ 134,386	\$ 3,780

Operating lease maturity amounts included in the table above do not include sublease income expected to be received under our sublease. Under the sublease agreement, we expect to receive sublease income for fiscal years ending December 31, 2023, 2024 and 2025 of \$0.9 million, \$0.9 million and \$0.1 million, respectively.

### Debt financing

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.

As of December 31, 2022, the fair value of the 2020 Term Loan was \$130.0 million. The estimated fair value of the 2020 Term Loan, which use Level 2 fair value inputs, was determined based on a discounted cash flow approach using the contractual term of the loan, market-based parameters such as the three-month LIBOR forward rate, and an estimate for our standalone credit risk. 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 (defined below), was \$24.3 million, \$23.7 million and \$7.4 million for the years ended December 31, 2022, 2021 and 2020, 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 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. Since issuance, these notes were convertible at the option of the holders beginning on January 1, 2021 and April 1, 2021 due to the sale price of our common stock during the quarters ended December 31, 2020 and March 31, 2021, respectively. The notes were not convertible during the year ended December 31, 2022 and there have been no significant conversions in the periods in which they were convertible.

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 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. None of the 2028 Notes have been converted to date.

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 in cash 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.

#### *Summary of convertible senior notes*

We adopted the provisions of ASU 2020-06 on January 1, 2021. See Note 2, "Summary of significant accounting policies" for additional information. Our 2024 Notes and 2028 Notes (collectively, our "Convertible Senior Notes") consisted of the following (in thousands):

	December 31,	
	2022	2021
Outstanding principal	\$ 1,499,996	\$ 1,499,996
Unamortized debt discount and issuance costs	(29,213)	(35,858)
Net carrying amount, liability component	\$ 1,470,783	\$ 1,464,138

As of December 31, 2022, the fair value of the 2024 Notes and 2028 Notes was \$261.6 million and \$576.7 million, 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 \$30.8 million, \$24.9 million and \$22.0 million of interest expense related to our Convertible Senior Notes during the years ended December 31, 2022, 2021 and 2020, respectively. Of the interest expense recognized during the years ended December 31, 2022, 2021 and 2020, \$6.7 million, \$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, 2022, our total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year were as follows (in thousands):

2023	19,756
2024	11,065
2025	1,844
2026	500
2027	250
Total	\$ 33,415

#### **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, 2022 or 2021.

#### **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, 2022, 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 STRATAFIDE, 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 STRATAFIDE, 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 STRATAFIDE, 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 STRATAFIDE, 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 ("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 ("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. The court denied the parties' respective summary judgment motions by order dated February 6, 2023. Trial is set for May 8, 2023.

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 denied that motion on March 14, 2022. The court granted an order granting the parties' stipulated request to stay the case on April 1, 2022.

#### *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. On September 30, 2022, the court issued an order denying QIAGEN's post-trial motion for a new trial or altered verdict, granting QIAGEN's post-trial motion to reduce damages to approximately \$4.0 million, granting ArcherDX's post-trial motion for ongoing royalty at a rate of 7% along with supplemental damages and interest, and denying ArcherDX's motion for an injunction with leave to renew after an evidentiary hearing. No date has been set for the hearing on ArcherDX's request for an injunction.

## 9. Stockholders' equity

### Shares outstanding

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

	Year Ended December 31,		
	2022	2021	2020
Convertible preferred stock:			
Shares outstanding, beginning of period	—	125	125
Conversion into common stock	—	(125)	—
Shares outstanding, end of period	—	—	125
Common stock:			
Shares outstanding, beginning of period	228,116	185,886	98,796
Common stock issued in private placement	—	—	16,320
Common stock issued in connection with public offering	2,429	8,932	24,005
Common stock issued on exercise of stock options, net	159	2,068	2,659
Common stock issued pursuant to vesting of RSUs	10,486	4,325	5,304
Common stock issued pursuant to exercises of warrants	—	208	968
Common stock issued pursuant to employee stock purchase plan	2,231	654	671
Common stock issued pursuant to acquisitions	2,141	25,918	37,163
Common stock issued upon conversion of preferred stock	—	125	—
Shares outstanding, end of period	245,562	228,116	185,886

## **Common Stock**

As of December 31, 2022, we had 600 million shares of common stock authorized with a par value of \$0.0001. The number of authorized shares increased from 400 million to 600 million during the year ended December 31, 2022.

## **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, 2022 and 2021, we had 20 million shares of preferred stock authorized, of which 3,458,823 shares were designated as Series A convertible preferred stock. As of December 31, 2022 and 2021, there were no shares of preferred stock or Series A convertible preferred stock outstanding.

## **Sales Agreements**

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.

During the year ended December 31, 2022, we sold a total of 2.4 million shares of common stock under the 2021 Sales Agreement at an average price of \$3.99 per share, for gross proceeds of \$10.0 million and net proceeds of \$9.7 million. During the year ended December 31, 2020, we sold a total of 3.6 million shares of common stock under the common stock sales agreement entered into with Cowen in August 2018 at an average price of \$26.33 per share, for gross proceeds of \$93.7 million and net proceeds of \$90.7 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 ratably in annual installments over a period of three years, commencing on the first anniversary of the grant date, with certain awards that include a portion that vests immediately upon grant. The vesting schedule for the 2022 grants approved in April 2022 provides that the awards vest ratably in quarterly installments over a period of two years, with certain awards that include a portion that vests immediately upon grant. Grants to the executive team in 2022 vest ratably in annual installments over a period of three years. We have also granted certain awards 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 an acquisition and PRSUs that vested based on the achievement of performance conditions, both of which were fully vested as of December 31, 2022. In December 2020, we granted RSUs in connection with an asset acquisition which were fully vested as of December 31, 2022.

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 vested 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 vested 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 years ended December 31, 2022, 2021 and 2020, \$2.7 million, \$2.7 million and \$0.7 million were recorded as stock-based compensation expense related to the awards, respectively.

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

	Shares Available For Grant	Stock Options Outstanding	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Balances at December 31, 2021	10,242	3,034	\$ 11.98	5.5	\$ 16,431
Additional shares reserved	9,125	—			
Options granted	(1,121)	1,121	\$ 3.03		
Options cancelled	1,455	(1,455)	\$ 12.04		
Options exercised	—	(159)	\$ 4.06		
RSUs and PRSUs granted	(12,508)	—			
RSUs and PRSUs cancelled	5,432	—			
Balances at December 31, 2022	<u>12,625</u>	<u>2,541</u>	\$ 8.49	6.6	\$ 16
Options exercisable at December 31, 2022		<u>1,384</u>	\$ 11.21	4.1	\$ 16
Options vested and expected to vest at December 31, 2022		<u>2,383</u>	\$ 8.84	6.1	\$ 16

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 \$2.07, \$22.46 and \$10.10 in the years ended December 31, 2022, 2021 and 2020, respectively.

The total grant-date fair value of options to purchase common stock vested was \$1.8 million, \$2.4 million and \$2.8 million in the year ended December 31, 2022, 2021, and 2020, respectively.

The intrinsic value of options to purchase common stock exercised was \$0.7 million, \$55.0 million and \$104.4 million in the years ended December 31, 2022, 2021 and 2020, 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, 2021	16,247	\$ 26.21
RSUs granted	11,622	\$ 5.58
Time-based RSUs and PRSUs granted - variable	886	\$ 2.47
RSUs vested	(11,428)	\$ 23.03
RSUs cancelled	(5,432)	\$ 16.67
Balance at December 31, 2022	11,895	\$ 11.70

## 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, 2022, cash received from payroll deductions pursuant to the ESPP was \$1.3 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, 2022, 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.

*Fair value of common stock*—The fair value of each share of common stock is based on the closing price of our common stock on the date of grant as reported on the NYSE.

*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,		
	2022	2021	2020
Fair value of common stock	\$2.85 - \$5.22	\$34.90	\$16.17 - \$16.55
Expected term (in years)	6.0	6.0	6.0
Expected volatility	77.6%	73.5%	71.0%
Risk-free interest rate	3.0%	1.1%	0.5%

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, 2022, 2021 and 2020, the weighted-average grant date fair value per share for the ESPP was \$2.34, \$8.10 and \$10.98, respectively.

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

	Year Ended December 31,		
	2022	2021	2020
Expected term (in years)	0.5	0.5	0.5
Expected volatility	200.6%	66.1%	105.7%
Risk-free interest rate	3.6%	0.0%	0.1%

The following table summarizes stock-based compensation expense for the years ended December 31, 2022, 2021 and 2020, included in the consolidated statements of operations (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Cost of revenue	\$ 6,868	\$ 12,033	\$ 8,713
Research and development	113,843	92,407	91,762
Selling and marketing	12,897	15,641	14,418
General and administrative	35,378	59,994	43,854
Restructuring and other costs	30,318	—	—
Total stock-based compensation expense	\$ 199,304	\$ 180,075	\$ 158,747

Stock-based compensation expense included in restructuring and other costs was related to the accelerated vesting of RSUs held by certain employees whose employment was terminated as part of the strategic realignment. Pursuant to the terms and conditions of the Ciitizen transaction, employees were deemed vested in any unvested RSUs at the time of their termination. See Note 11, "Restructuring and other costs" for additional information.

At December 31, 2022, unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was \$3.4 million, which we expect to recognize on a straight-line basis over a weighted-average period of 3.3 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, 2022, net of estimated forfeitures, was \$154.0 million, which we expect to recognize on a straight-line basis over a weighted-average period of 1.5 years.

## 11. Restructuring and other costs

On July 18, 2022, we initiated a strategic realignment of our operations to reduce operating costs and drive future growth aligned with our core genetic testing and data platform and patient network. The strategic realignment includes a reduction in workforce, lab and office space consolidation, portfolio optimization, decrease in other operating expenses, as well as a reduced international footprint. Under this strategic realignment, we reduced our workforce by approximately 1,000 employees with a majority of these employees separating from the Company by September 30, 2022 and the remaining affected employees transitioning over varying periods of time up to 12 months. Employees who were impacted by the restructuring were eligible to receive severance benefits contingent upon an impacted employee's execution (and non-revocation, where applicable) of a separation agreement, which included a general release of claims against us.

The following table summarizes the expenses related to our strategic realignment recognized in restructuring and other costs in our consolidated statement of operations (in thousands):

	Year Ended December 31,	
	2022	
Employee severance and benefits	\$	65,556
Impairments and losses on disposals of long-lived assets		60,507
Other restructuring costs		14,268
Total restructuring and other costs	\$	140,331

Employee severance and benefits are comprised of severance, other termination benefit costs, and stock-based compensation expense for the acceleration of RSUs related to workforce reductions. See Note 10, "Stock incentive plans" for additional information about the accelerated vesting of RSUs. Asset impairments and losses on asset disposals include operating lease impairments, losses on disposals of property and equipment and leasehold

improvements associated with exiting lines of business, consolidating lab and office space, and reducing our international footprint. See Note 8, "Commitments and contingencies" under the heading "Leases" for additional information about operating lease impairments. See Note 5, "Goodwill and intangible assets" for additional information about the loss on disposal of property and equipment related to the Singular Bio acquisition and Note 6, "Balance sheet components" for additional information about losses on disposal of property and equipment. Other restructuring costs include the write-off of prepaid assets related to the exit of certain product offerings, legal and professional fees, and contract exit costs.

We expect to incur additional employee severance and benefits expenses up to \$1.2 million, and additional other restructuring costs primarily related to third-party costs up to \$3.5 million. This reflects the best estimate of the Company, which may be revised in subsequent periods as the strategic realignment progresses.

The following table summarizes the changes in liabilities associated with our strategic realignment initiatives, including restructuring and other costs incurred and cash payments as of December 31, 2022 (in thousands):

	Employee severance and benefits	Other restructuring costs	Total
Beginning balance	\$ —	\$ —	\$ —
Accruals	35,237	7,405	42,642
Payments	(32,974)	(5,464)	(38,438)
Balance at December 31, 2022	\$ 2,263	\$ 1,941	\$ 4,204

The restructuring liabilities are included in accrued liabilities in the consolidated balance sheets. We expect that substantially all of the remaining accrued restructuring liabilities will be paid in cash over the next 12 months. The charges recognized in the roll forward of our accrued restructuring liabilities do not include items charged directly to expense for losses on asset disposals, accelerated vesting of RSUs, and other periodic exit costs, as those items are not reflected in our restructuring liabilities in our consolidated balance sheets.

## 12. Income taxes

We recorded a benefit for income taxes in the years ended December 31, 2022, 2021 and 2020. The components of net loss before taxes by U.S. and foreign jurisdictions are as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
United States	\$ 3,147,669	\$ 414,657	\$ 712,409
Foreign	3,528	1,206	1,861
Total	\$ 3,151,197	\$ 415,863	\$ 714,270

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

	Year Ended December 31,		
	2022	2021	2020
Current:			
Foreign	1,338	(2,069)	(171)
Total current benefit (expense) for income taxes	1,338	(2,069)	(171)
Deferred:			
Federal	22,368	28,348	94,279
State	19,512	8,809	17,730
Foreign	1,686	1,769	262
Total deferred benefit for income taxes	43,566	38,926	112,271
Total income tax benefit	\$ 44,904	\$ 36,857	\$ 112,100

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,		
	2022	2021	2020
U.S. federal taxes at statutory rate	21.0 %	21.0 %	21.0 %
State taxes (net of federal benefit)	0.9 %	7.3 %	3.4 %
Stock-based compensation	(1.2)%	(1.2)%	(1.6)%
Research and development credits	0.4 %	3.8 %	1.1 %
Non-deductible expenses	— %	(0.9)%	(0.7)%
Foreign tax differential	0.1 %	(0.1)%	— %
Acquisition contingent liabilities	0.1 %	18.5 %	(0.8)%
Non-deductible impairment expense	(14.9)%	— %	— %
Change in valuation allowance	(4.9)%	(39.5)%	(6.7)%
Total	1.5 %	8.9 %	15.7 %

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,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 595,301	\$ 530,663
Tax credits	49,615	36,188
R&D capitalization and amortization	72,358	6,202
Revenue recognition differences	—	2,560
Leasing liabilities	36,986	34,403
Accruals and other	41,198	36,689
Gross deferred tax assets	795,458	646,705
Valuation allowance	(542,900)	(386,950)
Total deferred tax assets	252,558	259,755
Deferred tax liabilities:		
Amortization and depreciation	(216,899)	(277,719)
Revenue recognition differences	(14,180)	—
Leasing assets	(29,609)	(33,732)
Total deferred tax liabilities	(260,688)	(311,451)
Net deferred tax liabilities	\$ (8,130)	\$ (51,696)

The Company historically established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding realization of such assets. In 2022 the Company released approximately \$41.9 million of its valuation allowance, primarily due to the release of federal and state valuation allowances as a result of the reclassification of ArcherDX's IVD and PCM in-process research and development intangibles from indefinite-lived intangibles to developed technology, which enabled the associated deferred tax liability to serve as a source of income to existing finite-lived deferred tax assets for which a valuation allowance had previously been established.

Effective for tax years beginning on or after January 1, 2022, pursuant to the Tax Cuts and Jobs Act of 2017, companies are required to capitalize and amortize Internal Revenue Code Section 174 research and experimental expenses paid or incurred over five years for research and development performed in the United States and 15 years for research and development performed outside of the United States. As a result of the Internal Revenue Code Section 174 research and experimental expense capitalization, the Company recognized a deferred tax asset for the future tax benefit of the amortization deductions with offsetting increase in the valuation allowance on 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 \$155.9 million, \$177.6 million, and \$64.0 million during the years ended December 31, 2022, 2021 and 2020, respectively.

As of December 31, 2022, the Company had net operating loss carryforwards of approximately \$2.4 billion and \$1.5 billion available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. Of the \$2.4 billion, \$285.0 million will begin to expire in 2030 while \$2.1 billion have no expiration date. The state net operating loss carryforwards will begin to expire in 2030.

As of December 31, 2022, the Company had research and development credit carryforwards of approximately \$79.9 million and \$32.2 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, the Company also performed a section 382 analysis in 2022 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, 2022, we had unrecognized tax benefits of \$59.3 million, which primarily relates to research and development credits, \$0.2 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.

On November 3, 2022, the Dutch tax authorities published a decree on the Anti-Tax Avoidance Directive 2 ("ATAD2") that relieves the Company of the application of ATAD2 in Netherlands. As a result, the Company has released \$1.7 million of related reserve for the uncertain tax position.

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

	Year ended December 31,		
	2022	2021	2020
Unrecognized tax benefits, beginning of period	\$ 46,669	\$ 21,965	\$ 26,985
Gross increases—current period tax positions	14,161	18,165	8,368
Gross increases—prior period tax positions	243	6,539	53
Gross decreases—prior period tax positions	(1,739)	—	(13,441)
Unrecognized tax benefits, end of period	\$ 59,334	\$ 46,669	\$ 21,965

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, 2022, 2021 and 2020.

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.



### 13. 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,		
	2022	2021	2020
Net loss	\$(3,106,293)	\$ (379,006)	\$ (602,170)
Shares used in computing net loss per share, basic and diluted	235,676	210,946	134,587
Net loss per share, basic and diluted	\$ (13.18)	\$ (1.80)	\$ (4.47)

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,		
	2022	2021	2020
Shares of common stock subject to outstanding options	3,113	4,069	6,878
Shares of common stock subject to outstanding warrants	—	29	405
Shares of common stock subject to outstanding RSUs	17,874	9,146	5,590
Shares of common stock subject to outstanding PRSUs	148	737	1,658
Shares of common stock pursuant to ESPP	1,891	425	294
Shares of common stock underlying Series A convertible preferred stock	—	93	125
Shares of common stock subject to Convertible Senior Notes conversion	38,403	38,403	8,371
Total shares of common stock equivalents	61,429	52,902	23,321

### 14. 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,		
	2022	2021	2020
United States	\$ 457,061	\$ 404,013	\$ 255,680
United Kingdom	9,185	5,485	2,185
Canada	8,779	7,553	4,529
Germany	5,445	8,102	2,299
Rest of world	35,833	35,296	14,905
Total revenue	\$ 516,303	\$ 460,449	\$ 279,598

As of December 31, 2022, 2021 and 2020, 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.

## 15. Selected quarterly data (unaudited)

The following tables summarize our quarterly financial information for 2022 and 2021 (in thousands, except per share amounts):

	Three Months Ended			
	March 31, 2022	June 30, 2022	September 30, 2022	December 31, 2022
Revenue	\$ 123,691	\$ 136,622	\$ 133,536	\$ 122,454
Cost of revenue	\$ 97,116	\$ 110,340	\$ 116,956	\$ 92,844
Loss from operations	\$ (213,233)	\$ (2,520,331)	\$ (289,951)	\$ (94,895)
Net loss	\$ (181,859)	\$ (2,523,461)	\$ (301,156)	\$ (99,817)
Net loss per share, basic and diluted <sup>(1)</sup>	\$ (0.80)	\$ (10.87)	\$ (1.27)	\$ (0.41)

	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) income per share, basic <sup>(1)</sup>	\$ (0.56)	\$ 0.66	\$ (0.91)	\$ (0.90)
Net (loss) income per share, diluted <sup>(1)</sup>	\$ (0.56)	\$ 0.53	\$ (0.91)	\$ (0.90)

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

## 16. Subsequent events

### *Payments made on 2020 Term Loan*

On February 7, 2023, the Company made a \$53.7 million payment which reduced the principal balance of the 2020 Term Loan by \$50.0 million and included a \$3.0 million prepayment fee, with the remainder attributable to interest. The payment was made by the Company at its sole election.

On February 28, 2023, the Company repaid the remaining principal balance outstanding of \$85.0 million plus outstanding interest of \$1.9 million and a prepayment fee of \$5.1 million.

### *Debt transactions*

On February 28, 2023, the Company announced it has entered into agreements with certain holders of the currently outstanding 2024 Notes. Under the terms of the agreement, Company will (a) exchange approximately \$305.7 million aggregate principal amount of the 2024 Notes for approximately \$275.3 million aggregate principal amount of its new 4.50% Series A Convertible Senior Secured Notes due 2028 ("New 2028 Notes") and \$30.6 million of the Company's common stock and (b) issue and sell \$30.0 million of New 2028 Notes for cash (collectively, the "Transactions"). The Transactions are subject to customary closing conditions and are expected to close on or about March 7, 2023. The New 2028 Notes will be issued pursuant to an indenture.

Under the terms of the agreement, the Company will have the option prior to the maturity date to redeem all or any portion of the principal amount of the New 2028 Notes for cash and warrants to purchase common stock at a ratio as outlined in the indenture. The New 2028 Notes will be convertible at any time prior to the maturity date at the option of the holders, subject to a beneficial ownership cap. In addition, prior to such time that the Company obtains stockholder approval for the issuance of shares of common stock in excess of the limitations imposed by the NYSE rules (the "NYSE Cap"), the holder is prohibited from converting New 2028 Notes into shares of common stock in excess of such NYSE Cap and the Company would instead be required to settle any conversion in cash if the Company is not able to obtain the stockholder approval within the grace period specified in the indenture. The New 2028 Notes will be secured by (i) a security interest in substantially all of the assets of the Company and its material subsidiaries and (ii) a pledge of the equity interests of the Company's direct and indirect material subsidiaries. The indenture includes specific affirmative and restrictive covenants agreed to by the Company.



## **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, 2022. 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, 2022, 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, 2022, 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, 2022, 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, 2022 and 2021, 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, 2022, and the related notes and our report dated February 28, 2023 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

San Mateo, California

February 28, 2023

**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, 2022 in connection with the solicitation of proxies for our 2023 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](http://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 for 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 [www.invitae.com](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, Kimber D. Lockhart and William H. Osborne. 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 “Director Compensation,” “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 captions “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 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

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herein
		Form	Exhibit	Filing Date	
2.1 <sup>@</sup>	<a href="#">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.</a>	8-K	2.1	6/24/2020	
2.2 <sup>@^</sup>	<a href="#">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.</a>	10-Q	2.2	8/4/2020	
3.1	<a href="#">Restated Certificate of Incorporation.</a>	8-K	3.1	2/23/2015	
3.1.1	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Invitae Corporation.</a>	8-K	3.1	8/1/2017	
3.2	<a href="#">Amended and Restated Bylaws.</a>	8-K	3.1	3/23/2021	
4.1	<a href="#">Form of Common Stock Certificate.</a>	10-K	4.1	2/26/2021	
4.2	<a href="#">Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.</a>				X
4.3	<a href="#">Indenture, dated as of September 10, 2019, between Invitae Corporation and U.S. Bank National Association, as trustee (including form of Note).</a>	8-K	4.1	9/11/2019	
4.4	<a href="#">Indenture, dated as of April 8, 2021, between Invitae Corporation and U.S. Bank National Association (including form of Note).</a>	8-K	4.1	4/8/2021	
4.5	<a href="#">Amended and Restated Registration Rights Agreement, dated as of July 31, 2017.</a>	8-K	10.4	8/1/2017	
4.6 <sup>@</sup>	<a href="#">Registration Rights Agreement, dated as of October 2, 2020, by and among Invitae Corporation and the investors party thereto.</a>	8-K	10.2	10/5/2020	
10.1 <sup>#</sup>	<a href="#">Form of Indemnification Agreement between Invitae Corporation and its officers and directors.</a>	S-1 (File No. 333-201433)	10.1	1/9/2015	
10.2	<a href="#">Lease Agreement dated as of September 2, 2015 by and between Invitae Corporation and 1400 16th Street LLC.</a>	8-K	10.1	9/4/2015	
10.3	<a href="#">Lease Agreement, dated as of April 20, 2021, by and between Invitae Corporation and APB Owned LLC.</a>	8-K	10.1	4/23/2021	
10.4 <sup>@^</sup>	<a href="#">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.</a>	8-K	10.3	10/5/2020	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herein
		Form	Exhibit	Filing Date	
10.5	<a href="#">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.</a>	8-K	10.2	4/5/2021	
10.6	<a href="#">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.</a>	10-Q	10.1	11/9/2021	
10.7 <sup>#</sup>	<a href="#">Invitae Corporation 2015 Stock Incentive Plan, as amended and restated as of August 31, 2021.</a>	10-Q	10.3	11/9/2021	
10.8 <sup>#</sup>	<a href="#">Form of Notice of Stock Option Grant and Non-Qualified Stock Option Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan.</a>	S-1 (File No. 333-201433)	10.6	2/11/2015	
10.9 <sup>#</sup>	<a href="#">Form of Notice of Restricted Stock Award and Restricted Stock Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan.</a>	S-1 (File No. 333-201433)	10.7	2/11/2015	
10.10 <sup>#</sup>	<a href="#">Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement for awards granted under the Invitae Corporation 2015 Stock Incentive Plan.</a>	8-K	10.1	8/6/2015	
10.11 <sup>#</sup>	<a href="#">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).</a>	10-Q	10.2	8/6/2019	
10.12 <sup>#^</sup>	<a href="#">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).</a>	10-Q	10.3	8/6/2019	
10.13 <sup>#</sup>	<a href="#">Form of Global Restricted Stock Unit Agreement under the Invitae Corporation 2015 Stock Incentive Plan.</a>	10-Q	10.4	11/9/2021	
10.14 <sup>#</sup>	<a href="#">Invitae Corporation Employee Stock Purchase Plan, as amended and restated as of October 14, 2021.</a>	10-Q	10.2	11/9/2021	
10.15 <sup>#</sup>	<a href="#">ArcherDX, Inc. 2015 Equity Incentive Plan, as amended, and forms of agreements thereunder.</a>	10-K	10.21	2/26/2021	
10.16 <sup>#</sup>	<a href="#">Stratify Genomics Inc. 2018 Equity Incentive Plan, as amended by Amendment No. 1 and Amendment No. 2.</a>	10-K	10.16	3/1/2022	
10.17	<a href="#">Form of Warrant to Purchase Common Stock between Oxford Capital, LLC and Invitae Corporation.</a>	10-K	10.14	3/16/2017	
10.18	<a href="#">Sales Agreement, dated May 4, 2021, between Invitae Corporation and Cowen and Company, LLC.</a>	8-K	1.1	5/4/2021	
10.19 <sup>#</sup>	<a href="#">Offer Letter, dated as of June 1, 2020, by and between Invitae Corporation and Kenneth D. Knight.</a>	8-K	10.1	6/26/2020	
10.20 <sup>#</sup>	<a href="#">Offer Letter, dated as of May 19, 2021, by and between Invitae Corporation and Roxi Wen.</a>	8-K	10.1	6/11/2021	
10.21 <sup>#</sup>	<a href="#">Change of Control and Severance Agreement, dated as of April 23, 2021, by and between Invitae Corporation and Sean George.</a>	10-Q	10.5	8/9/2021	
10.22 <sup>#</sup>	<a href="#">Form of Change of Control and Severance Agreement, between Invitae Corporation and certain officers.</a>	10-Q	10.6	8/9/2021	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herein
		Form	Exhibit	Filing Date	
10.23 <sup>@</sup>	<a href="#">Support Agreement, dated as of September 23, 2020, by and among Invitae Corporation and certain securityholders of ArcherDX, Inc.</a>	8-K	10.4	10/5/2020	
10.24	<a href="#">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).</a>	8-K	10.1	4/5/2021	
10.25 <sup>#</sup>	<a href="#">Change of Control and Severance Agreement, dated July 18, 2022, by and between Invitae Corporation and Kenneth D. Knight.</a>	10-Q	10.1	11/8/2022	
10.26 <sup>#</sup>	<a href="#">Transition and Separation Agreement, dated as of July 17, 2022, by and between Invitae Corporation and Sean George.</a>	10-Q	10.2	11/8/2022	
21.1	<a href="#">List of Subsidiaries.</a>				X
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm.</a>				X
24.1	Power of Attorney (contained on the signature page to this Form 10-K).				X
31.1	<a href="#">Principal Executive Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				X
31.2	<a href="#">Principal Financial Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				X
32.1 <sup>*</sup>	<a href="#">Principal Executive Officer's Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).</a>				X
32.2 <sup>*</sup>	<a href="#">Principal Financial Officer's Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).</a>				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.

\* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Exchange Act or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the Company specifically incorporates it by reference.

(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/ Kenneth D. Knight

Kenneth D. Knight  
Chief Executive Officer  
*Principal Executive Officer*

Date: February 28, 2023

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kenneth D. Knight 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
<u>/s/ Kenneth D. Knight</u> Kenneth D. Knight	Chief Executive Officer (Principal Executive Officer) and Director	February 28, 2023
<u>/s/ Yafei (Roxi) Wen</u> Yafei (Roxi) Wen	Chief Financial Officer (Principal Financial Officer)	February 28, 2023
<u>/s/ Robert F. Werner</u> Robert F. Werner	Chief Accounting Officer (Principal Accounting Officer)	February 28, 2023
<u>/s/ Randal W. Scott, Ph.D.</u> Randal W. Scott, Ph.D.	Chair of the Board and Director	February 28, 2023
<u>/s/ Eric Aguiar, M.D.</u> Eric Aguiar, M.D.	Director	February 28, 2023
<u>/s/ Geoffrey S. Crouse</u> Geoffrey S. Crouse	Director	February 28, 2023
<u>/s/ Christine M. Gorjanc</u> Christine M. Gorjanc	Director	February 28, 2023
<u>/s/ Kimber D. Lockhart</u> Kimber D. Lockhart	Director	February 28, 2023
<u>/s/ Chitra Nayak</u> Chitra Nayak	Director	February 28, 2023
<u>/s/ William H. Osborne</u> William H. Osborne	Director	February 28, 2023