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

Form 10-Q

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

For the quarterly period ended September 30, 2020

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

For the transition period from to

Commission File No. 001-36847

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

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

1400 16th Street, San Francisco, California 94103
(Address of principal executive offices, Zip Code)

(415) 374-7782
(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

The number of shares of the registrant's common stock outstanding as of October 30, 2020 was 176,699,713.

TABLE OF CONTENTS

PART I — Financial Information

ITEM 1. Consolidated Financial Statements.

INVITAE CORPORATION

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 106,436	$ 151,389
Marketable securities	254,848	240,436
Accounts receivable	27,328	32,541
Prepaid expenses and other current assets	26,492	18,032
Total current assets	415,104	442,398
Property and equipment, net	46,130	37,747
Operating lease assets	39,007	36,640
Restricted cash	6,685	6,183
Intangible assets, net	187,060	125,175
Goodwill	211,225	126,777
Other assets	7,961	6,681
Total assets	$ 913,172	$ 781,601
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 15,589	$ 10,321
Accrued liabilities	77,986	64,814
Operating lease obligations	6,628	4,870
Finance lease obligations	1,237	1,855
Total current liabilities	101,440	81,860
Operating lease obligations, net of current portion	42,363	42,191
Finance lease obligations, net of current portion	1,834	1,155
Convertible senior notes, net	279,870	268,755
Deferred tax liability	10,250	—
Other long-term liabilities	60,864	8,000
Total liabilities	496,621	401,961
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock	13	10
Accumulated other comprehensive income (loss)	199	(9)
Additional paid-in capital	1,542,848	1,138,316
Accumulated deficit	(1,126,509)	(758,677)
Total stockholders' equity	416,551	379,640
Total liabilities and stockholders' equity	$ 913,172	$ 781,601

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION

Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Test revenue	$ 67,326	$ 55,502	$ 175,503	$ 147,423
Other revenue	1,402	1,009	3,664	3,116
Total revenue	68,728	56,511	179,167	150,539
Cost of revenue	46,643	32,120	130,017	81,380
Research and development	37,802	46,951	168,433	90,247
Selling and marketing	37,800	32,690	119,440	87,662
General and administrative	27,306	21,733	81,966	56,326
Loss from operations	(80,823)	(76,983)	(320,689)	(165,076)
Other expense, net	(15,771)	(7,591)	(32,499)	(5,572)
Interest expense	(6,308)	(2,833)	(17,244)	(7,062)
Net loss before taxes	(102,902)	(87,407)	(370,432)	(177,710)
Income tax benefit	—	(8,700)	(2,600)	(12,650)
Net loss	$ (102,902)	$ (78,707)	$ (367,832)	$ (165,060)
Net loss per share, basic and diluted	$ (0.78)	$ (0.82)	$ (3.08)	$ (1.86)
Shares used in computing net loss per share, basic and diluted	132,484	95,577	119,386	88,663

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION

Condensed Consolidated Statements of Comprehensive Loss
(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss	$ (102,902)	$ (78,707)	$ (367,832)	$ (165,060)
Other comprehensive income (loss):				
Unrealized income (loss) on available-for-sale marketable securities, net of tax	(373)	—	208	5
Comprehensive loss	$ (103,275)	$ (78,707)	$ (367,624)	$ (165,055)

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION

Condensed Consolidated Statements of Stockholders' Equity
(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Common stock:				
Balance, beginning of period	$ 13	$ 9	$ 10	$ 8
Common stock issued	—	1	3	2
Balance, end of period	13	10	13	10
Accumulated other comprehensive income (loss):				
Balance, beginning of period	572	—	(9)	(5)
Unrealized income (loss) on available-for-sale marketable securities, net of tax	(373)	—	208	5
Balance, end of period	199	—	199	—
Additional paid-in capital:				
Balance, beginning of period	1,487,217	944,559	1,138,316	678,548
Common stock issued in connection with public offering, net	—	19,534	217,486	204,024
Common stock issued on exercise of stock options, net	1,992	553	4,163	2,985
Common stock issued pursuant to exercises of warrants	324	58	386	171
Common stock issued pursuant to employee stock purchase plan	—	—	4,527	2,578
Common stock issued or issuable pursuant to business combinations	31,939	35,778	134,445	95,220
Equity component of convertible senior notes, net	—	75,488	—	75,488
Stock-based compensation expense	21,376	9,673	53,912	26,629
Reclassification of stock payable liabilities	—	—	(10,387)	—
Balance, end of period	1,542,848	1,085,643	1,542,848	1,085,643
Accumulated deficit:				
Balance, beginning of period	(1,023,607)	(603,065)	(758,677)	(516,712)
Net loss	(102,902)	(78,707)	(367,832)	(165,060)
Balance, end of period	(1,126,509)	(681,772)	(1,126,509)	(681,772)
Total stockholders' equity	$ 416,551	$ 403,881	$ 416,551	$ 403,881

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION

Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (367,832)	$ (165,060)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	22,964	11,135
Stock-based compensation	102,329	47,826
Amortization of debt discount and issuance costs	11,115	855
Remeasurements of liabilities associated with business combinations	42,448	—
Benefit from income taxes	(2,600)	(12,650)
Debt extinguishment costs	—	8,926
Other	(570)	901
Changes in operating assets and liabilities, net of businesses acquired:		
Accounts receivable	5,516	(444)
Prepaid expenses and other current assets	(8,460)	(1,424)
Other assets	1,387	2,369
Accounts payable	3,118	87
Accrued expenses and other liabilities	5,665	9,692
Net cash used in operating activities	(184,920)	(97,787)
Cash flows from investing activities:		
Purchases of marketable securities	(180,021)	(20,781)
Proceeds from sales of marketable securities	12,832	—
Proceeds from maturities of marketable securities	152,465	34,500
Acquisition of businesses, net of cash acquired	(57,576)	(9,801)
Purchases of property and equipment	(13,991)	(13,530)
Other	(2,000)	—
Net cash used in investing activities	(88,291)	(9,612)
Cash flows from financing activities:		
Proceeds from public offerings of common stock, net	217,489	204,024
Proceeds from issuance of common stock, net	9,076	5,734
Proceeds from issuance of convertible senior notes, net	—	339,900
Payments of debt extinguishment costs	—	(10,638)
Loan payments	—	(75,000)
Finance lease principal payments	(1,543)	(1,590)
Other	3,738	—
Net cash provided by financing activities	228,760	462,430
Net increase (decrease) in cash, cash equivalents and restricted cash	(44,451)	355,031
Cash, cash equivalents and restricted cash at beginning of period	157,572	118,164
Cash, cash equivalents and restricted cash at end of period	$ 113,121	$ 473,195
Supplemental cash flow information of non-cash investing and financing activities:		
Equipment acquired through finance leases	$ 1,971	$ —
Purchases of property and equipment in accounts payable and accrued liabilities	$ 3,576	$ 1,339
Common stock issued for acquisition of businesses	$ 82,185	$ 104,801
Operating lease assets obtained in exchange for lease obligations, net	$ 6,157	$ 5,615

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION

Notes to Condensed 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 changed its name to Invitae Corporation in 2012. We utilize an integrated portfolio of laboratory processes, software tools and informatics capabilities to process DNA-containing samples, analyze information about patient-specific genetic variation and generate test reports for clinicians and patients. Our main production facility is located in San Francisco, California. We currently have more than 20,000 genes in production and provide a variety of diagnostic tests that can be used in multiple indications. We offer genetic testing across multiple clinical areas, including hereditary cancer, cardiology, neurology, pediatrics, metabolic conditions and rare diseases. To augment our offering and realize our mission, we acquired multiple assets including four businesses in 2017, which expanded our suite of genome management offerings and expanded our offering in reproductive health. In the first quarter of 2019, we introduced our non-invasive prenatal screen ("NIPS"). In June 2019, we launched a direct channel to consumers to increase accessibility to our testing platform. To improve our technology stack and reduce costs associated with variant interpretation, we acquired Singular Bio, Inc. ("Singular Bio") in June 2019, Jungla Inc. ("Jungla") in July 2019, and Oracle BV operating under the name "Diploid" in March 2020. To further expand our ability to scale and improve customer experience with patient support telehealth solutions and the use of chatbots, we acquired Clear Genetics, Inc. ("Clear Genetics") in November 2019. In April 2020, we acquired YouScript Incorporated ("YouScript") and Genelex Solutions, LLC ("Genelex") to expand content and improve customer experience by bringing pharmacogenetic testing and integrated clinical decision support to Invitae. In order to expand content and increase access to personalized oncology, in October 2020 we acquired ArcherDX, Inc. ("ArcherDX"), with a view towards integrating Invitae's germline testing with ArcherDX's tumor profiling and liquid biopsy technology and services into a single platform to enable precision medicine approaches from diagnostic testing to therapy optimization and monitoring. As of September 30, 2020, Invitae operates in one segment.

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) for interim financial information and in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2019. The results for the three and nine months ended September 30, 2020 are not necessarily indicative of the results expected for the full fiscal year or any other periods.

2. Summary of significant accounting policies

Principles of consolidation

Our unaudited condensed 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.

Concentrations of credit risk and other risks and uncertainties

Financial instruments that potentially subject us to a concentration of credit risk consist of cash, cash equivalents, marketable securities and accounts receivable. Our cash and cash equivalents are primarily 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 presented on the consolidated statements of operations. Our revenue from significant customers as a percentage of our total revenue was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Medicare	20%	27%	20%	23%

Cash, cash equivalents and restricted cash

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 statements of cash flows (in thousands):

	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 106,436	$ 151,389
Restricted cash	6,685	6,183
Total cash, cash equivalents and restricted cash	$ 113,121	$ 157,572

Inventory

We maintain test reagents and other consumables primarily used in sample collection kits which are valued at the lower of cost or net realizable value. Cost is determined using actual costs on a first-in, first-out basis. Our inventory was $14.9 million and $6.6 million as of September 30, 2020 and December 31, 2019, respectively, and was recorded in prepaid expenses and other current assets on our consolidated balance sheets. While we have not experienced significant disruption in our supply chain and we do not yet know the full impact COVID-19 will have on our supply chain, we have increased our inventory on hand to respond to potential future disruptions that may occur.

Fair value of financial instruments

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

Prior period reclassifications

We have reclassified certain amounts in prior periods to conform with current presentation.

Immaterial correction of an error

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

Recent accounting pronouncements

We evaluate all Accounting Standards Updates (“ASUs”) issued by the Financial Accounting Standards Board ("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.

In August 2020, the FASB issued ASU No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for certain convertible instruments, amends the guidance on derivative scope exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share calculations as a result of these changes. This new standard is effective for our interim and annual periods beginning January 1, 2022, and earlier adoption is permitted. We may elect to apply the amendments on a retrospective or modified retrospective basis. We are currently evaluating the impact of the adoption of this standard on our condensed consolidated financial statements.

Recently adopted accounting pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326),* which requires measurement and recognition of expected credit losses for financial assets. This guidance became effective for us beginning in the first quarter of 2020 and was adopted using a modified retrospective approach, with certain exceptions. The adoption of Topic 326 did not have a material impact on our consolidated financial statements as credit losses are not expected to be significant.

As part of our adoption of Topic 326, 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.

In accordance with Topic 326, we no longer evaluate whether our available-for-sale debt securities in an unrealized loss position are other than temporarily impaired. Instead, we assess whether such unrealized loss positions are credit-related. Our expected loss allowance methodology for these securities is developed by reviewing the extent of the unrealized loss, the issuers’ credit ratings and any changes in those ratings, as well as reviewing current and future economic market conditions and the issuers’ current status and financial condition. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other income (expense), net. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive income (loss).

3. Revenue, accounts receivable and deferred revenue

Test revenue is generated from sales of diagnostic tests to three groups of customers: institutions, such as hospitals, clinics and partners; patients who pay directly; and patients’ insurance carriers. Amounts billed and collected, and the timing of collections, vary based on whether the payer is an institution, a patient or an insurance carrier. Other revenue consists principally of revenue recognized under collaboration and genome network agreements and is accounted for under the provisions provided in Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers*.

The following table includes our revenues as disaggregated by payer category (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Test revenue:				
Institutions	$ 14,015	$ 10,407	$ 37,043	$ 28,375
Patient - direct	6,379	4,567	16,468	12,364
Patient - insurance	46,932	40,528	121,992	106,684
Total test revenue	67,326	55,502	175,503	147,423
Other revenue	1,402	1,009	3,664	3,116
Total revenue	$ 68,728	$ 56,511	$ 179,167	$ 150,539

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	$ 0.7	$ 1.2	$ 3.0	$ 4.0
Loss from operations	$ (0.7)	$ (1.2)	$ (3.0)	$ (4.0)
Net loss per share, basic and diluted	$ (0.01)	$ (0.01)	$ (0.03)	$ (0.05)

Influence of COVID-19

Our test volumes decreased significantly in the second half of March 2020 as compared to the first few months of 2020 as a result of COVID-19 and related limitations and priorities across the healthcare system. Our daily test volumes have consistently increased from the low in March 2020, although we are currently still experiencing changes in product mix due to the impact of COVID-19. COVID-19 could have a material impact on our financial results for at least the next quarter and for the foreseeable future, particularly on product mix and as a result, the revenue we recognize. We have reviewed and adjusted for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

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

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was signed into law which was 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, and in April 2020, we received $3.8 million as a part of this initiative. This payment was recognized as other income (expense), net in our consolidated statement of operations during the three months ended June 30, 2020. 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 institutions (e.g., hospitals, clinics, partners) and estimated amounts to be collected from third-party insurance payers for diagnostic test revenue recognized. Also included are amounts due under the terms of collaboration and genome network agreements for diagnostic testing and data aggregation reporting services provided and proprietary platform access rights transferred.

Deferred revenue

We record deferred revenue when cash payments are received or due in advance of our performance related to one or more performance obligations. The amounts deferred to date primarily consist of prepayments related to our consumer direct channel as well as consideration received pertaining to the estimated exercise of certain re-requisition rights. In order to comply with loss contract rules, our re-requisition rights revenue deferral is no less than the estimated cost of fulfilling related obligations. We recognize revenue related to re-requisition rights as the rights are exercised or expire unexercised, which is generally within 90 days of initial deferral.

4. Business combinations

Singular Bio

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

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

During the three and nine months ended September 30, 2020, we recorded research and development stock-based compensation expense of $6.3 million and $24.9 million, respectively, related to the Time-based RSUs, and $6.5 million of income and $23.6 million of expense, respectively, related to the PRSUs based on our evaluations of the probability of achieving performance conditions. During the three and nine months ended September 30, 2019, we recorded research and development stock-based compensation expense of $6.7 million and $7.6 million, respectively, related to the Time-based RSUs and $11.9 million and $13.6 million, respectively, related to the PRSUs. As of September 30, 2020, the Time-based RSUs and PRSUs had a total fair value of $46.5 million and $37.4 million, respectively, based on a total estimated issuance of 3.7 million shares and expectation of the achievement of the performance conditions. As of September 30, 2020, 1.7 million of the Time-based RSUs and 1.2 million of the PRSUs had vested with a total fair value of $60.9 million which was recorded in common stock issued or issuable pursuant to business combinations in the consolidated statements of stockholders' equity.

Jungla

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

We may be required to pay contingent consideration based on achievement of post-closing development milestones. As of the acquisition date, the fair value of this contingent consideration was $10.7 million including cash and common stock. These milestones are expected to be completed within two years of the date of acquisition, one of which was completed during the three months ended September 30, 2020. 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 milestones and the discount rate we 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 will be estimated at each reporting date with changes reflected as a general and administrative expense.

Upon acquisition, we had a stock payable liability related to our acquisition of Jungla which represents the hold-back obligation to issue 0.2 million shares subject to indemnification claims that may arise. This liability was adjusted at each reporting period based on the fair value of our common stock, which is a Level 3 input, with the change recorded in other income (expense), net. During July 2020, the hold-back shares were remitted in full to the former owners of Jungla.

Clear Genetics

In November 2019, we acquired 100% of the equity interest of Clear Genetics, a developer of software for providing genetic services at scale, for approximately $50.1 million. Of the cash and stock purchase price consideration issued, $0.2 million of cash and approximately 0.4 million shares of our common stock were subject to a 12-month hold back to satisfy indemnification obligations that may arise, 0.1 million of which were released during the three months ended June 30, 2020.

As of September 30, 2020, we had a stock payable liability related to our acquisition of Clear Genetics of $12.2 million which represents the hold-back obligation to issue 0.3 million shares subject to indemnification claims that may arise. This liability is adjusted at each reporting period based on the fair value of our common stock, which is a Level 3 input, with the change recorded in other income (expense), net.

Diploid

In March 2020, we acquired 100% of the equity interest of Diploid, a developer of artificial intelligence software capable of diagnosing genetic disorders using sequencing data and patient information, for approximately $82.3 million in cash and shares of our common stock. Of the stock purchase price consideration issued, approximately 0.4 million shares are subject to a hold-back to satisfy indemnification obligations that may arise. We included the financial results of Diploid in our consolidated financial statements from the acquisition date, which were not material for the nine months ended September 30, 2020.

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

	Purchase Price
Cash transferred	$ 32,323
Hold-back consideration - common stock	7,538
Common stock transferred	42,453
Total	$ 82,314

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

Cash	$ 124
Accounts receivable	26
Developed technology	41,789
Total identifiable assets acquired	41,939
Accounts payable	(30)
Deferred tax liability	(10,250)
Net identifiable assets acquired	31,659
Goodwill	50,655
Total purchase price	$ 82,314

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

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

We measured the identifiable assets and liabilities assumed at their acquisition date fair values separately from goodwill. The intangible asset acquired is developed technology related to Diploid's artificial intelligence technology platform. The fair value of the developed technology was estimated using an income approach with an estimated useful life of nine years. As of the acquisition date, we recorded a stock payable liability of $7.5 million to represent the hold-back obligation to issue 0.4 million shares subject to indemnification claims that may arise. This liability is adjusted at each reporting period based on the fair value of our common stock, which is a Level 3 input. As of September 30, 2020, the value of this liability was $18.3 million with the change recorded in other expense, net.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of Diploid resulted in the recognition of $50.7 million of goodwill which we believe relates primarily to expansion of the acquired technology to apply to new areas of genetic testing. Goodwill created as a result of the acquisition of Diploid is not deductible for tax purposes.

In June 2020, we granted 0.2 million RSUs with a fair value of $3.6 million under our 2015 Stock Incentive Plan as inducement awards in connection with our acquisition of Diploid. These RSUs vest in two equal installments, in April 2021 and April 2022. The value of the awards was recognized as research and development stock-based compensation upon grant in June 2020 as there were no ongoing obligations required by the award recipients.

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 are 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 remaining in shares of our common stock. Of the purchase price consideration for YouScript, approximately $1.4 million and 0.5 million shares of our common stock are subject to a hold-back to satisfy indemnification obligations that may arise. We included the financial results of Genelex and YouScript in our consolidated financial statements from the acquisition date, which were not material for the nine months ended September 30, 2020. We recorded $1.1 million of transaction costs related to the acquisition of Genelex and YouScript as general and administrative expense during the nine months ended September 30, 2020.

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 in the form of shares of our common stock. 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 we 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 with changes reflected as general and administrative expense.

The following table summarizes the purchase prices recorded as a part of the acquisition of Genelex and YouScript (in thousands):

	Genelex	YouScript	Total
Cash transferred	$ 972	$ 24,462	$ 25,434
Hold-back consideration - cash	—	1,385	1,385
Hold-back consideration - common stock	781	5,392	6,173
Contingent consideration	1,994	—	1,994
Common stock transferred	9,463	21,464	30,927
Total	$ 13,210	$ 52,703	$ 65,913

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

	Genelex	YouScript	Total
Cash	$ 33	$ 24	$ 57
Accounts receivable	221	56	277
Prepaid expenses and other current assets	—	70	70
Operating lease assets	—	355	355
Developed technology	9,209	25,716	34,925
Total identifiable assets acquired	9,463	26,221	35,684
Current liabilities	(320)	(481)	(801)
Deferred tax liability	—	(2,600)	(2,600)
Other long-term liabilities	—	(163)	(163)
Net identifiable assets acquired	9,143	22,977	32,120
Goodwill	4,067	29,726	33,793
Total purchase price	$ 13,210	$ 52,703	$ 65,913

Based on the guidance provided in ASC 805, *Business Combinations*, we accounted for the acquisitions of Genelex and YouScript as business combinations in which we determined that 1) Genelex and YouScript were businesses which combine inputs and processes to create outputs, and 2) substantially all of the fair value of gross assets acquired were not concentrated in a single identifiable asset or group of similar identifiable assets.

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

We measured the identifiable assets and liabilities assumed at their acquisition date fair values separately from goodwill. The intangible assets acquired are the developed technologies related to Genelex's and YouScript's technology platforms. The fair value of the developed technologies were estimated using an income approach with an estimated useful life of eight years. 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. These liabilities are adjusted at each reporting period based on the fair value of our common stock, which is a Level 3 input. As of September 30, 2020, the value of this liability was $22.4 million with the change recorded in other income (expense), net.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisitions of Genelex and YouScript resulted in the recognition of $33.8 million of goodwill which we believe relates primarily to future functionality and expansion of the acquired technologies. Of the goodwill recognized, $29.7 million related to the YouScript acquisition is not deductible for tax purposes.

ArcherDX

In June 2020, we entered into a definitive agreement with ArcherDX, a genomics analysis company democratizing precision oncology, and in October 2020, the closing conditions were met and the transaction was consummated. 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.

In connection with the transaction with ArcherDX, 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. The private placement closed concurrently with the combination with ArcherDX. We received proceeds of $5.0 million from the private placement during September 2020 which are reflected as an accrued liability and classified as "Other" under cash flows from financing activities as of September 30, 2020; the remainder of the proceeds were received in October 2020. In addition, we borrowed $135.0 million on a senior secured term loan facility ("2020 Term Loan") concurrent with the closing of the ArcherDX transaction which bears interest at an annual rate equal to LIBOR, subject to a 2.00% LIBOR floor, plus a margin of 8.75%. The 2020 Term Loan will mature on (i) June 1, 2024 if at such time our 2.00% convertible senior notes due 2024 are outstanding and are due to mature on or prior to September 1, 2024, or (ii) otherwise, on June 1, 2025. 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. During October 2020, these warrants were exercised in full.

Given the timing of the closing of the transaction with ArcherDX, we are currently in the process of valuing the assets acquired and liabilities assumed. As a result, we are not yet able to provide the amounts to be recognized as of the acquisition date for the major classes of assets acquired and liabilities assumed and other related disclosures. We will disclose this and other related information in our Annual Report on Form 10-K for the year ending December 31, 2020.

5. Goodwill and intangible assets

Goodwill

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

Balance as of December 31, 2019	$	126,777
Goodwill acquired - Diploid		50,655
Goodwill acquired - Genelex		4,067
Goodwill acquired - YouScript		29,726
Balance as of September 30, 2020	$	211,225

Intangible assets

The following table presents details of our intangible assets (in thousands):

	September 30, 2020				December 31, 2019			
	Cost	Accumulated Amortization	Net	Weighted-Average Useful Life (in Years)	Cost	Accumulated Amortization	Net	Weighted-Average Useful Life (in Years)
Customer relationships	$ 23,763	$ (7,241)	$ 16,522	10.0	$ 23,763	$ (5,141)	$ 18,622	10.0
Developed technology	161,110	(21,038)	140,072	8.6	84,396	(8,476)	75,920	8.6
Non-compete agreement	286	(215)	71	5.0	286	(172)	114	5.0
Trade name	576	(570)	6	2.7	576	(480)	96	2.7
Patent licensing agreement	496	(95)	401	15.0	496	(70)	426	15.0
Favorable leases	247	(247)	—	2.2	247	(238)	9	2.2
In-process research and development	29,988	—	29,988	n/a	29,988	—	29,988	n/a
	$ 216,466	$ (29,406)	$ 187,060	8.8	$ 139,752	$ (14,577)	$ 125,175	8.9

Acquisition-related intangibles included in the above table are finite-lived, other than in-process research and development which has an indefinite life, and are carried at cost less accumulated amortization. Customer relationships 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 realized. Amortization expense was $5.6 million and $2.2 million for the three months ended September 30, 2020 and 2019, respectively, and $14.8 million and $4.9 million for the nine months ended September 30, 2020 and 2019, respectively. Amortization expense is recorded to cost of revenue, research and development, sales and marketing and general and administrative expense.

The following table summarizes our estimated future amortization expense of intangible assets with finite lives as of September 30, 2020 (in thousands):

2020 (remainder of year)	$ 5,597
2021	22,792
2022	21,087
2023	20,074
2024	19,796
Thereafter	67,726
Total estimated future amortization expense	$ 157,072

6. Balance sheet components

Property and equipment, net

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

	September 30, 2020	December 31, 2019
Leasehold improvements	$ 23,350	$ 18,352
Laboratory equipment	32,676	24,873
Computer equipment	8,126	5,995
Software	2,649	2,611
Furniture and fixtures	1,277	1,198
Automobiles	58	58
Construction-in-progress	10,703	10,795
Total property and equipment, gross	78,839	63,882
Accumulated depreciation and amortization	(32,709)	(26,135)
Total property and equipment, net	$ 46,130	$ 37,747

Depreciation expense was $2.4 million and $1.8 million for the three months ended September 30, 2020 and 2019, respectively, and $6.8 million and $5.2 million for the nine months ended September 30, 2020 and 2019, respectively.

Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Accrued compensation and related expenses	$ 20,552	$ 16,440
Compensation and other liabilities associated with business combinations	38,905	30,560
Deferred revenue	1,917	1,429
Other	16,612	16,385
Total accrued liabilities	$ 77,986	$ 64,814

7. Fair value measurements

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

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

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

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

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

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

	September 30, 2020						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	$ 7,017	$ —	$ —	$ 7,017	$ 7,017	$ —	$ —
U.S. treasury notes	162,163	182	—	162,345	162,345	—	—
U.S. government agency securities	92,486	17	—	92,503	—	92,503	—
Total financial assets	$ 261,666	$ 199	$ —	$ 261,865	$ 169,362	$ 92,503	$ —
Financial liabilities:							
Stock payable liability				$ 53,330	$ —	$ —	$ 53,330
Contingent consideration				12,290	—	—	12,290
Total financial liabilities				$ 65,620	$ —	$ —	$ 65,620

	September 30, 2020
Reported as:	
Cash equivalents	$ 332
Restricted cash	6,685
Marketable securities	254,848
Total cash equivalents, restricted cash, and marketable securities	$ 261,865
Accrued liabilities	$ 10,500
Other long-term liabilities	$ 55,120

	December 31, 2019						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	$ 39,396	$ —	$ —	$ 39,396	$ 39,396	$ —	$ —
Certificates of deposit	300	—	—	300	—	300	—
U.S. treasury notes	150,627	—	(15)	150,612	150,612	—	—
U.S. government agency securities	193,302	6	—	193,308	—	193,308	—
Total financial assets	$ 383,625	$ 6	$ (15)	$ 383,616	$ 190,008	$ 193,608	$ —
Financial liabilities:							
Contingent consideration				$ 11,300	$ —	$ —	$ 11,300
Total financial liabilities				$ 11,300	$ —	$ —	$ 11,300

	December 31, 2019
Reported as:	
Cash equivalents	$ 136,997
Restricted cash	6,183
Marketable securities	240,436
Total cash equivalents, restricted cash, and marketable securities	$ 383,616
Accrued liabilities	$ 3,300
Other long-term liabilities	$ 8,000

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented. The total fair value of investments with unrealized losses at September 30, 2020 was $11.9 million. Our certificates of deposit and debt securities of U.S. government agency entities 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.

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 three and nine months ended September 30, 2020, the change in fair value related to stock payable liabilities recorded to other income (expense), net was expense of $16.2 million and $37.9 million, respectively.

As of September 30, 2020, we had contingent obligations of $10.5 million of our common stock to the former owners of Jungla in connection with our acquisition of Jungla in July 2019. The amount of the contingent obligation is dependent upon achievement of certain post-close development milestones. We estimated the fair value of the contingent consideration as $10.7 million at the acquisition date in July 2019 using a discounted cash flow technique based on estimated achievement of the post-close milestones and discount rates which were Level 3 inputs not supported by market activity. These inputs can significantly affect the estimated fair value of the contingent consideration. The value of the liability is subsequently remeasured to fair value at each reporting date with changes recorded as general and administrative expense.

As of September 30, 2020, we had contingent obligations of $1.8 million of our common stock to the former owners of Genelex in connection with our acquisition of Genelex in April 2020. The amount of the contingent obligation is dependent upon achievement of a certain post-close milestone and 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. We estimated the fair value of the contingent consideration as $2.0 million at the acquisition date in April 2020 using a discounted cash flow technique based on estimated achievement of the post-close milestone, our estimate of amounts to ultimately be paid, and discount rates which were Level 3 inputs not supported by market activity. These inputs can significantly affect the estimated fair value of the contingent consideration. The value of the liability is subsequently remeasured to fair value at each reporting date with changes recorded as general and administrative expense.

8. Commitments and contingencies

Leases

Operating leases

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

As of September 30, 2020, the weighted-average remaining lease term for our operating leases was 5.7 years and the weighted-average discount rate used to determine our operating lease liability was 11.3%. Cash payments included in the measurement of our operating lease liabilities were $3.0 million and $2.7 million for the three months ended September 30, 2020 and 2019, respectively, and $8.4 million and $7.6 million for the nine months ended September 30, 2020 and 2019, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating lease costs	$ 2,746	$ 2,666	$ 8,014	$ 7,747
Sublease income	—	(43)	—	(129)
Finance lease costs	515	386	1,474	1,197
Total lease costs	$ 3,261	$ 3,009	$ 9,488	$ 8,815

Future minimum payments under non-cancelable operating leases as of September 30, 2020 are as follows (in thousands):

2020 (remainder of year)	$	1,991
2021		12,230
2022		11,530
2023		11,039
2024		11,182
Thereafter		19,698
Future non-cancelable minimum operating lease payments		67,670
Less: imputed interest		(18,679)
Total operating lease liabilities		48,991
Less: current portion		(6,628)
Operating lease obligations, net of current portion	$	42,363

Finance leases

We have entered into various finance lease agreements to obtain laboratory equipment. The terms of our finance leases are generally three years with a weighted-average remaining lease term of 2.5 years as of September 30, 2020 and are typically secured by the underlying equipment. The weighted-average discount rate used to determine our finance lease liability was 4.9%. The portion of the future payments designated as principal repayment and related interest was classified as a finance lease obligation on our consolidated balance sheets. Finance lease assets are recorded within other assets on our consolidated balance sheet and were $6.2 million and $5.6 million as of September 30, 2020 and December 31, 2019, respectively. Cash payments included in the measurement of our finance lease liabilities were $0.4 million and $0.5 million for the three months ended September 30, 2020 and 2019, respectively, and $1.7 million and $1.6 million for the nine months ended September 30, 2020 and 2019, respectively.

Future payments under finance leases at September 30, 2020 are as follows (in thousands):

2020 (remainder of year)	$	459
2021		1,184
2022		1,184
2023		436
Total finance lease obligations		3,263
Less: interest		(192)
Present value of net minimum finance lease payments		3,071
Less: current portion		(1,237)
Finance lease obligations, net of current portion	$	1,834

Debt financing

In November 2018, we entered into a Note Purchase Agreement (the "2018 Note Purchase Agreement") pursuant to which we were eligible to borrow an aggregate principal amount up to $200.0 million over a seven year maturity term which included an initial borrowing of $75.0 million in November 2018. We received net proceeds of $10.3 million after terminating and repaying the balance of our obligations of approximately $64.7 million with our previous lender.

In September 2019, we settled our obligations under the 2018 Note Purchase Agreement in full for $85.7 million, which included repayment of principal of $75.0 million, accrued interest of $2.4 million, and prepayment fees of $8.9 million which were recorded as debt extinguishment costs in other income (expense), net in our consolidated statement of operations during the three months ended September 30, 2019.

Interest expense related to our debt financings, excluding the impact of our Convertible Senior Notes (defined below), was nil and $1.6 million for the three months ended September 30, 2020 and 2019, respectively, and nil and $5.5 million for the nine months ended September 30, 2020 and 2019, respectively.

Convertible Senior Notes

In September 2019, we issued, at par value, $350.0 million aggregate principal amount of 2.00% Convertible Senior Notes due 2024 ("Convertible Senior Notes") in a private offering. The Convertible Senior Notes are our senior unsecured obligations and will mature on September 1, 2024, unless earlier converted, redeemed or repurchased. The Convertible Senior 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 Convertible Senior 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. Our current intent is to settle the principal amount of the Convertible Senior Notes in cash upon conversion, with any remaining conversion value being delivered in shares of our common stock. The initial conversion rate for the Convertible Senior Notes is 33.6293 shares of our common stock per $1,000 principal amount of the Convertible Senior 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 Convertible Senior Notes), the holders of the Convertible Senior Notes may require us to repurchase all or any portion of their Convertible Senior Notes for cash at a repurchase price equal to 100% of the principal amount of the Convertible Senior Notes to be repurchased plus accrued and unpaid interest to, but excluding, the redemption date.

The Convertible Senior 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 Convertible Senior 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 Convertible Senior 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 Convertible Senior 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 Convertible Senior Notes at any time, regardless of the foregoing circumstances. As of September 30, 2020, none of the above circumstances had occurred and therefore the Convertible Senior Notes could not have been converted.

We may not redeem the Convertible Senior Notes prior to September 6, 2022. We may redeem for cash all or any portion of the Convertible Senior 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.

The Convertible Senior Notes as of September 30, 2020 consisted of the following (in thousands):

Outstanding principal	$	350,000
Unamortized debt discount and issuance costs		(70,130)
Net carrying amount, liability component	$	279,870

As of September 30, 2020, the fair value of the Convertible Senior Notes was $579.3 million. The estimated fair value of the Convertible Senior Notes, which are classified as Level 2 financial instruments, was determined based on the estimated or actual bid prices of the Convertible Senior Notes in an over-the-counter market. We recognized $5.5 million and $16.4 million of interest expense related to the Convertible Senior Notes during the three and nine months ended September 30, 2020, respectively, and $1.1 million during both the three and nine months ended September 30, 2019.

Other commitments

In the normal course of business, we enter into various purchase commitments primarily related to service agreements and laboratory supplies. At September 30, 2020, our total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year were $7.7 million.

Guarantees and indemnifications

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 September 30, 2020 or December 31, 2019.

Contingencies

We were not a party to any material legal proceedings at September 30, 2020, or at the date of this report other than listed below which are related to ArcherDX which we acquired in October 2020. We cannot currently predict the outcome of these actions. We are and may from time to time become involved in various legal proceedings and claims arising in the ordinary course of business. 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.

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. The litigations have now been consolidated for all purposes, are ongoing, and trial has been scheduled for May 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. This litigation is ongoing, and trial is currently scheduled for August 2021.

9. Stockholders' equity

Shares outstanding

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Convertible preferred stock:				
Shares outstanding, beginning of period	125	125	125	3,459
Conversion into common stock	—	—	—	(3,334)
Shares outstanding, end of period	125	125	125	125
Common stock:				
Shares outstanding, beginning of period	131,289	93,763	98,796	75,481
Common stock issued in connection with public offering	—	786	23,058	11,136
Common stock issued on exercise of stock options, net	245	71	553	411
Common stock issued pursuant to vesting of RSUs	1,322	476	4,803	1,721
Common stock issued pursuant to exercises of warrants	54	10	202	29
Common stock issued pursuant to employee stock purchase plan	—	—	342	235
Common stock issued pursuant to business combinations	358	1,409	5,514	4,168
Common stock issued upon conversion of preferred stock	—	—	—	3,334
Shares outstanding, end of period	133,268	96,515	133,268	96,515

2018 Sales Agreement

In August 2018, we entered into a Common Stock Sales Agreement (the "2018 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 $75.0 million. Cowen may sell the shares by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933, or Securities Act, including without limitation sales made directly on The New York Stock Exchange, and also may sell the shares in privately negotiated transactions, subject to our prior approval. Per the terms of the agreement, Cowen receives a commission equal to 3% of the gross proceeds of the sales price of all shares sold through it as sales agent under the 2018 Sales Agreement. In March 2019, we amended the 2018 Sales Agreement to increase the aggregate amount of our common stock to be sold under this agreement not to exceed $175.0 million. During the second quarter of 2020, we sold a total of 2.6 million shares of common stock under the 2018 Sales Agreement at an average price of $17.60 per share for aggregate gross proceeds of $46.0 million and net proceeds of $44.5 million.

Public offering

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.

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 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 (“IPO”). 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. We amended and restated the 2015 Plan to create a pool of shares to be awarded solely as a material inducement to employees.

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.

RSUs generally vest over a period of three years. Typically, the vesting schedule for RSUs provides that 1/3 of the award vests upon each anniversary of the grant date, with certain awards that include a portion that vests immediately upon grant. In June 2019, we granted Time-based RSUs in connection with the acquisition of Singular Bio which vest in three equal installments over a period of 18 months and PRSUs that vest based on the achievement of performance conditions; see further details in Note 4, "Business combinations."

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 nine months ended September 30, 2020 and the remaining awards will continue to vest over a period of two years. 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. These PRSUs will vest beginning in 2021 over a period of one year and may range from 0% to 100% of the target amount of shares, depending on eligibility and performance. As of September 30, 2020, these PRSUs had a fair value of $2.8 million based on an estimated issuance of 0.2 million shares and expectation of the performance condition.

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

	Shares Available For Grant	Stock Options Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balances at December 31, 2019	5,444	3,542	$ 9.49	6.1	$ 24,966
Additional shares reserved	4,649	—			
Options granted	(295)	295	17.26		
Options exercised	—	(553)	7.53		
RSUs and PRSUs granted[1]	(3,241)	—			
RSUs and PRSUs cancelled	433	—			
Balances at September 30, 2020	6,990	3,284	$ 10.54	5.9	$ 107,733
Options exercisable at September 30, 2020		2,767	$ 9.50	5.4	$ 93,648
Options vested and expected to vest at September 30, 2020		3,200	$ 10.39	5.9	$ 105,483

(1) Includes the changes in the Time-based RSUs and PRSUs granted as a part of the Singular Bio acquisition in June 2019 which are based on a fixed dollar value. The number of shares issued will be variable until the awards vest. See further details in Note 4, "Business combinations."

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.

In the nine months ended September 30, 2020 and 2019, the weighted-average fair value per share of options to purchase common stock granted was $10.10 and $14.52, respectively, and the total grant-date fair value of options to purchase common stock vested was $2.3 million and $3.6 million, respectively. The intrinsic value of options to purchase common stock exercised was $9.9 million and $5.8 million in the nine months ended September 30, 2020 and 2019, respectively.

The following table summarizes RSU activity, which includes the changes in Time-based RSUs and PRSUs granted in connection with our acquisition of Singular Bio (in thousands, except per share data):

	Number of Shares	Weighted- Average Grant Date Fair Value Per Share
Balance at December 31, 2019	8,885	$ 15.17
RSUs granted	4,545	$ 18.53
Time-based RSUs and PRSUs granted - Singular Bio [1]	(1,578)	$ 25.85
PRSUs granted	274	$ 16.17
RSUs vested	(4,803)	$ 17.98
RSUs cancelled	(433)	$ 18.40
Balance at September 30, 2020	6,890	$ 12.82

(1) Includes the changes in the Time-based RSUs and PRSUs granted as a part of the Singular Bio acquisition in June 2019 which are based on a fixed dollar value. The number of shares issued will be variable until the awards vest which are adjusted above. The weighted-average grant date fair value per share reflects the fair value pricing of the full award. See further details in Note 4, "Business combinations."

2015 Employee Stock Purchase Plan

In January 2015, we adopted the 2015 Employee Stock Purchase Plan (the “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 September 30, 2020, cash received from payroll deductions pursuant to the ESPP was $3.6 million. At September 30, 2020, a total of 1.2 million shares of common stock were reserved for issuance under the ESPP.

Stock-based compensation

The following table summarizes stock-based compensation expense included in the consolidated statements of operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Cost of revenue	$ 2,104	$ 822	$ 5,321	$ 3,678
Research and development	7,185	22,181	70,954	30,753
Selling and marketing	4,078	1,752	9,198	5,909
General and administrative	7,838	3,531	16,856	7,486
Total stock-based compensation expense	$ 21,205	$ 28,286	$ 102,329	$ 47,826

11. Net loss per share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss	$ (102,902)	$ (78,707)	$ (367,832)	$ (165,060)
Shares used in computing net loss per share, basic and diluted	132,484	95,577	119,386	88,663
Net loss per share, basic and diluted	$ (0.78)	$ (0.82)	$ (3.08)	$ (1.86)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Shares of common stock subject to outstanding options	3,365	3,647	3,419	3,691
Shares of common stock subject to outstanding warrants	330	586	396	596
Shares of common stock subject to outstanding RSUs	5,800	5,915	5,589	4,878
Shares of common stock subject to outstanding PRSUs	1,531	2,722	1,945	994
Shares of common stock pursuant to ESPP	312	229	316	219
Shares of common stock underlying Series A convertible preferred stock	125	125	125	896
Shares of common stock subject to convertible senior notes exercise	8,074	2,616	8,074	872
Total shares of common stock equivalents	19,537	15,840	19,864	12,146

12. Geographic information

Revenue by country is determined based on the billing address of the customer. The following presents revenue by country (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
United States	$ 64,322	$ 52,687	$ 167,462	$ 140,700
Canada	1,101	1,158	3,117	3,005
Rest of world	3,305	2,666	8,588	6,834
Total revenue	$ 68,728	$ 56,511	$ 179,167	$ 150,539

ITEM 2. 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 condensed consolidated financial statements and the related notes included in Item 1 of Part I of this report, and together with our audited consolidated financial statements and the related notes included in our Annual Report on Form 10-K for the year ended December 31, 2019. Historic results are not necessarily indicative of future results.

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 COVID-19 on our business and the actions we may take in response thereto;
- our mission and strategy for our business, products and technology, including our ability to expand our content and develop new content while maintaining attractive pricing, further enhance our genetic testing service and the related user experience, build interest in and demand for our tests and attract potential partners;
- the implementation of our business model;
- the expected benefits from and our ability to integrate our acquisitions, including ArcherDX;
- the rate and degree of market acceptance of our tests and genetic testing generally;
- our ability to scale our infrastructure and operations in a cost-effective manner;
- the timing of and our ability to introduce improvements to our genetic testing platform and to expand our assays to include additional genes;
- the timing and results of studies with respect to our tests;
- developments and projections relating to our competitors and our industry;
- our competitive strengths;
- the degree to which individuals will share genetic information generally, as well as share any related potential economic opportunities with us;
- our commercial plans, including our sales and marketing expectations as well as our ability to expand internationally;
- our ability to obtain and maintain adequate reimbursement for our tests;
- regulatory developments in the United States and foreign countries;
- our ability to attract and retain key scientific or management personnel;
- our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- our ability to obtain funding for our operations and the growth of our business, including potential acquisitions;
- our financial performance;
- the impact of accounting pronouncements and our critical accounting policies, judgments, estimates and assumptions on our financial results;
- our expectations regarding our future revenue, cost of revenue, operating expenses and capital expenditures, and our future capital requirements; and
- the impact of tax laws on our business.

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

This report contains statistical data and estimates that we obtained from industry publications and reports. These publications typically indicate that they have obtained their information from sources they believe to be reliable, but do not guarantee the accuracy and completeness of their information. Some data contained in this report is also based on our internal estimates. Although we have not independently verified the third-party data, we believe it to be reasonable.

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.

Mission and strategy

Our mission is to bring comprehensive genetic information into mainstream medical practice, improving the quality of healthcare for billions of people. Our business model is to aggregate the world's genetic tests into a single platform, consolidate and grow the genetic testing market, and on that foundation, build a new industry in which a network of customers and partners can work together to continue improving healthcare for every individual in the modernized healthcare system around the world.

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

- **Expanding our content offering.** We intend to continue steadily adding additional content to the Invitae platform, ultimately leading to affordable access to the personal molecular information relevant in enabling personalized medicine. The breadth and depth of our offering is a core and central contribution to an improved user experience.
- **Creating a unique user experience.** A state-of-the-art interactive platform will enhance our service offering, leverage the uniquely empowering characteristics of online sharing of genetic information and, we believe, enable a superior economic offering to clients. We intend to continue to expend substantial efforts developing, acquiring and implementing technology-driven improvements to our customers' experience. We believe that an enhanced user experience and the resulting benefits to our brand and reputation will help draw customers to us over and above our direct efforts to do so.
- **Driving volume.** We intend to increase our brand equity and visibility through excellent service and a variety of marketing and promotional techniques, including scientific publications and presentations, sales, marketing, public relations, social media and web technology vehicles. We believe that rapidly increasing the number of customers using our platform helps us to attract partners.
- **Attracting partners.** As we add more customers to our platform, we believe our business becomes particularly attractive to potential partners that can help the patients in our network further benefit from their genetic information or that provide us access to new customers who may wish to join our network. We believe the cumulative effect of the increased volume brought by these strategic components will allow us to lower the cost of our service.

- **Lowering the costs and price of genetic information.** Our goal is to provide customers with a broad menu of genetic content at a reasonable price and rapid turn-around time in order to grow volume and further achieve economies of scale. As we do so and experience further cost savings, we expect that those cost savings will allow us to deliver still more comprehensive information at decreasing prices and further improve the customer experience, allowing us to experience cumulative benefits from all of the efforts outlined above.

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

1) the needs of our customers;
2) motivating our employees to serve the needs of our customers; and
3) our long-term stockholder value.

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

Business overview

We offer high-quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, reproductive health, cardiology, neurology, pediatrics, metabolic conditions and rare diseases. In addition to our own research and development expertise, we have established a track record of building for the near- and long-term with our M&A strategy. We acquired multiple assets including four businesses in 2017, which expanded our suite of genome management offerings and strengthened our offering in reproductive health. In the first quarter of 2019, we expanded our reproductive offering by introducing our non-invasive prenatal screen ("NIPS"). In June 2019, we launched a direct channel to consumers to increase accessibility to our testing platform. To improve our technology stack and reduce costs associated with variant interpretation, we acquired Singular Bio, Inc. ("Singular Bio") in June 2019, Jungla Inc. ("Jungla") in July 2019, and Oracle BV operating under the name "Diploid" in March 2020. To further expand our ability to scale and improve customer experience with patient support telehealth solutions and the use of intuitive chatbots, we acquired Clear Genetics, Inc. ("Clear Genetics") in November 2019. In April 2020, we acquired YouScript Incorporated ("YouScript") and Genelex Solutions, LLC ("Genelex") to expand content and improve customer experience by bringing pharmacogenetic testing and integrated clinical decision support to Invitae. In order to expand content and increase access to personalized oncology, we acquired ArcherDX, Inc. ("ArcherDX") in October 2020, with a view towards integrating Invitae's germline testing with ArcherDX's tumor profiling and liquid biopsy technology and services into a single platform to enable precision medicine approaches from diagnostic testing to therapy optimization and monitoring.

We have experienced rapid growth. For the years ended December 31, 2019, 2018 and 2017, our revenue was $216.8 million, $147.7 million, and $68.2 million, respectively, and we incurred net losses of $242.0 million, $129.4 million and $123.4 million, respectively. For the nine months ended September 30, 2020 and 2019, our revenue was $179.2 million and $150.5 million, respectively, and we incurred net losses of $367.8 million and $165.1 million, respectively. At September 30, 2020, our accumulated deficit was $1.1 billion. To meet the demands of scaling our business, we increased our number of employees to approximately 1,500 at September 30, 2020 from approximately 1,100 on September 30, 2019. Our sales force grew to approximately 270 at September 30, 2020 from approximately 190 at September 30, 2019. Upon the closing of the ArcherDX acquisition, our headcount increased by approximately 400 employees to approximately 1,900 in October 2020.

Sales of our tests have grown significantly. In 2019, 2018 and 2017, we accessioned 482,000, 303,000, and 150,000 samples, respectively, and generated 469,000, 292,000, and 145,000 billable tests, respectively. In the nine months ended September 30, 2020, we accessioned 444,000 samples and generated 421,000 billable tests compared to approximately 334,000 accessioned samples and 322,000 billable tests in the same period in 2019. Approximately 41% of the billable tests we performed in the first nine months of 2020 were billable to institutions and patients, and the remainder were billable to third-party payers. Many of the gene tests on our assays are tests for which insurers reimburse. However, when we do not have reimbursement policies or contracts with private insurers, our claims for reimbursement may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. Even if we are successful in achieving reimbursement, we may be paid at lower rates than if we were under contract with the third-party payer. When there is not a contracted rate for reimbursement, there is typically a greater coinsurance or copayment requirement from the patient which may result in further delay in payment for these tests.

We expect to incur operating losses for the near-term as we invest in our business to achieve our revenue growth objectives and may need to raise additional capital in order to fund our operations. If we are unable to achieve these objectives and successfully manage our costs, we may not be able to achieve profitability in the near-term or at all.

We believe that the keys to our future growth will be to increase billable test volumes, achieve broad reimbursement coverage for our tests from third-party payers, drive down the price for genetic analysis and interpretation, steadily increase the amount of genetic content we offer, consistently improve the client experience, drive physician and patient utilization of our website for ordering and delivery of results and increase the number of strategic partners working with us to add value for our clients.

Merger with ArcherDX

On June 21, 2020, we, Apollo Merger Sub A Inc., a Delaware corporation and a wholly-owned subsidiary of Invitae ("Merger Sub A"), Apollo Merger Sub B LLC, a Delaware limited liability company and a wholly-owned subsidiary of Invitae ("Merger Sub B"), ArcherDX and Kyle Lefkoff, solely in his capacity as holders' representative, entered into an Agreement and Plan of Merger and Plan of Reorganization that provided for the acquisition of ArcherDX by Invitae. We acquired ArcherDX through a two-step merger which was consummated on October 2, 2020. Merger Sub A merged with and into ArcherDX, with ArcherDX surviving the merger as a wholly owned subsidiary of Invitae, referred to as the first merger. Promptly following the first merger, ArcherDX merged with and into Merger Sub B, with Merger Sub B surviving as a wholly owned subsidiary of Invitae, referred to as the second merger. Such first merger and second merger are referred to collectively as the merger or the transaction.

Under the terms of the agreement, we acquired ArcherDX for upfront consideration consisting of 30.0 million shares of common stock and $325.0 million in cash, plus up to an additional 27.0 million shares of common stock payable in connection with the achievement of certain milestones. In connection with the transaction, we entered into a definitive agreement to issue $275.0 million in common stock in a private placement at a price of $16.85 per share which closed concurrently with the merger. In addition, we borrowed $135.0 million on a senior secured term loan facility ("2020 Term Loan") concurrent with the closing of the transaction. 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. The 2020 Term Loan is available (i) to finance, in whole or in part, the merger, (ii) to pay fees, costs and expenses related to the merger, the debt financing and the other transactions related to the merger and (iii) for other general working capital purposes.

ArcherDX offers a suite of products and services that are highly accurate, personal, actionable and easy to use in local settings. Additionally, ArcherDX's products and services enable biopharmaceutical companies to cost-effectively accelerate drug development. Its product development platform, with proprietary Anchored Multiplex PCR, or AMP, chemistry at the core, has enabled ArcherDX to develop industry-leading products and services that allow for therapy optimization and cancer monitoring.

ArcherDX has developed and commercialized research use only, or RUO, products, is developing in-vitro diagnostic, or IVD, products, and offers services that meet the unique needs of its customers and their clinical applications. ArcherDX's five RUO product lines consist of DNA-based VariantPlex, RNA-based FusionPlex, ctDNA-based LiquidPlex and RNA-based Immunoverse, which are collectively referred to as ArcherPlex, and Personalized Cancer Monitoring, or PCM. ArcherDX offerings include commercial RUO products and services that laboratories use to conduct genomic analysis for therapy optimization and cancer monitoring. ArcherDX intends to submit STRATAFIDE, in 2020, and PCM, in the future, for United States Federal Drug Administration, or FDA, approval and/or clearance so they can be marketed as IVDs. STRATAFIDE and PCM have both received Breakthrough Device designation from the FDA, which offers potentially faster review through priority review for certain medical devices. Additionally, ArcherDX offers Assay Designer and Designer Pro as services to clinical and biopharmaceutical customers, which allow them to customize biomarker targets and develop new applications. ArcherDX's analyte- and sample-agnostic products and services enable clinicians to quickly and locally generate actionable genomic information to deliver industry-leading care to patients with solid tumors, blood cancers or sarcomas.

We expect the merger with ArcherDX to have a significant impact on our results of operations and financial condition as of and for the fourth quarter ending December 31, 2020 and in future periods as we integrate ArcherDX's tumor profiling and liquid biopsy technologies and services in a single platform. We expect the integration to include investments to continue our mission to offer comprehensive genetic information into mainstream medical practice while also expecting to realize synergies from enhancing our product offering and ability to serve our customers. The merger with ArcherDX will significantly increase our billable units and revenue we recognize as well as expenses we incur as a combined company, including expenses related to ongoing litigation involving ArcherDX.

Impact of COVID-19

Our test volumes decreased significantly in the second half of March 2020 as compared to the first few months of 2020 as a result of COVID-19 and related limitations and priorities across the healthcare system. Our daily test volumes have consistently increased from the low in March 2020, although we are currently still experiencing changes in product mix due to the impact of COVID-19. COVID-19 could have a material impact on our financial results for at least the next quarter and for the foreseeable future, particularly on product mix and as a result, the revenue we recognize. We have reviewed and adjusted for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

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

Many announced healthcare guidelines call for a shift of regular physician visits and healthcare delivery activities to remote/telehealth formats. This is particularly important for patients who, despite the fall-out from COVID-19, continue to be diagnosed with critical diseases, like cancer, and for women who are pregnant or are trying to conceive. We believe our investments in new access platforms and technologies will 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. Gia, developed by Clear Genetics which we acquired in 2019, expands access to remote interaction between patients and clinicians as well as direct ordering of genetic tests. Such access helped to counteract some of the adverse in-office impacts of COVID-19, allowing continuation of key testing categories in a safe environment.

Given the unknown duration and extent of COVID-19’s impact on our business, and the healthcare system in general, we are adapting our spending and investment levels to evolving market conditions, including efforts to focus operating expense on increasing gross profit, otherwise managing cash burn, and focusing commercial execution on workflows that support remote ordering, online support and telehealth. Approximately 8% of our workforce as of March 2020 was impacted by a reduction in force in April 2020 in an initiative to manage costs and cash burn, which resulted in one-time costs in the second quarter of 2020 of $3.8 million. In addition, effective May 2020, we reduced the salaries of our named executive officers by approximately 20%.

Factors affecting our performance

Number of billable tests

The growth in our test revenue is tied to the number of tests for which we bill third-party payers, institutions, partners or patients, which we refer to as billable tests. We typically bill for our services following delivery of the billable test report derived from testing samples and interpreting the results. We incur the expenses associated with a test in the period in which the test is processed regardless of when payment is received with respect to that test. We believe the number of billable tests in any period is the most important indicator of the growth in our test revenue, and with time, this will translate into the number of customers we add to our platform.

Success obtaining and maintaining reimbursement

Our ability to increase the number of billable tests and our revenue will depend in part on our success achieving broad reimbursement coverage and laboratory service contracts for our tests from third-party payers and agreements with institutions and partners. Reimbursement may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary and cost-effective, as well as whether we are in contract, where we get paid more consistently and at higher rates. Because each payer makes its own decision as to whether to establish a policy or enter into a contract to reimburse for our testing services and specific tests, seeking these approvals is a time-consuming and costly process. In addition, clinicians and patients may decide not to order our tests if the cost of the test is not covered by insurance. Because we require an ordering physician to requisition a test, our revenue growth also depends on our ability to successfully promote the adoption of our testing services and expand our base of ordering clinicians. We believe that establishing coverage and obtaining contracts from third-party payers is an important factor in gaining adoption by ordering clinicians. Our arrangements for laboratory services with payers cover approximately 310 million lives, comprised of Medicare, all national commercial health plans, and Medicaid in most states, including California (Medi-Cal), our home state.

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 may vary from payer to payer, and it may be time-consuming and require substantial resources to meet these requirements. We may also experience delays in or denials of coverage if we do not adequately comply with these requirements. 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, tests provided by companies we acquire and any future tests we may develop. However, if we are not able to continue to obtain and maintain adequate reimbursement from third-party payers, institutions and partners for our testing services and expand the base of clinicians and patients ordering our tests, we may not be able to effectively increase the number of billable tests or our revenue.

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. Our acquisition of Singular Bio is a component of this objective, and we expect the technology acquired in this transaction, once developed, to help decrease the costs associated with our NIPS offering. We also intend to continue to design and implement hardware and software tools that are designed to reduce personnel-related costs for both laboratory and clinical operations/medical interpretation by increasing personnel efficiency and thus lowering labor costs per test. Finally, we will need to reduce our costs of providing tests internationally to enable us to expand more rapidly outside of the United States.

Ability to expand our genetic content

Our focus on reducing the average cost per test will have a countervailing force — increasing the number of tests we offer and the content of each test. We intend to continue to expand our test menu by steadily releasing additional genetic content for the same or lower prices per test, ultimately leading to affordable whole genome services. The breadth and flexibility of our offering will be a critical factor in our ability to address new markets, including internationally, for genetic testing services. Both of these, in conjunction with our continued focus on strategic partnerships, will be important to our ability to continue to grow the volume of billable tests we deliver.

Investment in our business and timing of expenses

We plan to continue to invest in our genetic testing and information management business. We deploy state-of-the-art and costly technologies in our genetic testing services, and we intend to continue to scale our infrastructure, including our testing capacity and information systems. We also expect to incur software development costs as we seek to further automate our laboratory processes and our genetic interpretation and report sign-out procedures, scale our customer service capabilities to improve our customers' experience, and expand the functionality of our website. We will incur costs related to marketing and branding as we spread our initiatives beyond our current customer base and focus on providing access to customers through our website. We have hired additional personnel as necessary to support anticipated growth, including software engineers, sales

and marketing personnel, billing personnel, research and development personnel, medical specialists, biostatisticians and geneticists. We will also incur additional costs related to the expansion of our production facilities to accommodate growth and as we expand internationally. In addition, we expect to 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. 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 copayments, the existence of secondary payers and claim denials.

Financial overview

Revenue

We primarily generate revenue from the sale of our tests, which provide the analysis and associated interpretation of the sequencing of parts of the genome. Clients are billed upon delivery of test results. Our ability to increase our revenue will depend on our ability to increase our market penetration, obtain contracted reimbursement coverage from third-party payers, sign contracts with institutions and partners, and increase the rate at which we are paid for tests performed.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering test results to clinicians and patients and includes expenses for materials and supplies, personnel-related costs, equipment and infrastructure expenses associated with testing and allocated overhead including rent, information technology, equipment depreciation, amortization of acquired intangibles and utilities. Costs associated with performing our tests are recorded as the patient's sample is processed. We expect cost of revenue to generally increase in line with the increase in the number of tests we perform, however we expect future increases in amortization of acquired intangible assets which are not dependent on sample volume. We anticipate our cost per test will generally decrease over time due to the efficiencies we expect to gain as test volume increases and from automation and other cost reductions, although the cost per test may fluctuate from quarter to quarter. These reductions in cost per test will be likely be offset by new tests which often have a higher cost per test during the introductory phases before we are able to gain efficiencies.

Operating expenses

Our operating expenses are classified into three categories: research and development, selling and marketing, and general and administrative. For each category, the largest component is personnel-related costs, which include salaries, employee benefit costs, bonuses, commissions, as applicable, and stock-based compensation expense. While we are focusing on growing our business which will generate increased operating expenses in future periods, we are also mindful of the resurgence of COVID-19 which could cause a disruption in our business and the need to respond accordingly.

Research and development

Research and development expenses represent costs incurred to develop our technology and future tests. These costs are principally for process development associated with our efforts to expand the number of genes we can evaluate in our tests and with our efforts to lower the cost of performing our tests. In addition, we incur process development costs to further develop the software we use to operate our laboratory, analyze the data it generates, process customer orders, 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 and allocated overhead including rent, information technology, equipment depreciation, amortization of acquired intangible assets and utilities.

We expense all research and development costs in the periods in which they are incurred. Our research and development expenses have increased as we continued our efforts to develop additional tests, made investments to reduce testing costs, streamlined our technology to provide patients access to testing, scaled our business

domestically and internationally and acquired and integrated new technologies. We expect these costs to increase in the future as we invest in our technologies, however, certain costs could fluctuate significantly from quarter to quarter, specifically related to our stock-based compensation.

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 costs to increase as we build our brand.

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; changes in the fair value of contingent consideration; and post-combination expenses incurred in relation to companies we acquire. We expect our general and administrative expenses to increase in the future as our business grows.

Other expense, net

Other expense, net, primarily consists of adjustments to the fair value of our stock payable liabilities arising from business combinations and we expect it to fluctuate significantly from period to period due to the volatility of our common stock. Other 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 attributable to debt financing, including our convertible senior notes issued in September 2019 ("Convertible Senior Notes"), and finance leases. See Note 8, “Commitments and contingencies” in the Notes to Condensed Consolidated Financial Statements included elsewhere in this report.

Income tax benefit

The income tax benefit is comprised of changes in our deferred income taxes and associated valuation allowances resulting from business combinations.

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 are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates.

There have been no material changes to our critical accounting policies and estimates as compared to the critical accounting policies and estimates described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

Results of operations

Three Months Ended September 30, 2020 and 2019

The following sets forth our consolidated statements of operations data for each of the periods indicated (in thousands, except percentage changes). Our historical results are not necessarily indicative of our results of operations to be expected for any future period.

	Three Months Ended September 30,		Dollar Change	% Change
	2020	2019		
Revenue:				
Test revenue	$ 67,326	$ 55,502	$ 11,824	21%
Other revenue	1,402	1,009	393	39%
Total revenue	68,728	56,511	12,217	22%
Cost of revenue	46,643	32,120	14,523	45%
Research and development	37,802	46,951	(9,149)	(19)%
Selling and marketing	37,800	32,690	5,110	16%
General and administrative	27,306	21,733	5,573	26%
Loss from operations	(80,823)	(76,983)	(3,840)	5%
Other expense, net	(15,771)	(7,591)	(8,180)	108%
Interest expense	(6,308)	(2,833)	(3,475)	123%
Net loss before taxes	(102,902)	(87,407)	(15,495)	18%
Income tax benefit	—	(8,700)	8,700	(100)%
Net loss	$ (102,902)	$ (78,707)	$ (24,195)	31%

Revenue

The increase in total revenue of $12.2 million for the three months ended September 30, 2020 compared to the same period in 2019 was due primarily to increased test volume as well as product mix and pricing. Billable test volumes increased to approximately 157,000 in the three months ended September 30, 2020 compared to 124,000 in the same period of 2019, an increase of 27 percent. Average revenue per test decreased to $429 per test in the three months ended September 30, 2020 compared to $448 per test in the comparable prior period primarily due to changes in payer and product mix, as well as reductions in pricing for some payers as we focus on providing cost effective genetic testing.

Cost of revenue

The increase in the cost of revenue of $14.5 million for the three months ended September 30, 2020 compared to the same period in 2019 was primarily due to increased costs per sample as well as increased test volume, partially offset by the effect of cost efficiencies. For the three months ended September 30, 2020, the number of samples accessioned increased to 170,000 from 129,000 for the same period in 2019. Cost per sample accessioned was $274 in the three months ended September 30, 2020 compared to $249 for the same period in 2019. The cost per sample accessioned increased primarily due to an increase in amortization of acquired intangible assets of $3.3 million as well as changes in product mix. These increases were partially offset by production improvements which resulted in material efficiencies and automation and software improvements which reduced the medical interpretation time per report.

Research and development

The decrease in research and development expense of $9.1 million for the three months ended September 30, 2020 compared to the same period in 2019 was due primarily to reductions in stock-based compensation related to our acquisition of Singular Bio, Inc. in June 2019 of $18.8 million and increased allocations of resources from research and development to cost of revenue to support the increase in production volumes of $3.7 million. These decreases were partially offset by an increase in other personnel-related costs of $11.3 million, principally reflecting increased headcount; an increase in professional fees of $0.7 million; an increase in technology costs of $0.6 million; and an increase in occupancy costs of $0.5 million.

Selling and marketing

The increase in selling and marketing expense of $5.1 million for the three months ended September 30, 2020 compared to the same period in 2019 was due primarily to the growth of the business and principally consisted of increases in personnel-related costs of $7.7 million primarily reflecting increased headcount and includes an increase in sales commissions of $2.6 million, partially offset by decreases in marketing costs of $2.2 million and travel-related costs of $1.6 million due to reductions in spending in response to COVID-19.

General and administrative

The increase in general and administrative expense of $5.6 million for the three months ended September 30, 2020 compared to the same period in 2019 was due primarily to the growth of the business and the effect of our business acquisitions, and principally consisted of the following elements: personnel-related costs increased by $6.6 million; a $2.4 million increase in legal and accounting services which was primarily due to increased acquisition-related transaction costs incurred related to our acquisition of ArcherDX; a $0.7 million increase in costs related to our co-development agreements and a $0.4 million increase in information technology expenses for software licenses and related expenses.

These cost increases were partially offset by a decrease in post-combination expense related to our acquisitions of $2.9 million, a decrease of $0.6 million in fair value adjustments to our contingent consideration obligations and an increase of $0.6 million in allocations of technology and facilities-related expenses to other functional areas.

Other expense, net

The increase in other expense, net of $8.2 million for the three months ended September 30, 2020 compared to the same period in 2019 was due principally to fair value adjustments related to our stock payable liabilities of $16.2 million due to the increase in the price of our common stock during the period offset by a reduction of debt extinguishment costs of $8.9 million incurred in September 2019 with no similar expense in the current period.

Interest expense

The increase in interest expense of $3.5 million for the three months ended September 30, 2020 compared to the same period in 2019 was due to increased debt outstanding compared to the prior year period.

Income tax benefit

The decrease in income tax benefit of $8.7 million was due to the net deferred tax liabilities assumed in connection with our acquisition of Jungla during the three months ended September 30, 2019, while there was no similar income tax benefit in the current year period.

Nine Months Ended September 30, 2020 and 2019

The following sets forth our consolidated statements of operations data for each of the periods indicated (in thousands, except percentage changes). Our historical results are not necessarily indicative of our results of operations to be expected for any future period.

	Nine Months Ended September 30,		Dollar Change	% Change
	2020	2019		
Revenue:				
Test revenue	$ 175,503	$ 147,423	$ 28,080	19%
Other revenue	3,664	3,116	548	18%
Total revenue	179,167	150,539	28,628	19%
Cost of revenue	130,017	81,380	48,637	60%
Research and development	168,433	90,247	78,186	87%
Selling and marketing	119,440	87,662	31,778	36%
General and administrative	81,966	56,326	25,640	46%
Loss from operations	(320,689)	(165,076)	(155,613)	94%
Other expense, net	(32,499)	(5,572)	(26,927)	483%
Interest expense	(17,244)	(7,062)	(10,182)	144%
Net loss before taxes	(370,432)	(177,710)	(192,722)	108%
Income tax benefit	(2,600)	(12,650)	10,050	(79)%
Net loss	$ (367,832)	$ (165,060)	$ (202,772)	123%

Revenue

The increase in total revenue of $28.6 million for the nine months ended September 30, 2020 compared to the same period in 2019 was due primarily to increased test volume offset by changes in product mix. Billable test volumes increased to approximately 421,000 in the nine months ended September 30, 2020 compared to 322,000 in the same period of 2019, an increase of 31 percent. While our test volumes increased during the nine months ended September 30, 2020 as compared to the prior year period, we began to see a significant decrease in the second half of March 2020 as a result of COVID-19 and our test volumes continued to be impacted through the second quarter. Average revenue per test decreased to $417 per test in the nine months ended September 30, 2020 compared to $458 per test in the comparable prior period primarily due to changes in payer and product mix, as well as reductions in pricing for some payers as we focus on providing cost effective genetic testing.

Cost of revenue

The increase in the cost of revenue of $48.6 million for the nine months ended September 30, 2020 compared to the same period in 2019 was primarily due to costs associated with increased test volume and increased cost per sample, partially offset by the effect of cost efficiencies. For the nine months ended September 30, 2020, the number of samples accessioned increased to 444,000 from 334,000 for the same period in 2019. Cost per sample accessioned was $293 in the nine months ended September 30, 2020 compared to $244 for the same period in 2019. The increase in cost per sample accessioned in the nine months ended September 30, 2020 was primarily attributable to an increase in amortization of acquired intangible assets of $9.7 million as well as changes in product mix and the influence of COVID-19. These increases were partially offset by production improvements which resulted in material efficiencies and automation and software improvements which reduced the medical interpretation time per report.

Research and development

The increase in research and development expense of $78.2 million for the nine months ended September 30, 2020 compared to the same period in 2019 was due to the growth of the business as well as to costs related to our acquisitions of Singular Bio in June 2019 and Diploid in March 2020. The increase principally consisted of the following elements as we invest in research and development initiatives as we grow: personnel-related costs increased by $75.3 million, primarily reflecting increased headcount as well as an increase in stock-based compensation of $42.2 million primarily related to equity awards granted to new employees who joined Invitae in connection with our acquisitions of Singular Bio and Diploid; technology expense increased by $3.4 million primarily reflecting increased headcount; professional fees increased by $3.2 million; general lab expenses increased by $1.6 million and occupancy expenses increased by $1.4 million.

These cost increases were partially offset by increased allocations of resources from research and development to cost of revenue to support the increase in production volumes, and allocations from other functional areas which reduced research and development expense by $7.1 million.

Selling and marketing

The increase in selling and marketing expense of $31.8 million for the nine months ended September 30, 2020 compared to the same period in 2019 was due primarily to the growth of the business and our increased spending on marketing initiatives prior to our cut backs in the second quarter of 2020 as a response to COVID-19. The increase in selling and marketing expenses principally consisted of the following elements: personnel-related costs increased by $26.4 million reflecting increased headcount and included an increase in sales commissions of $7.8 million; allocated technology and facilities-related expenses increased by $3.2 million; marketing costs principally for branding initiatives and advertising increased by $2.7 million; technology expense increased by $0.9 million and professional fees increased by $0.7 million. These costs were partially offset by reductions in travel-related costs of $2.4 million due to reductions in spending in response to COVID-19.

General and administrative

The increase in general and administrative expense of $25.6 million for the nine months ended September 30, 2020 compared to the same period in 2019 was due primarily to the growth of the business and the effect of our business acquisitions and principally consisted of the following elements: personnel-related costs increased by $18.5 million principally due to increased headcount; legal and accounting services increased by $8.3 million which was primarily due to increased acquisition-related transaction costs incurred in 2020 related to Diploid, Genelex, YouScript and ArcherDX; a $4.4 million increase in fair value adjustments to our contingent consideration obligations; information technology costs increased by $1.6 million due to software licenses and related expenses; professional fees increased by $1.2 million; occupancy costs increased by $0.7 million and depreciation and amortization expense increased by $0.6 million.

These cost increases were partially offset by a decrease in post-combination expense related to our acquisitions of $5.5 million and an increase of $5.2 million in allocations of technology and facilities-related expenses to other functional areas.

Other expense, net

The increase in other expense, net of $26.9 million for the nine months ended September 30, 2020 compared to the same period in 2019 was due principally to fair value adjustments related to our stock payable liabilities of $37.9 million due to the increase in the price of our common stock partially offset by a reduction of debt extinguishment costs of $8.9 million incurred in September 2019 with no similar expense in the current period and by $3.8 million received under the CARES Act during the current year period.

Interest expense

The increase in interest expense of $10.2 million for the nine months ended September 30, 2020 compared to the same period in 2019 was due principally to increased debt outstanding as compared to the prior year period.

Income tax benefit

The decrease in income tax benefit of $10.1 million was due to the net deferred tax liabilities assumed in connection with our acquisition of YouScript of $2.6 million in April 2020 as compared to $12.7 million assumed in our acquisition of Singular Bio in June 2019 and Jungla in July 2019.

Liquidity and capital resources

Liquidity and capital expenditures

We have incurred net losses since our inception. For the nine months ended September 30, 2020 and 2019, we had net losses of $367.8 million and $165.1 million, respectively, and we expect to incur additional losses in the future. At September 30, 2020, we had an accumulated deficit of $1.1 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 March 2019, we issued, in an underwritten public offering, an aggregate of 10.4 million shares of our common stock at a price of $19.00 per share, for gross proceeds of $196.7 million and net proceeds of $184.5 million. During 2019, we issued 0.8 million shares of common stock at an average price of $25.71 per share in "at the market" offerings for aggregate proceeds of $20.2 million and net proceeds of $19.5 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 approximately $173.0 million. In June 2020, we issued approximately 2.6 million shares of common stock at an average price of $17.59 per share in an "at the market" offering for aggregate proceeds of $46.0 million and net proceeds of $44.5 million.

In September 2019, we issued $350.0 of aggregate principal amount of Convertible Senior Notes 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 to settle a note purchase agreement we entered into in November 2018.

In October 2020 in connection with the merger with ArcherDX, we issued $275.0 million of our common stock in a private placement at a price of $16.85 per share to a syndicate of life sciences investors. We also entered into a credit facility to borrow $135.0 million. The private placement and credit facility closed concurrently with the merger in October 2020. In connection with the credit facility, we issued warrants to purchase 1.0 million shares of our common stock at an exercise price of $16.85 per share which were exercised in October 2020. In addition, the terms of this credit facility restrict our ability to incur certain indebtedness.

At September 30, 2020 and December 31, 2019, we had $368.0 million and $398.0 million, respectively, of cash, cash equivalents, restricted cash and marketable securities.

Our primary uses of cash are to fund our operations as we continue to grow our business, enter into partnerships and potentially to acquire businesses and technologies. Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We have incurred substantial losses since inception, and we expect to continue to incur losses in the future. We believe our existing cash, cash equivalents and marketable securities as of September 30, 2020 and fees collected from the sale of our tests will be sufficient to meet our anticipated cash requirements for the foreseeable future.

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

	Nine Months Ended September 30,	
	2020	2019
Cash used in operating activities	$ (184,920)	$ (97,787)
Cash used in investing activities	(88,291)	(9,612)
Cash provided by financing activities	228,760	462,430
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (44,451)	$ 355,031

Cash flows from operating activities

For the nine months ended September 30, 2020, cash used in operating activities of $184.9 million principally resulted from our net loss of $367.8 million and a $2.6 million income tax benefit generated from our acquisition of YouScript, partially offset by non-cash charges of $102.3 million for stock-based compensation, remeasurements of liabilities in connection with business combinations of $42.4 million, $23.0 million for depreciation and amortization and $11.1 million for amortization of debt discount and issuance costs related to our Convertible Senior Notes. The net effect on cash of changes in net operating assets was an increase of cash of $7.2 million.

For the nine months ended September 30, 2019, cash used in operating activities of $97.8 million principally resulted from our net loss of $165.1 million, partially offset by non-cash charges of $47.8 million for stock-based compensation, $12.7 million related to our income tax benefit generated from business combinations, $11.1 million for depreciation and amortization, and $8.9 million for debt extinguishment costs related to the settlement of our 2018 note purchase agreement. The net effect on cash of changes in net operating assets was an increase of cash of $10.3 million.

Cash flows from investing activities

For the nine months ended September 30, 2020, cash used in investing activities of $88.3 million was due to net cash used to acquire Diploid, Genelex and YouScript of $57.6 million, net purchases of marketable securities of $14.7 million and cash used for purchases of property and equipment of $14.0 million.

For the nine months ended September 30, 2019, cash used in investing activities of $9.6 million was due to net maturities of marketable securities of $13.7 million partially offset by cash used for purchases of property and equipment of $13.5 million and net cash used to acquire Singular Bio and Jungla of $9.8 million.

Cash flows from financing activities

For the nine months ended September 30, 2020, cash provided by financing activities of $228.8 million consisted of net proceeds from the public offerings of common stock of $217.5 million, cash received from issuances of common stock of $9.1 million, partially offset by finance lease principal payments of $1.5 million.

For the nine months ended September 30, 2019, cash provided by financing activities of $462.4 million consisted of net proceeds from the issuance of Convertible Senior Notes of $339.9 million, net proceeds from the public offering of common stock of $204.0 million and cash received from issuances of common stock totaling $5.7 million, including cash received from exercises of stock options of $3.0 million and employee stock purchase plan purchases of $2.6 million. These cash inflows were partially offset by payments related to the settlement of our note purchase agreement through repayment of loan obligations of $75.0 million and payment of debt extinguishment costs of $10.6 million, as well as finance lease payments of $1.6 million.

Contractual obligations

The following table summarizes our contractual obligations, including interest, as of September 30, 2020 (in thousands):

Contractual obligations:	Remainder of 2020	2021 and 2022	2023 and 2024	2025 and beyond	Total
Operating leases	$ 1,991	$ 23,760	$ 22,221	$ 19,698	$ 67,670
Finance leases	459	2,368	436	—	3,263
Convertible Senior Notes	—	—	350,000	—	350,000
Purchase commitments	1,164	4,771	1,619	108	7,662
Total	$ 3,614	$ 30,899	$ 374,276	$ 19,806	$ 428,595

See Note 8, "Commitments and contingencies" in the Notes to Condensed Consolidated Financial Statements for additional details regarding our leases, Convertible Senior Notes 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 the Notes to Condensed Consolidated Financial Statements included elsewhere in this 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 3. 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 $368.0 million at September 30, 2020, and consisted 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 September 30, 2020, 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 portfolio of marketable securities. Fluctuations in the value of our cash equivalents and portfolio of 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 only if we sell the underlying securities prior to maturity or declines in fair value are determined to be other-than-temporary.

Although our Convertible Senior Notes are based on a fixed rate, changes in interest rates could impact their fair market value. As of September 30, 2020, the fair market value of the Convertible Senior Notes was $579.3 million. For additional information about the Convertible Senior Notes, see Note 8, “Commitments and contingencies” in Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report.

ITEM 4. Controls and Procedures.

(a) 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 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 Quarterly Report on Form 10-Q, 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.

(b) Changes in internal control over financial reporting

During the quarterly period covered by this Quarterly Report on Form 10-Q, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — Other Information

ITEM 1. Legal Proceedings.

Other than as listed below, we are not a party to any material legal proceedings on the date of this report. We cannot currently predict the outcome of these actions. We are and may from time to time become involved in various legal proceedings and claims arising in the ordinary course of business. 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.

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. The litigations have now been consolidated for all purposes, are ongoing, and trial has been scheduled for May 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. This litigation is ongoing, and trial is currently scheduled for August 2021.

ITEM 1A. Risk Factors.

Risks related to our business and strategy

We face risks related to health epidemics, including the recent 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 recent pandemic of respiratory illness caused by a novel coronavirus known as COVID-19. Global health concerns relating to COVID-19 have negatively affected the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty.

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

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

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

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

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

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 nine months ended September 30, 2020, our net loss was $367.8 million. For the years ended December 31, 2019, 2018 and 2017, our net losses were $242.0 million, $129.4 million and $123.4 million, respectively. At September 30, 2020, our accumulated deficit was $1.1 billion. While our revenue has increased over time, we expect to continue to incur significant losses as we invest in our business. We incurred research and development expenses of $141.5 million, $63.5 million and $46.5 million in 2019, 2018, and 2017, respectively, and selling and marketing expenses of $122.2 million, $74.4 million, and $53.4 million in 2019, 2018, and 2017, respectively. We expect these losses may increase as we focus on scaling our business and operations and expanding our testing capabilities, which may also increase our operating expenses, and we may face decreases in test volume due to the impact of COVID-19. In addition, as a result of the integration of acquired businesses, we may be subject to unforeseen or additional expenditures, costs or liabilities. 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; accordingly, we have a relatively limited operating history upon which you can evaluate our business and prospects. Our limited commercial history makes it difficult to evaluate our current business and makes predictions about our future results, prospects or viability subject to significant uncertainty. Our prospects must be considered in light of the risks and difficulties frequently encountered by companies in their early 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; implement and successfully execute our business and marketing strategy; identify, acquire and successfully integrate companies, assets or technologies in areas that are complementary to our business strategy; successfully enter into other strategic collaborations or relationships; obtain access to capital on acceptable terms and effectively utilize that capital; identify, attract, hire, retain, motivate and successfully integrate additional employees; continue to expand, automate and upgrade our laboratory, technology and data systems; obtain, maintain and expand coverage and reimbursement by healthcare payers; provide rapid test turnaround times with accurate results at low prices; provide superior customer service; and respond to competitive developments. We cannot assure you that we will be successful in addressing these risks, and the failure to do so could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

We expect capital expenditures and operating expenses to increase over the next several years as we expand our infrastructure, commercial operations, research and development and selling and marketing activities and pursue and integrate acquisitions. We believe our existing cash and cash equivalents as of September 30, 2020 and revenue from sales of our tests will be sufficient to meet our anticipated cash requirements for our currently-planned operations for the foreseeable future. We may 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 term loan agreement restrict our ability to incur certain indebtedness. 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 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 that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to tests we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, selling and marketing initiatives, or potential acquisitions. In addition, we may have to work with a partner on one or more aspects of our tests or market development programs, which could lower the economic value of those tests or programs to our company.

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

As part of our business strategy, we have pursued and expect to continue to pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies.

In 2017, we established a leading position in family health genetic information services through the strategic acquisition of reproductive health testing capabilities, which included our acquisition of Good Start Genetics, Inc., or Good Start, a molecular diagnostics company focused on preimplantation and carrier screening for inherited disorders, and CombiMatrix Corporation, a company specializing in prenatal diagnosis, miscarriage analysis and pediatric developmental disorders. In 2017 we also acquired AltaVoice, formerly PatientCrossroads, a patient-centered data company with a global platform for collecting, curating, coordinating and delivering safeguarded data from patients and clinicians, and Ommdom, Inc. and its product, CancerGene Connect, an end-to-end platform for collecting and managing genetic family histories to deliver personalized genetic risk information.

In 2019, we acquired Singular Bio, Inc., to assist in lowering the costs of our NIPS offering, and we acquired Jungla Inc. to further enhance our genetic variant interpretation and the quality of results we deliver. In 2019 we also acquired Clear Genetics, Inc. to expand our ability to scale and deliver genetic information. In 2020, we acquired Orbicule BV operating under the name "Diploid" to enable us to quickly diagnose genetic disorders using artificial intelligence, as well as Genelex Solutions, LLC and YouScript Incorporated to bring pharmacogenetic testing and integrated clinical decision support to our offerings. In order to expand content and increase access to personalized oncology, in October 2020 we acquired ArcherDX, with a view towards integrating Invitae's germline testing with ArcherDX's tumor profiling and liquid biopsy technology and services into a single platform to enable precision medicine approaches from diagnostic testing to therapy optimization and monitoring.

With respect to our acquired businesses and any acquisitions we may make in the future, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Furthermore, as we experienced in the past, the loss of customers, payers, partners or suppliers following the completion of any acquisitions by us could harm our business. Changes in services, sources of revenue, and branding or rebranding initiatives may involve substantial costs and may not be favorably received by customers, resulting in an adverse impact on our financial results, financial condition and stock price. Integration of an acquired company or business also may require management's time and resources that otherwise would be available for ongoing development of our existing business. We may also need to divert cash from other uses in order 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.

To finance any acquisitions or investments, we may raise additional funds. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. 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 share price. Alternatively, we may raise additional funds for our acquisition activities through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

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

Our ability to increase the number of billable tests and our revenue will depend on our success achieving reimbursement for our tests from third-party payers. Reimbursement by a payer may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary, cost-effective and has received prior authorization.

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 tests from most of the large commercial third-party payers in the United States, and the Centers for Medicare and 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 market. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.

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

- dozens of relatively specialized competitors focused on genetics applied to healthcare, such as Ambry Genetics, a subsidiary of Konica Minolta Inc.; Athena Diagnostics and Blueprint Genetics, subsidiaries of Quest Diagnostics Incorporated; Baylor-Miraca Genetics Laboratories; Caris Life Sciences, Inc.; Centogene AG; Connective Tissue Gene Test LLC, a subsidiary of Health Network Laboratories, L.P.; Cooper Surgical, Inc.; Emory Genetics Laboratory, a subsidiary of Eurofins Scientific; Foundation

Medicine, a subsidiary of Roche Holding AG; Fulgent Genetics, Inc., Guardant Health, Inc.; GeneDx, a subsidiary of OPKO Health, Inc.; Integrated Genetics, Sequenom Inc., Correlagen, and MNG Laboratories, subsidiaries of Laboratory Corporation of America Holdings; Myriad Genetics, Inc.; Natera, Inc.; Perkin Elmer, Inc.; PreventionGenetics, LLC; Progenity, Inc.; and Sema4 Genomics;

- a few large, established general testing companies with large market share and significant channel power, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated;
- a large number of clinical laboratories in an academic or healthcare provider setting that perform clinical genetic testing on behalf of their affiliated institutions and often sell and market more broadly; and
- a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness including Illumina, Inc., which is also one of our suppliers.

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

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

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

We also face competition as a result of our recently completed acquisition of ArcherDX. In particular, ArcherDX competes with numerous companies in the life sciences research, clinical diagnostics and drug development spaces, including, among others, Natera, QIAGEN N.V., Guardant Health, Inc., Thermo Fisher, Inc., Foundation Medicine, Caris Life Sciences, Inc., Tempus, Laboratory Corporation of America, Quest Diagnostics, Inc., NeoGenomics, Inc., BioReference Laboratories, Inc. and Illumina, Inc.

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 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. In addition, some of our competitors have obtained approval or clearance for certain of their tests from the U.S. Food and Drug Administration, or FDA. If payers decide to reimburse only for tests that are FDA-approved or FDA-cleared, or if they are more likely to reimburse for such tests, we may not be able to compete effectively unless we obtain similar approval or clearance for our tests. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

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

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

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

In the ordinary course of our business, we collect and store sensitive data, including protected health information, or PHI, personally identifiable 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 sensitive patient data through our various customer tools and platforms. In addition to storing and transmitting sensitive personal information that is subject to myriad 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 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.

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 to protect sensitive information from unauthorized access or disclosure, 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, ArcherDX has been subject to phishing incidents and we may experience additional incidents in the future. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, altered, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could

result in legal claims or proceedings, liability under federal or state laws that protect the privacy of personal information, such as but not limited to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Health Information Technology for Economic and Clinical Heath Act, or HITECH, state data security and data breach notification laws, and related regulatory penalties. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, our various customer tools and platforms are currently accessible through our online portal and/or through our mobile applications, and there is no guarantee we can protect our online portal or our mobile applications from breach. Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business) and damage our reputation, any of which could adversely affect our business.

In addition to security risks, we also face privacy risks. While we have policies that govern our privacy practices and procedures that aim to keep our practices consistent with such policies, such procedures are not invulnerable to human error. Should we inadvertently break the privacy promises we make to patients or consumers, we could receive a complaint from an affected individual or interested privacy regulator, such as the Federal Trade Commission, or FTC, or a state Attorney General. This risk is heightened given the sensitivity of the data we collect.

Penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include civil monetary penalties of up to $1.5 million per calendar year for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. Penalties for unfair or deceptive acts or practices under the FTC Act or state Unfair and Deceptive Acts and Practices, or UDAP, statutes may also vary significantly.

There has been unprecedented activity in the development of data protection regulation around the world. As a result, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. The European Union's General Data Protection Regulation, or GDPR, took effect in May 2018. The GDPR applies to any business, regardless of its location, that provides goods or services to residents in the European Union. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects residing in the European Union. The GDPR also grants individuals various rights in relation to their personal data including the right to access, rectification, objection to processing and deletion, and 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 and the related national data protection laws of the member states of the European Union, which may deviate slightly from the GDPR, may result in significant fines.

Additionally, the implementation of GDPR has led other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, on June 28, 2018, California adopted the California Consumer Privacy Act of 2018, or CCPA. California amended the law in September 2018 to exempt all PHI collected by certain parties subject to HIPAA, and further amended the law in September 2020 to clarify that de-identified data as defined under HIPAA will also be exempt from the CCPA. The CCPA regulations were finalized and approved as of August 14, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation.

It is possible the GDPR, CCPA and other 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 regulations may differ from country to country and state to state, and may vary based on whether testing is performed in the United States or in the local country. 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 security

requirements in all of the jurisdictions in which we do business. Failure to comply with privacy and security requirements could result in civil or criminal penalties, which could have a material adverse effect on 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.

Our performance, including our research and development programs and laboratory operations, largely depend on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization, including software developers, geneticists, biostatisticians, certified laboratory scientists and other scientific and technical personnel to process and interpret our genetic tests. In addition, we may need to continue to expand our sales force with qualified and experienced personnel. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future due to the competition for qualified personnel among life science and technology businesses as well as universities and public and private research institutions, particularly in the San Francisco Bay Area. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees. If 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, support our research and development efforts and our clinical laboratory. We believe that our corporate culture fosters innovation, creativity and teamwork. However, as our organization grows, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

We need to scale our infrastructure in advance of demand for our tests, and our failure to generate sufficient demand for our tests 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 provide customers with high-quality test reports quickly and at a lower price than our competitors, and to achieve sufficient test volume to realize economies of scale. In order to execute our business model, we intend to continue to invest heavily in order to significantly scale our infrastructure, including our testing capacity and information systems, expand our commercial operations, customer service, billing and systems processes and enhance our internal quality assurance program. We expect that much of this growth will be in advance of demand for our tests. Our current and future expense levels are to a large extent fixed and are largely based on our investment plans and our estimates of future revenue. Because the timing and amount of revenue from our tests 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 tests 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.

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

Our business model assumes that we will be able to generate significant test volume, and we may not succeed in continuing to drive adoption of our tests to achieve sufficient volumes. Inasmuch as detailed genetic data from broad-based testing panels such as our tests have only recently become available at relatively affordable prices, the continued pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic testing that is specific to one or a few genes. Given the substantial amount of additional information available from a broad-based testing panel such as ours, there may be distrust as to the reliability of such information when compared with more limited and focused genetic tests. To generate further demand for our tests, we will need to continue to make clinicians aware of the benefits of our tests, including the price, the breadth of our testing options, and the benefits of having additional genetic data available from which to make treatment decisions. Because broad-based testing panels are relatively new, it may be more difficult or take more time for us to expand clinical adoption beyond our current customer base. In addition, clinicians in other areas of medicine may not adopt genetic testing for hereditary disease as readily as it has been adopted in hereditary cancer and our efforts to sell our tests to clinicians outside of oncology may not be successful. 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 is 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.

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 the past, we have increased our sales force each year in order to drive our growth. In addition to the efforts of our sales force, future sales will depend in large part on our ability to develop and substantially expand awareness of our company and our tests through alternative strategies including through education of key opinion leaders, through social media-related and online outreach, education and marketing efforts, and through focused channel partner strategies designed to drive demand for our tests. We also plan to continue to spend on consumer advertising in connection with our direct channel to consumers, which could be costly. We have limited experience implementing these types of marketing efforts. We may not be able to drive sufficient levels of revenue using these sales and marketing methods and strategies necessary to support our planned growth, and our failure to do so could limit our revenue and potential profitability.

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

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

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

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

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

We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot assure you that we will be able to secure alternative equipment, reagents and other materials, and bring such equipment, reagents and materials on line 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.

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

We perform all of our tests at our production facilities in San Francisco and Irvine, California, in Golden, Colorado and in Seattle, Washington. 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 by natural or man-made disasters, including earthquakes, 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 substantial 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. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

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

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

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

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

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

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

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

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

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 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.

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 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.

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, including the recent and ongoing outbreak and spreading of Coronavirus, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; 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 September 30, 2020, our total gross deferred tax assets were $204.5 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Furthermore, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with completed acquisitions, or other future transactions in our stock, our ability to utilize NOLs and tax credit carryovers could be further limited by Section 382 of the Internal Revenue Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss and tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. In addition, the Tax Cuts and Jobs Act limits the deduction for NOLs to 80% of current year taxable income and eliminates NOL carrybacks. Also, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks related to government regulation

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

We provide our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by the Clinical Laboratory Improvement Amendments of 1988, or 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 systems 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. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. Subsequently, on January 13, 2017, the FDA published a "discussion paper" in which it outlined a substantially revised "possible approach" to the oversight of LDTs. In December 2018, a draft bill titled the "Verifying Accurate Leading-edge IVCT Development Act of 2018," or VALID Act, was released for discussion. The draft bill proposes a risk-based approach to regulate LDTs and creates a new in vitro clinical test, or IVCT, category of regulated products, which includes LDTs, and a regulatory structure under the FDA. As proposed, the draft bill grandfathers many existing tests from the proposed premarket approval, quality systems, and labeling requirements, respectively, but would require such tests to comply with other regulatory requirements (e.g., registration and notification, adverse event reporting). We cannot predict if this draft bill will be enacted in its current (or any other) form and cannot quantify the effect of this draft bill on our business.

In March 2020, a bill titled the "Verifying Accurate Leading-edge IVCT Development Act of 2020," or VALID Act, was officially introduced in Congress. The bill proposes a risk-based approach to regulate LDTs and creates a new in vitro clinical test, or IVCT, category of regulated products, which includes LDTs, and a regulatory structure under the FDA. As proposed, the bill grandfathers many existing tests from the proposed premarket approval, quality systems, and labeling requirements, respectively, but would require such tests to comply with other regulatory requirements (e.g., registration and listing, adverse event reporting). Later that month, Senator Paul introduced the Verified Innovative Testing in American Laboratories Act of 2020, or VITAL Act, which proposes that all aspects of "laboratory-developed testing procedures" be subject to regulation under CLIA, and that no aspects of such procedures be subject to regulation by the FDA. We cannot predict if either of these bills will be enacted in their current (or any other) form and cannot quantify the effect of these bills on our business.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals may 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.

In April 2020, we completed our acquisition of Genelex Solutions, LLC, which offers certain pharmacogenetic, or PGx, tests as LDTs. Recently the FDA has taken a more active role in the oversight of PGx tests offered as LDTs. In 2019, the FDA contacted several clinical laboratories, including Genelex, to demand changes to PGx test reports and marketing materials. In February 2020, the FDA issued a statement indicating that it continues to have concerns about the claims that certain clinical laboratories make with respect to their PGx tests, and published tables that list PGx associations for which FDA has determined that the data support therapeutic management recommendations, a potential impact on safety or response, or a potential impact on pharmacokinetic properties only, respectively. To date, however, the FDA has not provided any general guidance on the type(s) of claims or other characteristics that will cause a PGx test to fall outside FDA's enforcement discretion. As such, the extent to which FDA will allow any laboratory, including Genelex or Invitae, to offer PGx tests in their current form without meeting FDA regulatory requirements for medical devices is unclear at this time.

If the FDA ultimately regulates certain LDTs (either as medical devices or as part of a new stand-alone regulatory category for IVCTs), whether via individualized enforcement action, or 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.

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

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

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

We are also required to maintain licenses to conduct testing in California and Washington. California and Washington laws establish standards for day-to-day operation of our clinical reference laboratories in San Francisco and Irvine, and in Seattle, respectively, which include the training and skills required of personnel and quality control. We also maintain out-of-state laboratory licenses to conduct testing on specimens from Maryland, New York, Pennsylvania and Rhode Island, and with respect to our laboratory in Washington, on specimens from California.

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

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, and cancellation of the laboratory's approval to receive Medicare and Medicaid payment for its services, 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, which establishes comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions;

- amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators and expand vicarious liability, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- the 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, 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 prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing clinicians for testing that they order; waiving coinsurance, copayments, deductibles and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payers; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

We have adopted policies and procedures designed to comply with these laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance may also be subject to governmental review. The growth of our business and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these 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 administrative, civil and criminal penalties, damages, fines, individual imprisonment, exclusion from participation in Federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

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

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

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA (as amended by the Further Consolidated Appropriations Act, 2020 and the Coronavirus Aid, Relief, and Economic Security Act, respectively) and its implementing regulations, clinical laboratories must report to CMS private payer rates beginning in 2017, and then in 2022 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 believe that our tests meet the definition of advanced diagnostic laboratory tests, but in the event that we seek designation for one or more of our tests as an advanced diagnostic laboratory test and the tests are determined by CMS to meet these criteria or new criteria developed by CMS, we would be required to report private payer data for those tests annually. Otherwise, we will be required to report private payer rates for our tests on an every three years basis starting in 2022. Laboratories that fail to timely report the required payment information may be subject to substantial civil money penalties.

As set forth in the PAMA final rule, for tests furnished on or after January 1, 2018, Medicare payments for clinical diagnostic laboratory tests are 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. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test. The payment rates calculated under PAMA went into effect starting January 1, 2018. Where applicable, reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2018 through 2020. Rates will be held at 2020 levels during 2021, and then, where applicable based upon median private payer rates reported in 2017 or 2022, reduced by up to 15% per test per year in each of 2022 through 2024 (with a second round of private payer rate reporting in 2022 to establish rates for 2023 through 2025).

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 CPT® Editorial Panel approved a proposal to create a new section of billing codes to facilitate implementation of this section of PAMA, but these codes would apply to our tests only if we apply for such codes.

In March 2018, CMS published a national coverage determination, or NCD, for next generation sequencing, or NGS tests for somatic (acquired) cancer testing. CMS subsequently updated this NCD in January 2020 to address coverage for NGS tests for germline (inherited) cancer testing and to clarify certain aspects of Medicare's coverage of NGS for somatic cancer testing. For somatic cancer testing, the updated NCD establishes full coverage for FDA-approved or FDA-cleared NGS-based companion diagnostic assays that report results using report templates that specify treatment options when offered for their FDA-approved or FDA-cleared use(s), ordered by the patient's treating physician for Medicare beneficiaries with advanced cancer (recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer) who have not have previously been tested with the same test using NGS for the same cancer genetic content, and have decided to seek further cancer treatment. 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 nationally non-covered under the NCD.

Effective January 27, 2020, the NCD also established full coverage for FDA-approved or FDA-cleared NGS-based germline tests that report results using report templates that specify treatment options when ordered by the patient's treating physician for patients with ovarian or breast cancer, a clinical indication for germline testing for hereditary breast or ovarian cancer, and a risk factor for germline breast or ovarian cancer, provided the patient has not previously been tested with the same germline test using NGS for the same germline genetic content. The NCD also gives MACs the authority to establish local coverage for NGS-based germline tests for ovarian or breast cancer that are not FDA-approved or FDA-cleared, as well as for NGS-based tests for any other cancer diagnosis (regardless of the test's FDA regulatory status) when offered to patients meeting the above-referenced criteria for germline testing. Since we already have local coverage for our germline tests for ovarian and breast cancer, we believe that the NCD will not have a material impact on which of our tests will be reimbursable by CMS for Medicare patients.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. For instance, the payment reductions imposed by the Affordable Care Act and the expansion of the federal and state governments' role in the U.S. healthcare industry as well as changes to the reimbursement amounts paid by payers for our tests and future tests or our medical procedure volumes may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Notably, Congress enacted legislation in 2017 that eliminated the Affordable Care Act's "individual mandate" beginning in 2019, which may significantly impact the number of covered lives participating in exchange plans. Moreover, 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 Cambridge, Massachusetts; however, we could be held liable for any damages resulting from our prior use of hazardous chemicals and biological materials at this facility. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

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

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

Risks related to our intellectual property

Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation may 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. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. We may be unaware of patents that a third party, including for example a competitor in the genetic testing market, might assert are infringed by our business. There may also be patent applications that, if issued as patents, could be asserted against us. Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales of any tests or other activities that are the subject of such suit. Defense of these claims, regardless of merit, could cause us to incur substantial expenses and be a substantial diversion of our employee resources. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our business and stock price. In the event of a successful claim of infringement against us by a third party, we may have to (1) pay substantial damages, possibly including treble damages and attorneys' fees if we are found to have willfully infringed patents; (2) obtain one or more licenses, which may not be available on commercially reasonable terms (if at all); (3) pay royalties; and/or (4) redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure, all of which could have a material adverse impact on our cash position and business and financial condition.

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

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

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

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

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

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

We expect to rely primarily upon trade secrets and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how or other confidential information. Among other things, we seek to protect our trade secrets and confidential information by entering into confidentiality agreements with employees and consultants. There can be no assurance that any confidentiality agreements that we have with our employees and consultants will provide meaningful protection for our trade secrets and confidential information or will provide adequate remedies in the event of unauthorized use or disclosure of such information. Accordingly, there also can be no assurance that our trade secrets will not otherwise become known or be independently developed by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

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

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

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

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

Risks related to being a public company

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

As a public company, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the 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. We need to maintain and enhance these processes and controls as we grow and we have required, and may continue to require, additional personnel and resources to do so.

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

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

Risks related to our Convertible Senior Notes

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

In September 2019, we issued $350.0 million aggregate principal amount of our 2.00% Convertible Senior Notes due 2024 in a private placement.

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

We may not have the ability to raise the funds necessary to settle conversions of the Convertible Senior Notes in cash or to repurchase the notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the notes.

Holders of the 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 in respect of the notes being converted. However, 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 indenture or to pay any cash payable on future conversions of the notes as required by the indenture would constitute a default under the indenture. A default under the indenture or the occurrence of the fundamental change itself could also lead to a default under 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 repurchase the notes or make cash payments upon conversions thereof.

The conditional conversion feature of the Convertible Senior Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the notes is triggered, holders of 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.

The accounting method for convertible debt securities that may be settled in cash, such as the notes, could have a material effect on our reported financial results.

In May 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)*, which has subsequently been codified as Accounting Standards Codification 470-20, *Debt with Conversion and Other Options*, or ASC 470-20. Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet at issuance, and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the notes to their face amount over the term of the notes. We will report larger net losses or lower net income in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's non-convertible coupon interest rate, which could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the notes.

In addition, under certain circumstances, convertible debt instruments (such as the notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the notes are not included in the calculation of diluted net income (loss) per share except to the extent that the conversion value of the notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable or otherwise elect not to use the treasury stock method in accounting for the shares issuable upon conversion of the notes, then our diluted earnings per share would be adversely affected. For example, the FASB recently published an exposure draft proposing to amend these accounting standards to eliminate the treasury stock method for convertible instruments and instead require application of the ''if-converted'' method. Under that method, if it is adopted, diluted net income (loss) per share would generally be calculated assuming that all the notes were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. The application of the ''if-converted'' method may reduce our reported diluted net income (or further increase our diluted net loss, as the case may be) per share.

Risks related to our common stock

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

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

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

- changes in reimbursement by current or potential payers;
- general economic and market conditions; and
- issuances of significant amounts of our common stock.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, including COVID-19, 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.

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. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. In addition, the sale of substantial amounts of our common stock could adversely impact its price. As of September 30, 2020, we had outstanding approximately 133.3 million shares of our common stock, options to purchase approximately 3.3 million shares of our common stock (of which approximately 2.8 million were exercisable as of that date), outstanding restricted stock units representing approximately 6.9 million shares of our common stock (which includes an estimated number of Time-based RSUs and PRSUs granted in connection with our acquisition of Singular Bio), outstanding Series A convertible preferred stock convertible into approximately 0.1 million shares of our common stock and warrants to purchase 0.3 million shares of our common stock. The foregoing does not include approximately 26.3 million additional shares and options to purchase 3.7 million shares issued on October 2, 2020 in connection with our acquisition of ArcherDX, 16.3 million shares of common stock issued on October 2, 2020 in a private placement pursuant to the Securities Purchase Agreement entered into in connection with our merger with ArcherDX, and 666,872 shares issued in October 2020 in connection with the exercise of a warrant issued in connection with our senior secured term loan facility entered into in connection with the merger with ArcherDX. The foregoing also does not include approximately 1.6 million shares that may be issuable in connection with indemnification hold-backs and contingent consideration related to our acquisitions other than ArcherDX, up to 27.0 million shares which may be issuable upon the achievement of certain milestones related to the merger with ArcherDX, inducement awards to be issued in connection with our acquisition of Diploid, or shares that may be issuable in the future in connection with the Convertible Senior Notes or the conversion of our Series A preferred stock, or upon the exercise of options or vesting of restricted stock units. In addition, up to $47.7 million of our common stock was available for sale as of September 30, 2020 pursuant to our "at the market" sales agreement. The shares issued in connection with our acquisition of ArcherDX are subject to a lock-up restriction until December 17, 2020, after which many of the shares will be freely tradable, with sales of the remainder subject to certain volume limitations until January 2, 2021. The sale or the availability for sale of a large number of shares of our common stock in the public market, including in connection with the expiration of lockup restrictions, could cause the price of our common stock to decline.

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. 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 chairman 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 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 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.

Certain Additional Risks Related to ArcherDX's Business

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

A significant portion of ArcherDX's commercial strategy, including for STRATAFIDE and PCM, relies on receiving regulatory approvals with guideline inclusion to strengthen its position in establishing coverage and

reimbursement of its IVD products with both public and private payers. If ArcherDX does not receive such regulatory approvals in a timely manner or at all, or ArcherDX is not successful in receiving such guideline inclusion, it may not be able to commercialize its IVD products. Additionally, third-party payers may be unwilling to provide sufficient coverage and reimbursement for ArcherDX's products necessary for hospitals and other healthcare providers to adopt ArcherDX solutions as part of their oncological treatment strategy. ArcherDX has also focused its efforts on the development of PCM for U.S. Food and Drug Administration, or FDA, clearance and approval as a prognostic device for predicting recurrence of a primary cancer after initial treatment, which can include surgery alone or surgery plus adjuvant therapy.

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

ArcherDX's revenues have been primarily generated by sales of its research use only, or RUO, products, but ArcherDX's future business growth is partially dependent upon regulatory approval and market acceptance of its IVD products, including STRATAFIDE and PCM.

Historically, ArcherDX's revenues and growth have been driven primarily by sales of its RUO products, but it anticipates that its future success will depend in large part on ArcherDX's ability to effectively introduce enhanced or new offerings of oncological in IVD products, such as STRATAFIDE. The development and launch of enhanced or new products and services, whether RUO or IVD, require the completion of certain clinical development and commercialization activities that are complex, costly, time-intensive and uncertain, and require ArcherDX to accurately anticipate patients', providers' and, if applicable, payers' attitudes and needs and emerging technology and industry trends. This process is conducted in various stages, and each stage presents the risk that ArcherDX will not achieve its goals on a timely basis, or at all.

ArcherDX has limited experience commercializing IVD products. As a result, ArcherDX has limited experience forecasting future financial performance for its planned IVD products, including STRATAFIDE and PCM, and its actual results may fall below ArcherDX's financial guidance or other projections, or the expectations of analysts or investors, which could cause the value of its common stock to decline. ArcherDX may experience research and development, regulatory, marketing and other difficulties that could delay or prevent its introduction of enhanced or new products or new services and result in increased costs and the diversion of management's attention and resources from other business matters. For example, any genomic tests that ArcherDX may enhance or develop may not prove to be clinically effective, or may not meet its desired target product profile or be offered at acceptable cost and with the sensitivity, specificity and other test performance metrics necessary to address the relevant clinical need or commercial opportunity; ArcherDX's genomic test performance in commercial settings may be inconsistent with its validation or other clinical data; ArcherDX may not be successful in achieving market awareness and demand, whether through its own sales and marketing operations or entering into collaborative arrangements; the collaborative arrangements ArcherDX enters into may not be successful or it may not be able to maintain those that are successful; healthcare providers may not order or use, or third-party payers may not reimburse for, any genomic tests that ArcherDX may enhance or develop; ArcherDX may not be able to obtain approval of any of its existing or future devices as a companion diagnostic for existing treatments approved by the FDA; or ArcherDX may otherwise have to abandon a product or service in which it has invested substantial resources.

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

One of ArcherDX's competitors has alleged that its Anchored Multiplex PCR, or AMP, chemistry and products using AMP are infringing on its intellectual property, and ArcherDX 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 ArcherDX's business as well as our financial condition and results of operations, and the intended benefits of our merger with ArcherDX.

ArcherDX's AMP chemistry underlies all of its research use only products and is also the foundation of STRATAFIDE and Personalized Cancer Monitoring, or PCM. On January 27, 2020, one of ArcherDX's competitors, Natera, Inc., or Natera, filed a complaint against ArcherDX 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 April 15, 2020, Natera amended its complaint to allege 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, 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. 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, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,731,220 (together with U.S. Patent Nos. 10,538,814, 10,557,172, 10,590,482, and 10,597,708, the "Natera Asserted Patents.") Natera seeks, among other things, damages and other monetary relief, costs and attorneys' fees, and an order enjoining ArcherDX from further infringement of The Natera Asserted Patents. The litigations have now been consolidated for all purposes, are ongoing, and trial has been scheduled for May 2022.

If any of ArcherDX's products or ArcherDX's use of AMP chemistry is found to infringe any of the Natera Asserted Patents, it could be required to redesign its technology or obtain a license from Natera to continue developing, manufacturing, marketing, selling and commercializing AMP and its products. However, ArcherDX 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 ArcherDX 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 ArcherDX, and it could require ArcherDX to make substantial licensing, royalty and other payments. ArcherDX also could be forced, including by court order, to permanently cease developing, manufacturing, marketing and commercializing ArcherDX's products that are found to be infringing. In addition, ArcherDX could be found liable for significant monetary damages, including treble damages and attorneys' fees, if ArcherDX is found to have willfully infringed any of the Natera Asserted Patents. Even if ArcherDX 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 ArcherDX of any of the Natera Asserted Patents could have a material adverse effect on the business of ArcherDX and the benefits we expected to achieve through our merger with ArcherDX, as well as our financial condition and results of operations.

If ArcherDX's products and services do not perform as expected, we may not realize the expected benefits of the merger.

The success of ArcherDX's products depends on the market's confidence that it can provide reliable products that enable high quality diagnostic testing with high sensitivity and specificity and short turnaround times. There is no guarantee that the accuracy and reproducibility ArcherDX has demonstrated to date will continue as its product deliveries increase and its product portfolio expands.

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

In addition, ArcherDX's test reports for STRATAFIDE are planned to match identified mutations with FDA-approved targeted therapies or relevant clinical trials of targeted therapies, and in the case of its future companion diagnostic applications, ArcherDX's plan to include relevant companion diagnostic claims. If a patient or physician who orders a test using one of ArcherDX's products is unable to obtain, or be reimbursed for the use of, targeted

therapies because they are not indicated in the FDA-approved label for treatment, the patient is unable to enroll in an identified clinical trial due to the enrollment criteria of the trial, or some other reason, the ordering physician may conclude the test report does not contain actionable information. If physicians do not believe ArcherDX's products consistently generate actionable information about their patients' disease or condition, they may be less likely to use its products.

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

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

ArcherDX has sourced and will continue to source components of its technology, including sequencers, reagents, enzymes, tubes and other laboratory materials, from third parties. In particular, its sequencers and many of its reagents and enzymes are sole sourced.

For example, ArcherDX's planned STRATAFIDE and PCM products are currently being developed to use only Illumina's sequencing platform. Without access to these sequencers, ArcherDX would be unable to run its tests and commercialize its products. In addition, ArcherDX's product customers are required to use Illumina sequencers and reagents to run the tests that they develop based on ArcherDX's technology. ArcherDX's failure to maintain a continued supply of the sequencers and reagents, along with the right to use certain hardware and software, would adversely impact its business, financial condition, and results of operations. In particular, while ArcherDX is seeking to validate its tests on additional sequencing platforms, it has not, to date, validated any alternative sequencing platform on which its testing could be run in a commercially viable manner. These efforts will require significant resources, expenditures and time and attention of ArcherDX's management, and there is no guarantee that ArcherDX will be successful in implementing any such sequencing platforms in a commercially sustainable way. ArcherDX also cannot guarantee that it will appropriately prioritize or select alternative sequencing platforms on which to focus its efforts, in particular given ArcherDX's limited product and research and development resources and various business initiatives, which could result in increased costs and delayed timelines.

Because ArcherDX relies on third-party suppliers, it does not control the manufacture of the components of its technology, including whether such components will meet ArcherDX's quality control requirements, nor the ability of ArcherDX's suppliers to comply with applicable legal and regulatory requirements. In many cases, ArcherDX's suppliers are not contractually required to supply these components to the quality or performance standards that ArcherDX requires. If the supply of components ArcherDX receives does not meet its quality control or performance standards, it may not be able to use the components, or if it uses them not knowing that they are of inadequate quality, which occasionally occurs with respect to certain reagents, ArcherDX's tests may not work properly or at all, or they may provide erroneous results, and ArcherDX may be subject to significant delays caused by interruption in production or manufacturing or to lost revenue from such interruption or from spoiled tests. In addition, any natural or other disaster, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at ArcherDX's third-party manufacturers' facilities that cause a loss of manufacturing capacity would heighten the risks that ArcherDX faces.

In the event of any adverse developments with ArcherDX's suppliers, in particular for those products that are sole sourced, or if any of ArcherDX's suppliers modifies any of the components they supply to it, ArcherDX's ability to supply its products may be interrupted, and obtaining substitute components could be difficult or require ArcherDX to re-design or re-validate its products. In addition, if ArcherDX obtains FDA clearance, approval or authorization for any of its tests as an IVD, such issues with suppliers or the components that ArcherDX sources from suppliers could affect its commercialization efforts for such an IVD. ArcherDX's failure to maintain a continued supply of components that meets its quality control requirements, or changes to or termination of its agreements or inability to renew its agreements with these parties or enter into new agreements with other suppliers, particularly in the case of sole suppliers, could result in the loss of access to important components of ArcherDX's tests and impact ArcherDX's test performance or affect its ability to perform its tests in a timely manner or at all, which could impair, delay or suspend its commercialization activities.

Moreover, in the event that ArcherDX transitions to a new supplier from any of its sole suppliers, doing so could be time-consuming and expensive, may result in interruptions in ArcherDX's ability to supply its products to the market, could affect the performance of its tests or could require that ArcherDX re-validate its processes and its other tests using replacement equipment and supplies, which could hinder the adoption of ArcherDX's products and services, resulting in increased costs.

ArcherDX relies on third-party laboratories to perform portions of its service offerings.

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

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

ArcherDX's research and development efforts to add additional indications to its IVD products, if approved, will be hindered if ArcherDX is not able to contract with third parties for access to tissue samples.

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

ArcherDX may never obtain approval in any other foreign country, including Japan, for any of its products or services and, even if it does, ArcherDX or its collaborators may never be able to commercialize them in any other jurisdiction, which would limit ArcherDX's ability to realize their full market potential.

In order to eventually market any of ArcherDX's current or future products and services in any particular foreign jurisdiction, ArcherDX 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 ArcherDX's 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 ArcherDX and its 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 ArcherDX's 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. ArcherDX currently sells its RUO products outside the United States but has no experience in obtaining regulatory clearance, authorization or approval in international markets other than Japan, where ArcherDX has submitted a companion diagnostic device application to the Pharmaceuticals and Medical Devices Agency, or the PDMA. If ArcherDX or its 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, ArcherDX's target market will be reduced and its ability to realize the full market potential of its products and services will be unrealized.

If a clinical trial subject's informed consent is challenged or proven invalid, unlawful, or otherwise inadequate for ArcherDX's purposes, ArcherDX's product development efforts may be hindered and ArcherDX could become involved in legal challenges.

ArcherDX has implemented measures designed to ensure that all clinical data and genomic and other biological samples that it receives from its biopharmaceutical collaborators have been collected from subjects who have provided appropriate informed consent for purposes that extend to ArcherDX's product development activities. ArcherDX seeks to ensure such data and samples are provided to ArcherDX in a subject de-identified manner. ArcherDX also implemented measures in an effort to ensure that the subjects from whom the data and samples are collected do not have any proprietary or commercial rights to the data or any discoveries derived from them. ArcherDX's biopharmaceutical collaborators conduct clinical trials in a number of different countries. The collection of data and samples in many different countries results in complex legal questions regarding the adequacy of informed consent and the status of genomic material under a large number of different legal systems. Therefore, in addition to the measures ArcherDX has implemented, ArcherDX relies on its biopharmaceutical and contract laboratories to comply with the subject's informed consent and with applicable local law and international regulation. The subject's informed consent obtained in any particular country could be challenged in the future, and those informed consents could prove invalid, unlawful, or otherwise inadequate for ArcherDX's purposes. Any findings against ArcherDX, or its biopharmaceutical collaborators, could deny ArcherDX access to or force ArcherDX to stop using some of its clinical samples, which would hinder ArcherDX's molecular information product development efforts.

ITEM 6. Exhibits.

Exhibit Number	Description
10.1+	Support Agreement, dated as of September 23, 2020, by and among the Company and certain securityholders of ArcherDX, Inc. (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed October 5, 2020).
31.1	Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Principal Financial Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
32.2*	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
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.
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document).

+ Certain schedules and exhibits to this agreement have been omitted pursuant to Item 601(b) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

* 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 Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (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 registrant specifically incorporates it by reference.

SIGNATURES

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

INVITAE CORPORATION

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

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

By: /s/ Shelly D. Guyer

Shelly D. Guyer
Chief Financial Officer
Principal Financial Officer

Date: November 5, 2020

Exhibit 31.1

PRINCIPAL EXECUTIVE OFFICER'S CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sean E. George, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Invitae Corporation for the period ended September 30, 2020;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a—15(e) and 15d—15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 5, 2020

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

Sean E. George, Ph.D.

Chief Executive Officer and Director

(Principal Executive Officer)

Exhibit 31.2

PRINCIPAL FINANCIAL OFFICER'S CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Shelly D. Guyer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Invitae Corporation for the period ended September 30, 2020;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a—15(e) and 15d—15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 5, 2020

/s/ Shelly D. Guyer

Shelly D. Guyer

Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Invitae Corporation (the "Company") on Form 10-Q for the period ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 5, 2020

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

Sean E. George, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Invitae Corporation (the "Company") on Form 10-Q for the period ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 5, 2020

/s/ Shelly D. Guyer

Shelly D. Guyer
Chief Financial Officer
(Principal Financial Officer)