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 June 30, 2021

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

For the transition period from to

Commission File No. 001-36847

Invitae Corporation

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

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

1400 16th Street, San Francisco, California 94103

(Address of principal executive offices, Zip Code)

(415) 374-7782

(Registrant's telephone number, including area code)

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

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

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 July 30, 2021 was 217,339,666.

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PART I — Financial Information

ITEM 1. Condensed Consolidated Financial Statements.

INVITAE CORPORATION

Condensed Consolidated Balance Sheets

(in thousands)
(unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 1,107,745	$ 124,794
Marketable securities	422,473	229,186
Accounts receivable	55,714	47,722
Inventory	29,982	32,030
Prepaid expenses and other current assets	28,089	20,200
Total current assets	1,644,003	453,932
Property and equipment, net	82,760	66,102
Operating lease assets	120,844	45,109
Restricted cash	10,275	6,686
Intangible assets, net	1,057,389	981,845
Goodwill	2,060,889	1,863,623
Other assets	19,303	13,188
Total assets	$ 4,995,463	$ 3,430,485
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 31,244	$ 25,203
Accrued liabilities	88,045	86,058
Operating lease obligations	11,930	8,789
Finance lease obligations	2,422	1,695
Total current liabilities	133,641	121,745
Operating lease obligations, net of current portion	122,840	48,357
Finance lease obligations, net of current portion	3,540	3,123
Debt	108,920	104,449
Convertible senior notes, net	1,460,873	283,724
Deferred tax liability	50,998	51,538
Other long-term liabilities	460,666	841,256
Total liabilities	2,341,478	1,454,192
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock	20	19
Accumulated other comprehensive income	34	1
Additional paid-in capital	3,973,479	3,337,120
Accumulated deficit	(1,319,548)	(1,360,847)
Total stockholders' equity	2,653,985	1,976,293
Total liabilities and stockholders' equity	$ 4,995,463	$ 3,430,485

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Test revenue	$ 111,496	$ 45,099	$ 210,772	$ 108,177
Other revenue	4,816	1,092	9,161	2,262
Total revenue	116,312	46,191	219,933	110,439
Cost of revenue	89,331	42,952	164,822	83,374
Research and development	106,454	74,963	186,812	130,631
Selling and marketing	56,964	39,520	108,204	81,640
General and administrative	38,303	26,006	110,820	49,828
Change in fair value of contingent consideration	(303,349)	4,832	(366,970)	4,832
Income (loss) from operations	128,609	(142,082)	16,245	(239,866)
Other income (expense), net	2,024	(21,436)	6,489	(16,728)
Interest expense	(13,407)	(5,485)	(21,800)	(10,936)
Net income (loss) before taxes	117,226	(169,003)	934	(267,530)
Income tax benefit	(16,560)	(2,600)	(23,360)	(2,600)
Net income (loss)	$ 133,786	$ (166,403)	$ 24,294	$ (264,930)
Net income (loss) per share, basic	$ 0.66	$ (1.29)	$ 0.12	$ (2.35)
Net income (loss) per share, diluted	$ 0.53	$ (1.29)	$ 0.11	$ (2.35)
Shares used in computing net income (loss) per share, basic	204,110	129,023	199,083	112,765
Shares used in computing net income (loss) per share, diluted	264,921	129,023	216,595	112,765

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION

Condensed Consolidated Statements of Comprehensive Income (Loss)

(in thousands)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net income (loss)	$ 133,786	$ (166,403)	$ 24,294	$ (264,930)
Other comprehensive income (loss):				
Unrealized income (loss) on available-for-sale marketable securities, net of tax	(16)	(722)	33	581
Comprehensive income (loss)	$ 133,770	$ (167,125)	$ 24,327	$ (264,349)

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION

Condensed Consolidated Statements of Stockholders' Equity

(in thousands)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Common stock:				
Balance, beginning of period	$ 20	$ 10	$ 19	$ 10
Common stock issued	—	3	1	3
Balance, end of period	20	13	20	13
Accumulated other comprehensive income (loss):				
Balance, beginning of period	50	1,294	1	(9)
Unrealized income (loss) on available-for-sale marketable securities, net of tax	(16)	(722)	33	581
Balance, end of period	34	572	34	572
Additional paid-in capital:				
Balance, beginning of period	3,829,553	1,182,033	3,337,120	1,138,316
Common stock issued in connection with public offering, net	—	217,486	434,263	217,486
Common stock issued on exercise of stock options, net	1,192	1,026	2,952	2,171
Common stock issued pursuant to exercises of warrants	—	35	1,242	62
Common stock issued pursuant to employee stock purchase plan	7,974	4,527	7,974	4,527
Common stock issued or issuable pursuant to acquisitions	89,054	60,053	163,876	102,506
Stock-based compensation expense	45,706	22,057	101,540	32,536
Reclassification of equity component of convertible senior notes	—	—	(75,488)	—
Reclassification of stock payable liabilities	—	—	—	(10,387)
Balance, end of period	3,973,479	1,487,217	3,973,479	1,487,217
Accumulated deficit:				
Balance, beginning of period	(1,453,334)	(857,204)	(1,360,847)	(758,677)
Cumulative effect of adoption of ASU 2020-06	—	—	17,005	—
Net income (loss)	133,786	(166,403)	24,294	(264,930)
Balance, end of period	(1,319,548)	(1,023,607)	(1,319,548)	(1,023,607)
Total stockholders' equity	$ 2,653,985	$ 464,195	$ 2,653,985	$ 464,195

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION

Condensed Consolidated Statements of Cash Flows

(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net income (loss)	$ 24,294	$ (264,930)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	35,262	14,500
Stock-based compensation	106,337	81,124
Amortization of debt discount and issuance costs	6,492	7,337
Remeasurements of liabilities associated with business combinations	(372,722)	26,749
Benefit from income taxes	(23,360)	(2,600)
Post-combination expense for acceleration of unvested equity	2,959	—
Other	5,273	(536)
Changes in operating assets and liabilities, net of businesses acquired:		
Accounts receivable	(6,953)	4,939
Inventory	2,048	(4,432)
Prepaid expenses and other current assets	(8,346)	1,383
Other assets	(2,165)	942
Accounts payable	3,781	9,185
Accrued expenses and other long-term liabilities	8,255	3,585
Net cash used in operating activities	(218,845)	(122,754)
Cash flows from investing activities:		
Purchases of marketable securities	(325,957)	(115,350)
Proceeds from sales of marketable securities	—	12,532
Proceeds from maturities of marketable securities	127,738	89,965
Acquisition of businesses, net of cash acquired	(134,006)	(57,576)
Purchases of property and equipment	(20,154)	(10,854)
Other	(1,880)	(1,334)
Net cash used in investing activities	(354,259)	(82,617)
Cash flows from financing activities:		
Proceeds from public offerings of common stock, net	434,263	217,489
Proceeds from issuance of common stock	11,717	6,760
Proceeds from issuance of convertible senior notes, net	1,116,850	—
Other	(3,186)	(1,904)
Net cash provided by financing activities	1,559,644	222,345
Net increase in cash, cash equivalents and restricted cash	986,540	16,974
Cash, cash equivalents and restricted cash at beginning of period	131,480	157,572
Cash, cash equivalents and restricted cash at end of period	$ 1,118,020	$ 174,546
Supplemental cash flow information of non-cash investing and financing activities:		
Equipment acquired through finance leases	$ 2,578	$ —
Purchases of property and equipment in accounts payable and accrued liabilities	$ 5,016	$ 1,570
Common stock issued for acquisition of businesses	$ 163,876	$ 75,682
Consideration payable for acquisition of businesses	$ —	$ 16,813
Operating lease assets obtained in exchange for lease obligations, net	$ 80,157	$ 4,046

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 we changed our name to Invitae Corporation in 2012. We offer high-quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, cardiology, neurology, pediatrics, personalized oncology, metabolic conditions and rare diseases. To augment our offering and realize our mission, we have acquired multiple assets and businesses that further expanded our test menu and suite of genome management offerings and accelerated our entry into key genomics markets. 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, 2020. The results for the three and six months ended June 30, 2021 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, restricted cash, 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.

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 consolidated statements of cash flows (in thousands):

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 1,107,745	$ 124,794
Restricted cash	10,275	6,686
Total cash, cash equivalents and restricted cash	$ 1,118,020	$ 131,480

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. During the current period, we have disclosed the change in fair value of our contingent consideration separately in our statements of operations; these amounts are general and administrative in nature and were disclosed in general and administrative expense previous periods.

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.

Recently adopted accounting pronouncements

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 elected to adopt the amendments on a modified retrospective basis effective January 1, 2021, which required a cumulative-effect adjustment to retained earnings. The cumulative-effect adjustment resulted in a decrease in accumulated deficit of $17.0 million related to the reversal of the equity component and associated issuance costs as well as adjustment of the related amortization costs of our existing convertible senior notes due in 2024. Reporting periods beginning on or after January 1, 2021 are presented under this new guidance while prior periods have not been adjusted and continue to be reported in accordance with our historic accounting under GAAP. See further information about our Senior Convertible Notes in Note 8, “Commitments and contingencies.”

3. Revenue, accounts receivable and deferred revenue

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

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

	Three Months Ended June 30, 2021				
	Patient		Biopharma partner	Other business-to-business	Total
	Insurance	Direct			
Test revenue:					
Centralized	$ 71,254	$ 10,523	$ 8,688	$ 12,172	$ 102,637
Decentralized	—	—	214	8,645	8,859
Total test revenue	71,254	10,523	8,902	20,817	111,496
Other revenue	—	—	1,768	3,048	4,816
Total revenue	$ 71,254	$ 10,523	$ 10,670	$ 23,865	$ 116,312

	Three Months Ended June 30, 2020				
	Patient		Biopharma partner	Other business-to-business	Total
	Insurance	Direct			
Test revenue:					
Centralized	$ 31,270	$ 4,298	$ 4,289	$ 5,242	$ 45,099
Total test revenue	31,270	4,298	4,289	5,242	45,099
Other revenue	—	—	477	615	1,092
Total revenue	$ 31,270	$ 4,298	$ 4,766	$ 5,857	$ 46,191

	Six Months Ended June 30, 2021				
	Patient				
	Insurance	Direct	Biopharma partner	Other business-to-business	Total
Test revenue:					
Centralized	$ 132,145	$ 19,472	$ 19,260	$ 22,348	$ 193,225
Decentralized	—	—	596	16,951	17,547
Total test revenue	132,145	19,472	19,856	39,299	210,772
Other revenue	—	—	4,830	4,331	9,161
Total revenue	$ 132,145	$ 19,472	$ 24,686	$ 43,630	$ 219,933

	Six Months Ended June 30, 2020				
	Patient				
	Insurance	Direct	Biopharma partner	Other business-to-business	Total
Test revenue:					
Centralized	$ 75,061	$ 10,089	$ 8,600	$ 14,427	$ 108,177
Total test revenue	75,061	10,089	8,600	14,427	108,177
Other revenue	—	—	929	1,333	2,262
Total revenue	$ 75,061	$ 10,089	$ 9,529	$ 15,760	$ 110,439

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue	$ 4.2	$ 0.9	$ 8.5	$ 2.3
Income (loss) from operations	$ 4.2	$ (0.9)	$ 8.5	$ (2.3)
Net income (loss) per share, basic	$ 0.02	$ (0.01)	$ 0.04	$ (0.02)
Net income (loss) per share, diluted	$ 0.02	$ (0.01)	$ 0.04	$ (0.02)

Impact of COVID-19

Our billable 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 the current COVID-19 pandemic continues to impact our business operations and practices. While we expect that it may continue to impact our business, we experienced limited disruption during the second quarter of 2021. We have reviewed and adjusted, when necessary, for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

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

Accounts receivable

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

We also record unbilled revenue for revenue recognized but yet to be billed for services provided to biopharmaceutical companies related to companion diagnostic development. This contract receivable was $3.7 million and $4.3 million as of June 30, 2021 and December 31, 2020, respectively, and was included in prepaid expenses and other current assets on the consolidated balance sheets.

Deferred revenue

We record a contract liability when cash payments are received or due in advance of our performance related to one or more performance obligations. The deferred revenue balance primarily consists of advanced billings for biopharmaceutical development services, including billings at the initiation of performance-based milestones, and recognized as revenue in the applicable future period when the revenue is earned. Also included are prepayments related to our consumer direct channel. During the three and six months ended June 30, 2021, we recognized revenue from deferred revenue recorded in prior periods of $2.3 million and $2.6 million, respectively.

4. Business combinations

Singular Bio

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

In June 2019, we granted approximately $90.0 million of 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 vested in three equal installments in December 2019, June 2020, and December 2020, subject to the employee's continued service with us ("Time-based RSUs") and $45.0 million of the RSUs are 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 these awards and the number of shares issued are not fixed until the awards vest.

During the three and six months ended June 30, 2021, we recorded research and development stock-based compensation expense of nil related to the Time-based RSUs, and income of $0.5 million and expense of $1.9 million, respectively, related to the PRSUs based on our evaluation of the probability of achieving performance conditions, primarily due to the change in value of our common stock. During the three and six months ended June 30, 2020, we recorded research and development stock-based compensation expense of $10.9 million and $18.5 million, respectively, related to the Time-based RSUs and $18.9 million and $30.1 million, respectively, related to the PRSUs. As of June 30, 2021, the Time-based RSUs and PRSUs had a total fair value of $43.9 million and $45.7 million, respectively, based on a total estimated issuance of 3.6 million shares and expectation of the achievement of the performance conditions. As of June 30, 2021, all of the Time-based RSUs and 1.5 million of the PRSUs had vested with a total fair value of $84.3 million, which was recorded in common stock issued or issuable pursuant to business combinations in the consolidated statements of stockholders' equity upon issuance.

Jungla

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

We may be required to pay contingent consideration based on achievement of post-closing development milestones. As of the acquisition date, the fair value of this contingent consideration was $10.7 million including cash and 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 milestones and the discount rate used to estimate the fair value. Significant changes in any of the probabilities of success would result in a significant change in the fair value, which is estimated at each reporting date with changes reflected as a general and administrative expense. As of June 30, 2021, the fair value of this contingent consideration was $3.6 million representing the fair value of the remaining milestone, which was achieved in July 2021.

Diploid

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

As of June 30, 2021, we had a stock payable liability related to our acquisition of Diploid of $14.2 million, which represents 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, with the change recorded in other income (expense), net.

Genelex and YouScript

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

As of the acquisition date, we recorded stock payable liabilities of $6.2 million to represent the hold-back obligation to issue shares subject to indemnification claims that may arise. 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 June 30, 2021, the value of this liability was $7.8 million with the change recorded in other income (expense), net. In April 2021, the amounts held back to satisfy indemnification obligations for Genelex were released in full to the former shareholders.

We may be required to pay contingent consideration in the form of additional shares of our common stock in connection with the acquisition of Genelex if, within a specified period following the closing, we achieve a certain product milestone, in which case we would issue shares of our common stock with a value equal to a portion of the gross revenues actually received by us for a pharmacogenetic product reimbursed through certain payers during an earn-out period of up to four years. As of the acquisition date, the fair value of this contingent consideration was $2.0 million. The material factors that may impact the fair value of the contingent consideration, and therefore, this liability, are the probabilities and timing of achieving the related milestone, the estimated revenues achieved for a pharmacogenetic product and the discount rate used to estimate the fair value. Significant changes in any of the probabilities of success would result in a significant change in the fair value, which is estimated at each reporting date. As of June 30, 2021, the fair value of this contingent consideration was $1.6 million.

ArcherDX

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

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 may be required to pay contingent consideration based on achievement of post-closing development and revenue milestones. As of the acquisition date, the total fair value of the contingent consideration was $945.2 million. Of the five milestones, one milestone was achieved in November 2020, which resulted in the issuance of 5.0 million shares of our common stock and a cash payment of $1.9 million, and three milestones were achieved or deemed to be achieved during the three months ended June 30, 2021, which resulted in the issuance of 13.8 million shares of our common stock and a cash payment of $3.3 million in July 2021. The remaining milestone is based upon receiving U.S. Food and Drug Administration ("FDA") clearance or approval of STRATAFIDE, which per the terms of the acquisition agreement, must be completed by March 31, 2022, subject to certain extensions (the "ArcherDX Final Milestone"). The material factors that may impact the fair value of the contingent consideration, and therefore the liability, are (i) the estimated number of shares to be issued, (ii) the volatility of our common stock, (iii) the probabilities of achievement of milestones within the timeframes prescribed in the acquisition agreement and (iv) discount rates, all of which are Level 3 inputs not supported by market activity. Significant changes in any of these inputs may result in a significant change in fair value, which is estimated at each reporting date. As of December 31, 2020, the fair value of the contingent consideration related to ArcherDX was $788.3 million. As of June 30, 2021, the fair value of the contingent consideration representing the remaining milestones was $423.9 million, which includes the three milestones achieved or deemed to be achieved during the three months ended June 30, 2021 and paid in July 2021 discussed above. With respect to the ArcherDX Final Milestone, the liability has been reduced to zero as of June 30, 2021 from $262.5 million as of March 31, 2021 and $287.7 million as of December 31, 2020, with the offsetting change recorded as changes in fair value of contingent consideration in our consolidated statements of operations. The removal of the liability balance and the associated change in fair value of contingent consideration was a result of our reassessment of the steps necessary to achieve clearance or approval based on FDA feedback received principally in the three months ended June 30, 2021. As a result of our reassessment, we do not believe achievement of the conditions will occur prior to the expiry date for achievement under the timeframe prescribed in the acquisition agreement. We expect FDA clearance or approval of STRATAFIDE at a later date upon resolution of the necessary steps.

In connection with the acquisition, we granted awards of Invitae common stock to new employees who joined Invitae in connection with our acquisition of ArcherDX that vest upon the achievement of the contingent consideration milestones discussed above and are subject to the employee's continued service with us, unless terminated without cause in which case vesting is only dependent on milestone achievement. As the number of shares that are expected to be issued are fixed, the awards are equity-classified. During the three months ended June 30, 2021, we recorded a net $1.2 million in stock-based compensation expense related to the ArcherDX milestones, which includes $28.3 million related to milestones achieved in the three months ended June 30, 2021, $2.6 million due to an accounting modification of certain awards whereby the employees' continued substantive services were no longer required, offset by a reversal of $29.7 million recognized in prior periods related to the determination that the ArcherDX Final Milestone will not be achieved within the specified timeframe prescribed in the acquisition agreement. During the six months ended June 30, 2021, we recorded a net $41.8 million in stock-based compensation expense related to the ArcherDX milestones, which includes $38.5 million related to milestones achieved in the three months ended June 30, 2021, $33.0 million due to an accounting modification of certain awards whereby the employees' continued substantive services were no longer required, offset by a reversal of $29.7 million recognized in prior periods related to the determination that the ArcherDX Final Milestone will not be achieved within the specified timeframe prescribed in the acquisition agreement.

One Codex

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

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

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

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

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

Based on the guidance provided in ASC 805, *Business Combinations*, we accounted for the acquisition of One Codex as a business combination and determined that 1) One Codex 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 assets acquired were developed technology related to One Codex's microbiome and infectious disease platform and its customer relationships in place at time of acquisition. The fair value of the intangible assets was estimated using an income approach with an estimated useful life of nine years.

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

Genosity

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

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

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

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

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

Based on the guidance provided in ASC 805, Business Combinations, we accounted for the acquisition of Genosity as a business combination and determined that 1) Genosity 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. Pursuant to the terms of the acquisition, we incorporated a provision to provide additional shares in the event that our common stock share price decreased after the acquisition, but prior to filing a resale registration statement. At acquisition we estimated this provision to be $7.0 million. On filing the resale registration statement the fair value was $3.2 million; the difference of $3.8 million was recorded as an expense in general and administrative expense during the three months ended June 30, 2021.

Our purchase price allocation for the acquisition is preliminary and subject to revision as additional information about fair value of assets and liabilities becomes available, primarily related to certain aspects of our asset valuations and 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 assets acquired were developed technology related to Genosity's genomic laboratory services and sequencing software in place at time of acquisition. The fair value of the intangible assets was estimated using an income approach with an estimated useful life of twelve years.

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

5. Goodwill and intangible assets

Goodwill

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

Balance as of December 31, 2020	$ 1,863,623
Goodwill adjustment	(1,176)
Goodwill acquired	198,442
Balance as of June 30, 2021	$ 2,060,889

Intangible assets

The following table presents details of our intangible assets (amounts in thousands, useful lives in years):

	June 30, 2021				December 31, 2020			
	Cost	Accumulated Amortization	Net	Weighted-Average Useful Life	Cost	Accumulated Amortization	Net	Weighted-Average Useful Life
Customer relationships	$ 41,515	$ (10,696)	$ 30,819	10.8	$ 41,075	$ (8,292)	$ 32,783	10.8
Developed technology	498,259	(52,628)	445,631	10.7	397,563	(31,013)	366,550	10.6
Non-compete agreement	286	(258)	28	5.0	286	(229)	57	5.0
Tradename	21,085	(1,327)	19,758	12.0	21,085	(447)	20,638	12.0
Patent assets and licenses	496	(122)	374	15.0	496	(103)	393	15.0
Right to develop new technology	19,359	(968)	18,391	15.0	19,359	(323)	19,036	15.0
In-process research and development	542,388	—	542,388	n/a	542,388	—	542,388	n/a
	$ 1,123,388	$ (65,999)	$ 1,057,389	10.9	$ 1,022,252	$ (40,407)	$ 981,845	10.9

Acquisition-related intangibles included in the above table are generally finite-lived, other than in-process research and development, which has an indefinite life, and are carried at cost less accumulated amortization. Customer relationships related to our 2017 business combinations are being amortized on an accelerated basis in proportion to estimated cash flows. All other finite-lived acquisition-related intangibles are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized. Amortization expense was $13.5 million and $5.7 million for the three months ended June 30, 2021 and 2020, respectively, and $25.6 million and $9.2 million for the six months ended June 30, 2021 and 2020, respectively. Amortization expense is recorded in cost of revenue, research and development, selling and marketing and general and administrative expense.

The following table summarizes our estimated future amortization expense of intangible assets with finite lives as of June 30, 2021 (in thousands):

2021 (remainder of year)	$ 28,037
2022	54,470
2023	53,458
2024	53,179
2025	51,426
Thereafter	274,076
Total estimated future amortization expense	$ 514,646

6. Balance sheet components

Inventory

Inventory consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Raw materials	$ 23,381	$ 21,324
Work in progress	5,752	8,847
Finished goods	849	1,859
Total inventory	$ 29,982	$ 32,030

While we have not experienced significant disruption in our supply chain and we do not yet know the full impact COVID-19 may have on our supply chain, we have increased our inventory on hand to respond to potential future disruptions that may occur. During the three and six months ended June 30, 2021, we recognized reductions in inventory of $5.3 million and $8.0 million, respectively, due to inventory determined to be obsolete.

Property and equipment, net

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

	June 30, 2021	December 31, 2020
Leasehold improvements	$ 30,199	$ 26,516
Laboratory equipment	55,072	45,342
Computer equipment	12,734	10,939
Software	930	566
Furniture and fixtures	1,996	1,967
Automobiles	58	58
Construction-in-progress	21,185	12,061
Total property and equipment, gross	122,174	97,449
Accumulated depreciation and amortization	(39,414)	(31,347)
Total property and equipment, net	$ 82,760	$ 66,102

Depreciation expense was $4.3 million and $2.3 million for the three months ended June 30, 2021 and 2020, respectively, and $8.1 million and $4.4 million for the six months ended June 30, 2021 and 2020, respectively.

Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Accrued compensation and related expenses	$ 32,024	$ 25,221
Accrued interest	6,263	2,333
Compensation and other liabilities associated with business combinations	15,545	25,600
Deferred revenue	5,559	6,378
Other	28,654	26,526
Total accrued liabilities	$ 88,045	$ 86,058

Other long-term liabilities

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

	June 30, 2021	December 31, 2020
Deferred revenue, non-current	1,146	1,380
Compensation and other liabilities associated with business combinations, non-current	444,222	825,976
Other	15,298	13,900
Total other long-term liabilities	$ 460,666	$ 841,256

7. Fair value measurements

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

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

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

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

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

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

	June 30, 2021						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	$ 1,092,689	$ —	$ —	$ 1,092,689	$ 1,092,689	$ —	$ —
U.S. Treasury notes	371,298	34	—	371,332	371,332	—	—
U.S. government agency securities	51,139	—	—	51,139	—	51,139	—
Total financial assets	$ 1,515,126	$ 34	$ —	$ 1,515,160	$ 1,464,021	$ 51,139	$ —
Financial liabilities:							
Stock payable liability				$ 22,010	$ —	$ —	$ 22,010
Contingent consideration				429,068	—	—	429,068
Total financial liabilities				$ 451,078	$ —	$ —	$ 451,078

	June 30, 2021
Reported as:	
Cash equivalents	$ 1,082,412
Restricted cash	10,275
Marketable securities	422,473
Total cash equivalents, restricted cash, and marketable securities	$ 1,515,160
Accrued liabilities	$ 6,856
Other long-term liabilities	444,222
Total liabilities	$ 451,078

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

	December 31, 2020
Reported as:	
Cash equivalents	$ 76,423
Restricted cash	6,686
Marketable securities	229,186
Total cash equivalents, restricted cash, and marketable securities	$ 312,295
Accrued liabilities	$ 10,592
Other long-term liabilities	825,284
Total liabilities	$ 835,876

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 June 30, 2021 was $34.9 million. Our debt securities of U.S. government agencies are classified as Level 2 as they are valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to benchmark yields, interest rate curves, reported trades, broker/dealer quotes and reference data.

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. The change in fair value related to stock payable liabilities recorded to other income (expense), net during the three months ended June 30, 2021 and 2020 was income of $2.4 million and expense of $25.4 million, respectively, and income of $5.8 million and expense of $21.7 million during the six months ended June 30, 2021 and 2020, respectively.

8. Commitments and contingencies

Leases

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

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

Debt financing

In October 2020, we entered into a credit agreement with a financial institution under which we borrowed $135.0 million (the "2020 Term Loan") concurrent with the closing of the ArcherDX acquisition. The 2020 Term Loan is secured by a first priority lien on all of our and our subsidiaries' assets, and is guaranteed by us and our subsidiaries. The 2020 Term Loan bears interest at an annual rate equal to three-month LIBOR, subject to a 2.00% LIBOR floor, plus a margin of 8.75%. If three-month LIBOR can no longer be determined or if the applicable governmental authority ceases to supervise or sanction such rates, then we shall endeavor to agree with the administrative agent, an alternate rate of interest that gives due consideration to the then prevailing market convention for determining interest for comparable loans in the United States; provided that until such alternative rate of interest is agreed, the 2020 Term Loan shall bear interest at the *Wall Street Journal* Prime Rate. The 2020 Term Loan will mature on (i) June 1, 2024 if at such time our 2024 Notes (defined below) are outstanding and are due to mature on September 1, 2024 (provided that if, prior to such date, the maturity date of at least 80% of the 2024 Notes is extended to a date that is prior to September 1, 2025, the maturity date for the 2020 Term Loan will be automatically extended to a date that is 90 days prior to such 2024 Notes maturity date as extended), or (ii) otherwise, on June 1, 2025. The full amount of the 2020 Term Loan is due upon maturity. Debt discounts, including debt issuance costs, related to the 2020 Term Loan of $32.8 million were recorded as a direct deduction from the debt liability and are being amortized to interest expense over the term of the 2020 Term Loan. Interest expense related to our debt financings, excluding the impact of our convertible senior notes, was $5.9 million and nil for the three months ended months ended June 30, 2021 and 2020, respectively, and $11.8 million and nil for the six months ended June 30, 2021 and 2020, respectively.

Convertible senior notes

Convertible senior notes due 2024

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

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

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

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

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

Convertible senior notes due 2028

In April 2021, we issued, at 99% of par value, $1.2 billion aggregate principal amount of 1.5% convertible senior notes due 2028 (the "2028 Notes") in a private offering. The 2028 Notes are our senior unsecured obligations and will mature on April 1, 2028, unless earlier converted, redeemed or repurchased. The 2028 Notes bear cash interest at a rate of 1.5% per year, payable semi-annually in arrears on April 1 and October 1 of each year, beginning on October 1, 2021. Upon conversion, the 2028 Notes will be convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

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

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

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

Convertible senior notes

We adopted the provisions of ASU 2020-06 on January 1, 2021; see further information in Note 2, "Summary of significant accounting policies." Our 2024 Notes and 2028 Notes (collectively, our "convertible senior notes") consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Outstanding principal	$ 1,500,000	$ 350,000
Unamortized debt discount and issuance costs	(39,127)	(66,276)
Net carrying amount, liability component	$ 1,460,873	$ 283,724

As of June 30, 2021, the fair value of the 2024 Notes and 2028 Notes was $481.3 million and $1.2 billion, respectively. The estimated fair value of the 2024 Notes and 2028 Notes, which are classified as Level 2 financial instruments, was determined based on the estimated or actual bid prices in an over-the-counter market and/or market conditions including the price and volatility of our common stock and comparable company information. We recognized $7.2 million and $5.5 million of interest expense related to our convertible senior notes during the three months ended June 30, 2021 and 2020, respectively, and $9.4 million and $10.9 million during the six months ended June 30, 2021 and 2020, respectively. Of the interest expense recognized during the three and six months ended June 30, 2021, $1.5 million and $2.0 million, respectively, was related to amortization of issuance costs and the remainder was related to contractual interest incurred.

Other commitments

In the normal course of business, we enter into various purchase commitments primarily related to service agreements and laboratory supplies. At June 30, 2021, our total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year were $73.1 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 June 30, 2021 or December 31, 2020.

Contingencies

We were not a party to any material legal proceedings at June 30, 2021, or at the date of this report except for matters listed below. 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. On January 12, 2021, the court issued an order granting Natera leave to amend its complaint to add Invitae as a co-defendant and plead allegations that ArcherDX and Invitae induce end-users to infringe the patents-in-suit. Natera filed its Second Amended Complaint on the same day, with service completed on January 15, 2021. ArcherDX and Invitae filed answers to the Second Amended Complaint on January 26, 2021 and February 5, 2021, respectively, denying Natera's allegations and restating certain affirmative defenses and counterclaims of non-infringement and invalidity. The litigations have now been consolidated for all purposes. A claim construction order was issued on June 28, 2021. Discovery is ongoing, and trial has been scheduled for May 2022.

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

QIAGEN Sciences

On July 10, 2018, ArcherDX and the General Hospital Corporation d/b/a Massachusetts General Hospital, which we refer to as MGH, filed a lawsuit in the United States District Court for the District of Delaware against QIAGEN Sciences, LLC, QIAGEN LLC, QIAGEN Beverly, Inc., QIAGEN Gaithersburg, Inc., QIAGEN GmbH and QIAGEN N.V., which is collectively referred to herein as QIAGEN, and a named QIAGEN executive who was a former member of ArcherDX's board of directors, alleging several causes of action, including infringement of the '810 Patent, trade secret misappropriation, breach of fiduciary duty, false advertising, tortious interference and deceptive trade practices. The '810 Patent relates to methods for preparing a nucleic acid for sequencing and aspects of ArcherDX's AMP technology. On October 30, 2019, with the permission of the Court, ArcherDX amended ArcherDX's complaint to add a claim for infringement of the '597 Patent. The '597 Patent relates to methods of preparing and analyzing nucleic acids, such as by enriching target sequences prior to sequencing, and aspects of ArcherDX's AMP technology. The QIAGEN products that ArcherDX alleges infringe the '810 Patent and the '597 Patent include, but are not limited to, QIAseq Targeted DNA Panels, QIAseq Targeted RNAscan Panels, QIAseq Index Kits and QIAseq Immune Repertoire RNA Library Kits. ArcherDX is seeking, among other things, damages for ArcherDX's lost profits due to QIAGEN's infringement and a permanent injunction enjoining QIAGEN from marketing and selling the infringing products and from using ArcherDX's trade secrets. On December 5, 2019, QIAGEN and the named QIAGEN executive submitted their answer denying the allegations in ArcherDX's complaint and asserting affirmative defenses that, among other things, the '810 Patent and '597 Patent are not infringed by QIAGEN's products, that both patents are invalid, and that the complaint fails to state any claim for which relief may be granted. On March 1, 2021, each of ArcherDX and QIAGEN moved for summary judgment on issues relating to infringement and validity of ArcherDX's patents, breach of fiduciary duty and trade secret misappropriation. On June 18, 2021, ArcherDX informed the court that it would not assert the following claims to streamline the issues for trial: trade secret misappropriation, false advertising, deceptive trade practices, and tortious interference. The court denied QIAGEN's motion for summary judgment on trade secret misappropriation as moot on June 21, 2021 and denied QIAGEN's motion for summary judgment on breach of fiduciary duty on July 26, 2021. The court has not yet issued a decision on the parties' motions relating to infringement and validity of ArcherDX's patents. 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Convertible preferred stock:				
Shares outstanding, beginning and end of period	125	125	125	125
Common stock:				
Shares outstanding, beginning of period	197,514	101,920	185,886	98,796
Common stock issued in connection with public offering	—	23,058	8,932	23,058
Common stock issued on exercise of stock options, net	178	130	579	308
Common stock issued pursuant to vesting of RSUs	2,671	3,055	3,383	3,481
Common stock issued pursuant to exercises of warrants	—	6	208	148
Common stock issued pursuant to employee stock purchase plan	271	342	271	342
Common stock issued pursuant to business combinations	2,384	2,778	3,759	5,156
Shares outstanding, end of period	203,018	131,289	203,018	131,289

Convertible preferred stock

In August 2017, in a private placement to certain accredited investors, we issued shares of our Series A convertible preferred stock which are convertible into common stock on a one-for-one basis, subject to adjustment for events such as stock splits, combinations and the like. The Series A convertible preferred stock is a non-voting common stock equivalent with a par value of $0.0001 and has the right to receive dividends first or simultaneously with payment of dividends on common stock. In the event of any liquidation or dissolution of the Company, the Series A preferred stock is entitled to receive $0.001 per share prior to the payment of any amount to any holders of capital stock ranking junior to the Series A preferred stock and thereafter shall participate pari passu with the holders of our common stock (on an as-if-converted-to-common-stock basis).

Sales Agreements

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

In August 2018, we entered into a common stock sales agreement (the “2018 Sales Agreement”) with Cowen under which we may have offered and sold from time to time at our sole discretion shares of our common stock through Cowen as our sales agent, in an aggregate amount not to exceed $75.0 million. Per the terms of the agreement, Cowen received a commission equal to 3% of the gross proceeds of the sales price of all shares sold through it as sales agent under the 2018 Sales Agreement. In March 2019, we amended the 2018 Sales Agreement to increase the aggregate amount of our common stock to be sold under this agreement not to exceed $175.0 million. During 2018, 2019 and 2020, we sold 8.7 million shares of our common stock for gross proceeds of the full $175.0 million under this agreement, and generated net proceeds of $169.1 million.

Public offering

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

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

Private placement

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

10. Stock incentive plans

Stock incentive plans

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

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

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

RSUs generally vest over a period of three years. Typically, the vesting schedule for RSUs provides that 1/3 of the award vests upon each anniversary of the grant date, with certain awards that include a portion that vests immediately upon grant. We also have certain awards granted in connection with our management incentive plan which vest over a period of two years. In June 2019, we granted Time-based RSUs in connection with the acquisition of Singular Bio which vested 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."

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, 2020	7,447	4,877	$ 7.75	6.8	$ 166,130
Additional shares reserved	8,498	—			
Options granted	(244)	244	34.90		
Options cancelled	40	(40)	26.64		
Options exercised	—	(579)	5.10		
RSUs and PRSUs granted [1]	(5,476)	—			
RSUs and PRSUs cancelled	412	—			
Balances at June 30, 2021	10,677	4,502	$ 9.39	6.4	$ 109,835
Options exercisable at June 30, 2021		4,003	$ 7.43	6.1	$ 105,304
Options vested and expected to vest at June 30, 2021		4,466	$ 9.32	6.4	$ 109,280

[1] Includes the changes in RSUs and PRSUs granted as a part of the Singular Bio acquisition in June 2019 and awards granted in an asset acquisition in December 2020 which are based on a fixed dollar value. The estimated number of shares issued will be variable until the awards vest.

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

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

	Number of Shares	Weighted- Average Grant Date Fair Value Per Share
Balance at December 31, 2020	6,602	$ 12.89
RSUs and PRSUs granted [1]	5,476	$ 31.47
RSUs and PRSUs vested	(3,383)	$ 20.86
RSUs and PRSUs cancelled	(412)	$ 21.90
Balance at June 30, 2021	8,283	$ 21.47

[1] Includes the changes in RSUs and PRSUs granted as a part of the Singular Bio acquisition in June 2019 and awards granted in an asset acquisition in December 2020 which are based on a fixed dollar value. The estimated 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.

Stock-based compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of revenue	$ 5,474	$ 2,356	$ 7,659	$ 3,217
Research and development	30,803	41,565	46,338	63,769
Selling and marketing	6,909	3,298	10,339	5,120
General and administrative	4,376	4,627	42,001	9,018
Total stock-based compensation expense	$ 47,562	$ 51,846	$ 106,337	$ 81,124

11. Net income (loss) per share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Numerator:				
Basic:				
Net income (loss)	$ 133,786	$ (166,403)	$ 24,294	$ (264,930)
Diluted:				
Net income (loss)	$ 133,786	$ (166,403)	$ 24,294	$ (264,930)
Interest effect of convertible debt, net	7,201	—	—	—
Total	$ 140,987	$ (166,403)	$ 24,294	$ (264,930)
Denominator:				
Basic:				
Shares used in computing net income (loss) per share, basic	204,110	129,023	199,083	112,765
Diluted:				
Shares used in computing net income (loss) per share, basic	204,110	129,023	199,083	112,765
Dilutive effect of contingently issuable shares	10,804	—	5,394	
Dilutive effect of convertible notes	38,403	—	—	—
Dilutive effect of Series A convertible preferred stock	125	—	125	—
Dilutive effect of equity awards	11,479	—	11,993	—
Shares used in computing net income (loss) per share, diluted	264,921	129,023	216,595	112,765
Net income (loss) per share, basic	$ 0.66	$ (1.29)	$ 0.12	$ (2.35)
Net income (loss) per share, diluted	$ 0.53	$ (1.29)	$ 0.11	$ (2.35)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Shares of common stock subject to outstanding options	181	3,416	100	3,447
Shares of common stock subject to outstanding warrants	—	369	—	429
Shares of common stock subject to outstanding RSUs and PRSUs	984	8,782	122	8,302
Shares of common stock pursuant to ESPP	—	313	—	318
Shares of common stock underlying Series A convertible preferred stock	—	125	—	125
Shares of common stock subject to convertible senior notes conversion	—	11,770	38,403	11,770
Total shares of common stock equivalents	1,165	24,775	38,625	24,391

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
United States	$ 102,499	$ 43,334	$ 192,911	$ 103,140
Rest of world	13,813	2,857	27,022	7,299
Total revenue	$ 116,312	$ 46,191	$ 219,933	$ 110,439

13. Subsequent events

In July 2021, we acquired 100% of the fully diluted equity of Medneon LLC ("Medneon"), a genetics insights platform. Given the timing of the transaction with Medneon, we are currently in the process of finalizing the accounting recognition, including 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.

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, 2020. 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 have taken or 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;
- our ability to obtain regulatory approvals for our tests;
- the rate and degree of market acceptance of our tests and genetic testing generally;
- our ability to scale our infrastructure and operations in a cost-effective manner;
- the timing of and our ability to introduce improvements to our genetic testing platform and to expand our assays to include additional genes;
- the timing and results of studies with respect to our tests;
- developments and projections relating to our competitors and our industry;
- our competitive strengths;
- the degree to which individuals will share genetic information generally, as well as share any related potential economic opportunities with us;
- our commercial plans, including our sales and marketing expectations as well as our ability to expand internationally;
- our ability to obtain and maintain adequate reimbursement for our tests;
- regulatory developments in the United States and foreign countries;
- our ability to attract and retain key scientific, sales, engineering or management personnel;
- our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- 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.

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

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

Summary of risk factors

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

- 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.
- We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.
- Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.
- We have acquired and may continue to acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, or cause us to incur debt or significant expense.
- If third-party payers, including managed care organizations, private health insurers and government health plans do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.
- We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the market. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.
- We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.
- Security breaches, privacy issues, loss of data and other incidents could compromise sensitive or personal information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.
- We need to scale our infrastructure in advance of demand for our tests, and our failure to generate sufficient demand for our tests would have a negative impact on our business and our ability to attain profitability.
- If we are not able to continue to generate substantial demand of our tests, our commercial success will be negatively affected.
- If our STRATAFIDE and PCM products and related services do not perform as expected, we may not realize the expected benefits of our recent acquisition of ArcherDX.

- The future growth of our distributed products business is partially dependent upon regulatory approval and market acceptance of our IVD products, including STRATAFIDE and PCM.
- Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.
- If the FDA regulates the tests we currently offer as LDTs as medical devices, we could incur substantial costs and our business, financial condition and results of operations could be adversely affected.
- If we are unable to transition to the new European Union IVDR regulations, we could lose the ability to serve the European market.
- We may not be able to obtain regulatory clearance or approval of our IVD products, or even if approved, such products may not be approved for guideline inclusion, which could adversely our ability to realize the intended benefits of our acquisition of ArcherDX.
- 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 acquisition of ArcherDX.
- We have a large amount of debt, servicing our debt requires a significant amount of cash, and our debt service obligations may prevent us from taking actions that we would otherwise consider to be in our best interests.

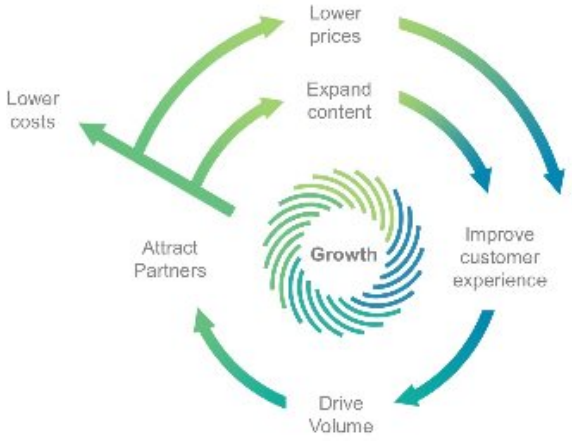
Mission and strategy

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

We were founded on four core principles:

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

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



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

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

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

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

Business overview

We offer high-quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, cardiology, neurology, pediatrics, personalized oncology, metabolic conditions and rare diseases. To augment our offering and realize our mission, we have acquired multiple assets and businesses, which expanded our suite of genome management offerings and established a broader entry into key genomics markets.

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

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

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

In October 2020, we completed the acquisition of ArcherDX, Inc., or ArcherDX, a genomics company democratizing precision oncology by offering a suite of products and services that are accurate, personal, actionable and easy to use in local settings, thereby empowering clinicians to control the sample, data, patient care and economics. As part of the acquisition we agreed to pay contingent consideration based on the achievement of five post-closing development, regulatory and revenue milestones. The first milestone was achieved in November 2020, and in June 2021, three additional milestones were achieved or deemed to be achieved. The remaining milestone is based upon receiving FDA clearance or approval of STRATAFIDE, which per the terms of the acquisition agreement, must be completed by March 31, 2022, subject to certain extensions. Based on the current development timeline, during the three months ended June 30, 2021, we determined that this milestone will not be met by the required achievement date per the acquisition agreement, although we expect to receive FDA clearance or approval at a later date. The underlying assets related to this acquisition remain unchanged.

We have experienced rapid growth. For the years ended December 31, 2020, 2019 and 2018, our revenue was $279.6 million, $216.8 million, and $147.7 million, respectively, and we incurred net losses of $602.2 million, $242.0 million, and $129.4 million, respectively. For the six months ended June 30, 2021 and 2020, our revenue was $219.9 million and $110.4 million, respectively, and we recognized net income of $24.3 million and net loss of $264.9 million, respectively. At June 30, 2021, our accumulated deficit was $1.3 billion. To meet the demands of scaling our business, we increased our number of employees to approximately 2,600 at June 30, 2021 from approximately 1,500 on June 30, 2020. Our sales force grew to approximately 310 employees at June 30, 2021 from approximately 270 at June 30, 2020.

Sales of our tests have grown significantly. In 2020, 2019 and 2018, we generated 659,000, 469,000 and 292,000 billable units, respectively. In the six months ended June 30, 2021, we generated 546,000 billable tests compared to 264,000 billable tests in the same period in 2020. We calculate volume using billable units, which are billable events that include individual test reports released and individual reactions shipped. We refer to the set of reagents needed to perform an NGS test as a "reaction." Approximately 57% of the billable volume generated in the first six months of 2021 were billable to patients, biopharmaceutical partners and other business-to-business customers (e.g., hospitals, clinics, medical centers), 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 payment requirement from the patient that may result in further delay in payment for these tests.

We expect to incur operating losses for the near term as we continue to invest in our business to achieve our revenue growth objectives, including expansion of our platform to capture the broad potential of genetics across healthcare and expansion into new laboratory and production facilities, and 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 volume, achieve broad reimbursement coverage for our tests from third-party payers and increase our payment amounts from other types of 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. We also believe that providing a unique genetic testing platform that is agnostic to stage of life or disease category will deliver unique benefits to customers, payers and other institutions that are seeking to make genetic information a standard element of healthcare decisions in the future.

Impact of COVID-19

Our billable 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 the current COVID-19 pandemic continues to impact our business operations and practices. While we expect that it may continue to impact our business, we experienced limited disruption during the second quarter of 2021. We have reviewed and adjusted, when necessary, for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

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

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

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

Factors affecting our performance

Number of billable units

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

Number and size of research and commercial partnerships

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

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

Success obtaining and maintaining reimbursement

Our ability to increase volume and revenue will depend in part on our success achieving broad reimbursement coverage and laboratory service contracts for our tests from third-party payers and agreements with institutions and partners. Reimbursement may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary and cost-effective, as well as whether we are in contract, where we get paid more consistently and at higher rates. Because each payer makes its own decision as to whether to establish a policy or enter into a contract to reimburse for our testing services and specific tests, seeking these approvals is a time-consuming and costly process. In addition, clinicians and patients may decide not to order our tests if the cost of the test is not covered by insurance. Because we require an ordering physician to requisition a test, our revenue growth also depends on our ability to successfully promote the adoption of our testing services and expand our base of ordering clinicians. We believe that establishing coverage and obtaining contracts from third-party payers is an important factor in gaining adoption by ordering clinicians. Our arrangements for laboratory services with payers cover approximately 315 million lives, comprised of Medicare, all national commercial health plans, and Medicaid in most states, including California (Medi-Cal), our home state.

Ability to lower the costs associated with performing our tests

Reducing the costs associated with performing our genetic tests is both a focus and a strategic objective of ours. Over the long term, we will need to reduce the cost of raw materials by improving the output efficiency of our assays and laboratory processes, modifying our platform-agnostic assays and laboratory processes to use materials and technologies that provide equal or greater quality at lower cost, improve how we manage our materials, port some tests onto a next generation sequencing platform and negotiate favorable terms for our materials purchases. Our acquisition of Singular Bio, Inc. 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 plan to reduce the cost of providing test equipment and software to laboratories and other facilities in the United States. and internationally. Those efforts are designed to enable a more rapid expansion of genetic testing and patient access, enlarging our geographic footprint outside the United States while achieving lower costs.

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

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

Investment in our business and timing of expenses

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

How we recognize revenue

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

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

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

Financial overview

Revenue

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

Cost of revenue

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

Operating expenses

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

Research and development

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

We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses to significantly increase as we continue our efforts to develop additional offerings, make investments to reduce costs, streamline our technology to provide patients access to testing, scale our business domestically and internationally and acquire and integrate new technologies.

Selling and marketing

Selling and marketing expenses consist of personnel-related costs, including commissions, client service expenses, advertising and marketing expenses, educational and promotional expenses, market research and analysis, and allocated overhead including rent, information technology, equipment depreciation, amortization of acquired intangibles, and utilities. We expect our selling and marketing expenses to increase as we continue to build our brand and focus on advertising our products and services.

General and administrative

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

Change in fair value of contingent consideration

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

Other income (expense), net

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

Interest expense

Interest expense is primarily attributable to interest incurred related to our debt and finance leases. See Note 8, “Commitments and contingencies” in Notes to Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report for more details.

Income tax benefit

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

Critical accounting policies and estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. We evaluate our estimates on an ongoing basis. Our estimates are based on current facts, our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that 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, 2020. See Note 2, "Summary of significant accounting policies" in the Notes to Condensed Consolidated Financial Statements for information regarding recent accounting pronouncements.

Results of operations

Three Months Ended June 30, 2021 and 2020

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 June 30,		Dollar Change	% Change
	2021	2020		
Revenue:				
Test revenue	$ 111,496	$ 45,099	$ 66,397	147%
Other revenue	4,816	1,092	3,724	341%
Total revenue	116,312	46,191	70,121	152%
Cost of revenue	89,331	42,952	46,379	108%
Research and development	106,454	74,963	31,491	42%
Selling and marketing	56,964	39,520	17,444	44%
General and administrative	38,303	26,006	12,297	47%
Change in fair value of contingent consideration	(303,349)	4,832	(308,181)	N/M
Income (loss) from operations	128,609	(142,082)	270,691	(191)%
Other income (expense), net	2,024	(21,436)	23,460	(109)%
Interest expense	(13,407)	(5,485)	(7,922)	144%
Net income (loss) before taxes	117,226	(169,003)	286,229	(169)%
Income tax benefit	(16,560)	(2,600)	(13,960)	537%
Net income (loss)	$ 133,786	$ (166,403)	$ 300,189	(180)%

Revenue

The increase in total revenue of $70.1 million for the three months ended June 30, 2021 compared to the same period in 2020 was due primarily to increased billable volume as well as product mix and pricing due to growth in our business as well as due to businesses acquired. Billable volume increased to approximately 287,000 in the three months ended June 30, 2021 compared to 113,000 in the same period of 2020, an increase of 154 percent, due to growth in the business as well as the impact of COVID-19 on billable volume in the prior year period. Average revenue per unit decreased to $388 per unit in the three months ended June 30, 2021 compared to $399 per unit in the comparable prior period primarily due to changes in payer and product mix, the impact of business acquisitions and 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 $46.4 million for the three months ended June 30, 2021 compared to the same period in 2020 was primarily due to increased billable volume, the impact of business acquisitions, and an increase in certain inventory reserves, partially offset by the effect of cost efficiencies. Cost per unit was $310 in the three months ended June 30, 2021 compared to $380 for the same period in 2020. The cost per unit decreased primarily due to lower billable volume during the prior year period as a result of COVID-19. These decreases were partially offset by an increase in amortization of acquired intangible assets of $6.6 million, an increase in write downs of certain inventory items of $4.9 million, as well as changes in product mix.

Research and development

The increase in research and development expense of $31.5 million for the three months ended June 30, 2021 compared to the same period in 2020 was due to growth in the business as well as the impact of business acquisitions and primarily relates to increases in personnel-related expenses of $11.1 million largely due to increases in headcount, $6.7 million in professional fees, $6.6 million in lab-related expenses due primarily to increased costs related to lab services and supplies, $3.0 million in technology costs, $1.7 million in depreciation and amortization costs, and a $0.8 million decrease in allocations from research and development to cost of revenue.

Selling and marketing

The increase in selling and marketing expense of $17.4 million for the three months ended June 30, 2021 compared to the same period in 2020 was due primarily to the growth of the business and principally consisted of increases in personnel-related costs of $12.5 million primarily reflecting increased headcount and includes an increase in sales commissions of $2.2 million, an increase in travel-related costs of $1.3 million, an increase in professional fees of $1.3 million, an increase in depreciation and amortization expense of $0.9 million and an increase in technology costs of $0.9 million.

General and administrative

The increase in general and administrative expense of $12.3 million for the three months ended June 30, 2021 compared to the same period in 2020 was due principally to growth in the business which resulted in an increase in personnel-related costs by $7.5 million, a $4.1 million increase in occupancy expense, a $2.7 million increase in legal and accounting services which was primarily due to increased acquisition-related transaction costs, a $2.6 million increase in information technology expenses for software licenses and related costs and a $0.8 million increase in professional fees. These increases in costs were partially offset by an increase of $6.5 million in allocations of technology and facilities-related expenses to other functional areas.

Change in fair value of contingent consideration

The increase in the change in fair value of contingent consideration of $308.2 million for the three months ended June 30, 2021 compared to the same period in 2020 was due principally to adjustments to decrease our contingent consideration liability related to ArcherDX resulting from a decrease in the value of our common stock and the removal of our contingent consideration liability relating to the outstanding milestone for FDA clearance or approval of STRATAFIDE due to our determination that this milestone will not be achieved in the timeframe prescribed in the acquisition agreement, although we expect to receive FDA clearance or approval at a later date.

Other income (expense), net

The increase in other income, net of $23.5 million for the three months ended June 30, 2021 compared to the same period in 2020 was primarily due to decreases in fair value adjustments related to our stock payable liabilities of $27.7 million due to the decrease in the price of our common stock, partially offset by a decrease of amounts received under the CARES Act.

Interest expense

The increase in interest expense of $7.9 million for the three months ended June 30, 2021 compared to the same period in 2020 was primarily due to increased debt outstanding compared to the prior year period, partially offset by the impact of the adoption of ASU 2020-06, which reduced the interest expense recognized related to our convertible senior notes during 2021.

Income tax benefit

The increase in income tax benefit of $14.0 million was primarily due to the net deferred tax liabilities assumed in connection with our acquisition of Genosity in April 2021 offset by the net deferred tax liabilities assumed in connection with our acquisition of YouScript in April 2020.

Six Months Ended June 30, 2021 and 2020

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.

	Six Months Ended June 30,		Dollar Change	% Change
	2021	2020		
Revenue:				
Test revenue	$ 210,772	$ 108,177	$ 102,595	95%
Other revenue	9,161	2,262	6,899	305%
Total revenue	219,933	110,439	109,494	99%
Cost of revenue	164,822	83,374	81,448	98%
Research and development	186,812	130,631	56,181	43%
Selling and marketing	108,204	81,640	26,564	33%
General and administrative	110,820	49,828	60,992	122%
Change in fair value of contingent consideration	(366,970)	4,832	(371,802)	N/M
Loss from operations	16,245	(239,866)	256,111	(107)%
Other income (expense), net	6,489	(16,728)	23,217	(139)%
Interest expense	(21,800)	(10,936)	(10,864)	99%
Net income (loss) before taxes	934	(267,530)	268,464	(100)%
Income tax benefit	(23,360)	(2,600)	(20,760)	798%
Net income (loss)	$ 24,294	$ (264,930)	$ 289,224	(109)%

Revenue

The increase in total revenue of $109.5 million for the six months ended June 30, 2021 compared to the same period in 2020 was due primarily to increased billable volume as well as product mix and pricing due to growth in our business as well as due to businesses acquired. Billable volume increased to 546,000 in the six months ended June 30, 2021 compared to 264,000 in the same period of 2020, an increase of 107 percent, due to growth in the business as well as the impact of COVID-19 on billable volume in the prior year period. Average revenue per test decreased to $386 per test in the six months ended June 30, 2021 compared to $410 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 $81.4 million for the six months ended June 30, 2021 compared to the same period in 2020 was primarily due to increased billable volume, the impact of business acquisitions, and an increase in certain inventory reserves, partially offset by the effect of cost efficiencies. Cost per unit was $300 in the six months ended June 30, 2021 compared to $316 for the same period in 2020. The decrease in cost per unit in the six months ended June 30, 2021 was primarily attributable to lower billable volume during the prior year period as a result of COVID-19 partially offset by an increase in amortization of acquired intangible assets of $13.7 million, an increase in write downs of certain inventory items of $7.5 million, as well as changes in product mix.

Research and development

The increase in research and development expense of $56.2 million for the six months ended June 30, 2021 compared to the same period in 2020 was due to the growth of the business as well as the impact of business acquisitions and primarily relates to increase in personnel-related expenses of $21.9 million, a $14.9 million increase in lab-related expenses due primarily to increased costs related to lab services and supplies, a $10.4 million increase in professional fees, a $5.0 million increase in technology costs, and a $3.5 million increase in depreciation and amortization costs.

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 $1.4 million.

Selling and marketing

The increase in selling and marketing expense of $26.6 million for the six months ended June 30, 2021 compared to the same period in 2020 was due primarily to the growth of the business and our increased spending on sales initiatives subsequent 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 $23.0 million reflecting increased headcount and included an increase in sales commissions of $4.2 million; allocated technology and facilities-related expenses increased by $2.0 million; a $1.8 million increase in depreciation and amortization and an increase in technology expense by $1.1 million. These costs were partially offset by reductions in marketing expenses for branding initiatives and advertising by $1.8 million.

General and administrative

The increase in general and administrative expense of $61.0 million for the six months ended June 30, 2021 compared to the same period in 2020 was due primarily to increases in costs due to the growth of the business and the effect of our business acquisitions, including: an increase in personnel-related costs by $46.7 million which includes an increase in stock-based compensation of $33.0 million, which was primarily due to the acceleration of certain awards granted in our acquisition of ArcherDX offset by a reduction in stock-based compensation due to the reduction in likelihood of completing a development milestone within the timeframe prescribed in the acquisition agreement; an increase in legal and accounting services by $7.3 million; an increase in occupancy costs by $6.6 million; an increase in information technology costs by $4.7 million due to software licenses and related expenses; an increase in post-combination expense related to our acquisitions of $3.3 million; and an increase in professional fees by $1.3 million. These increases in costs were partially offset by an increase of $9.6 million in allocations of technology and facilities-related expenses to other functional areas.

Change in fair value of contingent consideration

The increase in the change in fair value of contingent consideration of $371.8 million for the six months ended June 30, 2021 compared to the same period in 2020 was due principally to adjustments to decrease our contingent consideration liability related to ArcherDX resulting from a decrease in the value of our common stock and the removal of our contingent consideration liability relating to the outstanding milestone for FDA clearance or approval of STRATAFIDE due to our determination that this milestone will not be achieved in the timeframe prescribed in the acquisition agreement, although we expect to receive FDA clearance or approval at a later date.

Other income (expense), net

The increase in other income, net of $23.2 million for the six months ended June 30, 2021 compared to the same period in 2020 was due principally to fair value adjustments related to our stock payable liabilities of $27.5 million due to the decrease in the price of our common stock, partially offset by amounts received under the CARES Act and the net changes in amounts recognized related to our marketable securities.

Interest expense

The increase in interest expense of $10.9 million for the six months ended June 30, 2021 compared to the same period in 2020 was due principally to increased debt outstanding as compared to the prior year period, partially offset by the impact of the adoption of ASU 2020-06, which reduced the interest expense recognized related to our convertible senior notes during 2021.

Income tax benefit

The increase in income tax benefit of $20.8 million was due to the net deferred tax liabilities assumed in connection with our acquisition of One Codex and Genosity in 2021 as compared to the YouScript of $2.6 million in April 2020.

Liquidity and capital resources

Liquidity and capital expenditures

We have generally incurred net losses since our inception. For the six months ended June 30, 2021 and 2020, we had net income of $24.3 million and net loss of $264.9 million, respectively, and we expect to incur additional losses in the future. At June 30, 2021, we had an accumulated deficit of $1.3 billion. While our revenue has increased over time, we may never achieve revenue sufficient to offset our expenses.

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

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

In September 2019, we issued $350.0 million of aggregate principal amount of convertible senior notes due 2024, which bear cash interest at a rate of 2.0% per year. Also in September 2019, we used the funds received through the issuance of our convertible senior notes due 2024 to settle our Note Purchase Agreement we entered into in November 2018. In April 2021, we issued $1.2 billion of aggregate principal amount of convertible senior notes due 2028, which bear cash interest at a rate of 1.5% per year.

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

At June 30, 2021 and December 31, 2020, we had $1.5 billion and $360.7 million, respectively, of cash, cash equivalents, restricted cash and marketable securities.

Our primary uses of cash are to fund our operations as we continue to grow our business, enter into partnerships and 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 June 30, 2021 and fees collected from the sale of our products and services will be sufficient to meet our anticipated cash requirements for the foreseeable future.

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

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

	Six Months Ended June 30,	
	2021	2020
Net cash used in operating activities	$ (218,845)	$ (122,754)
Net cash used in investing activities	(354,259)	(82,617)
Net cash provided by financing activities	1,559,644	222,345
Net increase in cash, cash equivalents and restricted cash	$ 986,540	$ 16,974

Cash flows from operating activities

For the six months ended June 30, 2021, cash used in operating activities of $218.8 million principally resulted from our net income of $24.3 million, non-cash charges of remeasurements of liabilities in connection with business combinations of $372.7 million, primarily relating to ArcherDX development milestones and a $23.4 million income tax benefit primarily generated from our acquisitions of One Codex and Genosity. These were partially offset by non-cash charges of $106.3 million for stock-based compensation, $35.3 million for depreciation and amortization, $6.5 million for amortization of debt discount and issuance costs related to our outstanding debt and $3.0 million of post-combination expense related to the acceleration of unvested equity from our acquisition of One Codex. The net effect on cash of changes in net operating assets was a decrease of cash of $3.4 million.

For the six months ended June 30, 2020, cash used in operating activities of $122.8 million principally resulted from our net loss of $264.9 million and a $2.6 million income tax benefit generated from our acquisition of YouScript, partially offset by non-cash charges of $81.1 million for stock-based compensation, remeasurements of liabilities in connection with business combinations of $26.7 million, $14.5 million for depreciation and amortization and $7.3 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 $15.6 million.

Cash flows from investing activities

For the six months ended June 30, 2021, cash used in investing activities of $354.3 million was due primarily to net purchases of marketable securities of $198.2 million, net cash used to acquire One Codex and Genosity of $134.0 million and cash used for purchases of property and equipment of $20.2 million.

For the six months ended June 30, 2020, cash used in investing activities of $82.6 million was due to net sales and maturities of marketable securities of $12.9 million partially offset by net cash used to acquire Diploid, Genelex and YouScript of $57.6 million and cash used for purchases of property and equipment of $10.9 million.

Cash flows from financing activities

For the six months ended June 30, 2021, cash provided by financing activities of $1.6 billion primarily consisted of net proceeds from the issuance of our 2028 Notes of $1.1 billion and the public offering of common stock of $434.3 million as well as cash received from issuances of common stock of $11.7 million.

For the six months ended June 30, 2020, cash provided by financing activities of $222.3 million consisted of net proceeds from the public offering of common stock of $217.5 million, cash received from issuances of common stock of $6.8 million, partially offset by finance lease principal payments of $1.2 million.

Contractual obligations

The following table summarizes our contractual obligations, including interest, as of June 30, 2021 (in thousands):

Contractual obligations:	Remainder of 2021	2022 and 2023	2024 and 2025	2026 and beyond	Total
Operating leases	$ 9,497	$ 43,939	$ 52,747	$ 131,326	$ 237,509
Finance leases	1,329	4,778	286	—	6,393
Convertible senior notes	—	—	350,000	1,150,000	1,500,000
2020 Term Loan	—	—	135,000	—	135,000
Purchase commitments	14,937	49,427	8,458	278	73,100
Total	$ 25,763	$ 98,144	$ 546,491	$ 1,281,604	$ 1,952,002

See Note 8, "Commitments and contingencies" in the Notes to Condensed Consolidated Financial Statements for additional details regarding our leases, convertible senior notes, 2020 Term Loan and purchase commitments.

Off-balance sheet arrangements

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

Recent accounting pronouncements

See “Recent accounting pronouncements” in Note 2, “Summary of significant accounting policies” in 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 $1.5 billion at June 30, 2021, and consisted primarily of bank deposits, money market funds, U.S. treasury notes, and U.S. government agency securities. Such interest-bearing instruments carry a degree of risk; however, because our investments are primarily high-quality credit instruments with short-term durations with high-quality institutions, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. At June 30, 2021, a hypothetical 1.0% (100 basis points) increase or decrease in interest rates would not have resulted in a material change in the fair value of our cash equivalents and marketable securities. Fluctuations in the value of our cash equivalents and marketable securities caused by a change in interest rates (gains or losses on the carrying value) are recorded in other comprehensive gain (loss) and are realized if we sell the underlying securities prior to maturity.

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

Although our convertible senior notes are based on a fixed rate, changes in interest rates could impact their fair market value. As of June 30, 2021, the fair market value of the convertible senior notes due 2024 and due 2028 was $481.3 million and $1.2 billion respectively. 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.

For discussion of legal matters as of June 30, 2021, see Note 8, "Commitments and contingencies" in Notes to Consolidated Financial Statements in Part I, Item 1 of this report, which is incorporated to this item by reference.

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. In 2020, many of our customers, including hospitals and clinics, suspended non-emergency appointments and services, which resulted in a significant decrease in our test volume. Travel bans, restrictions and border closures have also impacted our ability to ship tests to and receive samples from our customers. While some of these measures have been lifted, they may be implemented again if COVID-19 is not contained or returns. These measures have adversely affected and may continue to adversely affect our test volume, sales activities and results of operations.

The spread of COVID-19 caused us to modify our business practices (including employee travel, mandating that all non-essential personnel work from home, temporary closures of our offices, cancellation of physical participation in sales activities, meetings, events and conferences and increasing inventories of certain supplies because, although we have not experienced significant disruption in our supply chain, we have experienced supply delays as a result of the COVID-19 pandemic and have also had to obtain supplies from new suppliers). We may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, customers and business partners. Such actions have impacted our ability to fully integrate businesses we have acquired and may impact those we may acquire in the future. There is no certainty that such actions will be sufficient to mitigate the risks posed by the virus or otherwise be satisfactory to government authorities. If significant portions of our workforce are unable to work effectively, including due to illness, quarantines, social distancing, government actions or other restrictions in connection with COVID-19, our operations will be impacted.

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

Specifically, difficult macroeconomic conditions, such as 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.

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

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 six months ended June 30, 2021 and 2020, we had net income of $24.3 million and a net loss of $264.9 million, respectively. For the years ended December 31, 2020, 2019 and 2018, our net losses were $602.2 million, $242.0 million and $129.4 million, respectively. At June 30, 2021, our accumulated deficit was $1.3 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 $240.6 million, $141.5 million and $63.5 million in 2020, 2019 and 2018, respectively, and selling and marketing expenses of $168.3 million, $122.2 million and $74.4 million in 2020, 2019 and 2018, 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 have experienced and may continue to experience 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, including costs and potential liabilities associated with litigation. Our prior losses and expected future losses have had and may continue to have an adverse effect on our stockholders' equity, working capital and stock price. Our failure to achieve and sustain profitability in the future would negatively affect our business, financial condition, results of operations and cash flows, and could cause the market price of our common stock to decline.

We began operations in January 2010 and commercially launched our initial assay in late November 2013; 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; continue to implement and successfully execute our business and marketing strategy; identify, acquire and successfully integrate companies, assets or technologies in areas that are complementary to our business strategy; successfully enter into other strategic collaborations or relationships; obtain access to capital on acceptable terms and effectively utilize that capital; identify, attract, hire, retain, motivate and successfully integrate additional employees; continue to expand, automate and upgrade our laboratory, technology and data systems; obtain, maintain and expand coverage and reimbursement by healthcare payers; obtain and maintain sufficient payment by partners, institutions and individuals; provide rapid test turnaround times with accurate results at low prices; provide superior customer service; and respond to competitive developments. We cannot assure you that we will be successful in addressing these risks, and the failure to do so could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

We expect capital expenditures and operating expenses to increase over the next several years as we expand our infrastructure, commercial operations, research and development and selling and marketing activities and pursue and integrate acquisitions. We believe our existing cash and cash equivalents as of June 30, 2021, including the net proceeds from our January public offering, our April convertible note issuance 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 credit agreement restrict our ability to incur certain indebtedness and issue certain equity securities. If we raise funds by issuing equity securities, dilution to our stockholders would result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings, if available, could impose significant restrictions on our operations.

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

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

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

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

In connection with certain of our completed acquisitions, we have agreed to pay cash and/or stock consideration that is contingent upon the achievement of specified objectives, such as development objectives, regulatory submissions, regulatory approvals and revenue related to certain products. As of the date of the applicable acquisition, we record a contingent liability representing the estimated fair value of the contingent consideration we expect to pay. On a quarterly basis, we reassess these obligations and, in the event our estimate of the fair value of the contingent consideration changes, we record increases or decreases in the fair value as an adjustment to operating expense, which could have a material impact on our results of operations. As of June 30, 2021, we accrued $429.1 million of contingent consideration, most of which related to milestone payments in the form of our common stock in connection with our acquisition of ArcherDX, and includes stock and cash pursuant to three milestones which were achieved in June 2021 resulting in the issuance of common stock in July 2021. In addition, our actual payments may differ materially from the amount of the contingent liability, which could have a material impact on our results of operations. In particular, the amount of contingent consideration we accrue related to the acquisition of ArcherDX may change depending on the value of our common stock and our assessment of the probability that the remaining milestone will be achieved within the timeframe required by the acquisition agreement.

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

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

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

Since each payer makes its own decision as to whether to establish a policy or enter into a contract to cover our tests, as well as the amount it will reimburse for a test, seeking these approvals is a time-consuming and costly process. In addition, the determination by a payer to cover and the amount it will reimburse for our tests will likely be made on an indication-by-indication basis. To date, we have obtained policy-level reimbursement approval or contractual reimbursement for some indications for our germline tests from most of the large commercial third-party payers in the United States, and the Centers for Medicare & Medicaid Services, or CMS, provides reimbursement for our multi-gene tests for hereditary breast and ovarian cancer-related disorders as well as colon cancer. We believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from third-party payers may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive and may not result in payment. In cases where there is not a contracted rate for reimbursement, there is typically a greater coinsurance or 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.; GeneDx, a subsidiary of OPKO Health, Inc.; Guardant Health, Inc.; Integrated Genetics; Sequenom Inc.; Correlagen Diagnostics, Inc.; and MNG Laboratories, subsidiaries of Laboratory Corporation of America Holdings; Myriad Genetics, Inc.; Natera, Inc.; Perkin Elmer, Inc.; PreventionGenetics, LLC; Progenity, Inc.; and Mount Sinai Genomics, Inc. d/b/a 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 2020 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, technology services, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand as it grows. We may need to continue expanding our sales force to facilitate our growth, and we may have difficulties locating, recruiting, training and retaining sales personnel. Our ability to manage our growth effectively will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. As we grow, any failure of our controls or interruption of our production facilities or systems could have a negative impact on our business and financial operations. We plan to implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain, and failure to complete these activities in a timely and efficient manner could adversely affect our operations. Future growth in our business could also make it difficult for us to maintain our corporate culture. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

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

In the ordinary course of our business, we collect and store sensitive data, including protected health information, or PHI, personally identifiable information, genetic information, credit card information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payers and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based systems. We also communicate PHI and other sensitive patient data through our various customer tools and platforms. In addition to storing and transmitting sensitive data that is subject to multiple legal protections, these applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure, inappropriate modification, and the risk of our being unable to adequately monitor and modify our controls over our critical information. Any technical problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions to our business and operations or exposure to security vulnerabilities. These types of problems may be caused by a variety of factors, including infrastructure changes, intentional or accidental human actions or omissions, software errors, malware, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. 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, including a formal, dedicated enterprise security program, to protect sensitive information from various compromises (including unauthorized access, disclosure, or modification or lack of availability), our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. For example, 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 therein could be accessed by unauthorized parties, altered, publicly disclosed, lost or stolen.

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

Any security compromise that causes an apparent privacy violation could also result in legal claims or proceedings; liability under federal, state, foreign, or multinational laws that regulate the privacy, security, or breach of personal information, such as but not limited to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, state data security and data breach notification laws, the European Union's General Data Protection Regulation, or GDPR, and the UK Data Protection Act of 2018; and related regulatory penalties. Penalties for failure to comply with a requirement of HIPAA or HITECH vary significantly, and, depending on the knowledge and culpability of the HIPAA-regulated entity, may include civil monetary penalties of up to $1.5 million per calendar year for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. Penalties for unfair or deceptive acts or practices under the FTC Act or state Unfair and Deceptive Acts and Practices, or UDAP, statutes may also vary significantly.

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

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

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

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

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, and support our research and development efforts and our clinical laboratory. We believe that our corporate culture fosters innovation, creativity and teamwork. However, as our organization grows, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

We need to scale our infrastructure in advance of demand for our tests, and 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. 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.

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

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

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

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

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

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

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

We anticipate that the future success of our distributed products business will depend in large part on our ability to effectively introduce enhanced or new offerings of IVD products, 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 us to accurately anticipate patients', providers' and, if applicable, payers' attitudes and needs and emerging technology and industry trends. This process is conducted in various stages, and each stage presents the risk that we will not achieve its goals on a timely basis, or at all.

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

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

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

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

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

The marketing, sale and use of our genetic tests could subject us to liability for errors in, misunderstandings of, or inappropriate reliance on, information we provide to clinicians, geneticists or patients, and lead to claims against us if someone were to allege that a test failed to perform as it was designed, if we failed to correctly interpret the test results, if we failed to update the test results due to a reclassification of the variants according to new published guidelines, or if the ordering physician were to misinterpret test results or improperly rely on them when making a clinical decision. In addition, our entry into the reproductive health and pharmacogenetic testing markets expose us to increased liability. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain liability insurance, including for errors and omissions, we cannot assure you that such insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any liability claim, including an errors and omissions liability claim, brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could cause injury to our reputation or cause us to suspend sales of our tests. The occurrence of any of these events could have an adverse effect on our reputation and results of operations.

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

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

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

We may not be able to market or sell our current tests and any future tests we may develop or acquire effectively enough to drive demand sufficient to support our planned growth. We currently sell our tests primarily through our internal sales force. Historically, our sales efforts have been focused primarily on hereditary cancer and more recently on reproductive health. Our efforts to sell our tests to clinicians and patients outside of oncology may not be successful, or may be difficult to do successfully without significant additional selling and marketing efforts and expense. In addition, following the acquisition of ArcherDX, our sales efforts have expanded to include distributed products sold to laboratories. In the past, we have increased our sales force each year in order to drive our growth, and in October 2020, we increased our sales force through the acquisition of ArcherDX. In addition to the efforts of our sales force, future sales will depend in large part on our ability to develop and substantially expand awareness of our company and our tests through alternative strategies including through education of key opinion leaders, through social media-related and online outreach, education and marketing efforts, and through focused channel partner strategies designed to drive demand for our tests. We also plan to continue to spend on consumer advertising in connection with our direct channel to consumers, which could be costly. We have limited experience implementing these types of marketing efforts. We may not be able to drive sufficient levels of revenue using these sales and marketing methods and strategies necessary to support our planned growth, and our failure to do so could limit our revenue and potential profitability.

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

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

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

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

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

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

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

We depend on our information technology systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems for significant elements of our operations, including our laboratory information management system, our bioinformatics analytical software systems, our database of information relating to genetic variations and their role in disease process and drug metabolism, our clinical report optimization systems, our customer-facing web-based software, our customer reporting, and our various customer tools and platforms. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including for example, systems handling human resources, financial controls and reporting, customer relationship management, regulatory compliance and other infrastructure operations. In addition, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design, and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation, and general administrative activities, including financial reporting.

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

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

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

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

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

Our success depends in large part upon the skills, experience and performance of members of our executive management team and others in key leadership positions. The efforts of these persons 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 person insurance for any of our executives or employees. In addition, we do not have a long-term retention agreement in place with our president and chief executive officer.

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

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

- conduct research and development;
- further develop and scale our laboratory processes; and

- further develop and scale our infrastructure to be able to analyze increasingly larger and more diverse amounts of data.

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

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

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

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

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

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

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

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

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

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

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

Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the use of our tests in various countries;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- logistics and regulations associated with shipping samples, including infrastructure conditions, customs and transportation delays;
- limits on our ability to penetrate international markets if we do not to conduct our tests locally;
- natural disasters, including the recent and ongoing outbreak and spreading of COVID-19, 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 June 30, 2021, our total gross deferred tax assets were $418.9 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, our net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets are primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Furthermore, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Some of our prior acquisitions have resulted in an ownership change, and we may experience ownership changes in the future. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with completed acquisitions, or other future transactions in our stock, our ability to utilize NOLs and tax credit carryovers could be further limited by Section 382 of the Internal Revenue Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss and tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. In addition, the Tax Cuts and Jobs Act limits the deduction for NOLs to 80% of current year taxable income and eliminates NOL carrybacks. Also, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks related to government regulation

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

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

Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). 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 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. The VALID Act was re-introduced in a slightly modified form in June 2021, however, 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.

In August 2020, the U.S. Department of Health and Human Services, the parent agency for FDA, announced that the FDA "will not require premarket review of LDTs absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances." It is unclear at this time whether this policy will be retained by the Biden Administration, and if so, when the FDA might seek to begin the notice and comment rulemaking process.

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

The European Union transitions to a new regulation for in vitro diagnostic devices in May 2022, the In Vitro Diagnostic Regulation, or IVDR, which changes the regulatory status of a substantial number of IVDs. The percentage of devices requiring approval from a notified body is estimated to be shifting from 15% of devices under the current directive to between 70% and 90% of devices under the new regulation. Notified bodies must themselves be certified to the new regulation, and few have as of 2021. Consequently, notified bodies may have little or no capacity for new clients. LDTs may newly be considered IVDs and subject to the IVDR, requiring approval from a notified body to be marketed. If we are unable to secure a notified body or complete registration in time for implementation of the new regulation, our existing tests cannot be marketed in Europe.

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

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers, for our tests. We have current CLIA certifications to conduct our tests at our laboratories in San Francisco and Irvine, California; Golden, Colorado; Iselin, New Jersey; and 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 in-state licenses to conduct testing in California, New Jersey and Washington. California, New Jersey and Washington laws establish standards for day-to-day operation of our clinical reference laboratories in San Francisco and Irvine, in Iselin, and in Seattle, respectively, which include the training and skills required of personnel and quality control. (Our Colorado laboratory is not required to maintain a state clinical laboratory license.)

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

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

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

Seeking foreign regulatory clearance, authorization or approval could result in difficulties and costs for us and our collaborators and require additional preclinical studies, clinical trials or clinical investigations which could be costly and time-consuming. Regulatory requirements and ethical approval obligations can vary widely from country to country and could delay or prevent the introduction of certain of our products and services in those countries. The foreign regulatory clearance, authorization or approval process involves all of the risks and uncertainties associated with FDA clearance, authorization or approval. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required regulatory clearances, authorizations or approvals in international markets, or if those approvals are delayed, our target market will be reduced and our ability to realize the full market potential of our products and services will be unrealized.

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

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

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

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

Moreover, development of the data necessary to obtain regulatory clearance and/or approval of an IVD, 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 our product candidates, any of which may materially impact our ability to realize the expected benefits of our acquisition of ArcherDX.

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

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

- HIPAA, which establishes comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions;
- amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators and expand vicarious liability, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- the GDPR, which imposes strict privacy and security requirements on controllers and processors of personal data, including enhanced protections for "special categories" of personal data, including sensitive information such as health and genetic information of data subjects;
- the CCPA, which, among other things, regulates how subject businesses may collect, use, and disclose the personal information of consumers who reside in California, affords rights to consumers that they may exercise against businesses that collect their information, and requires implementation of reasonable security measures to safeguard personal information of California consumers;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual, for the furnishing of or arrangement for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering, arranging for, or recommend purchasing, leasing or ordering, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program;

- The Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and reaches beyond federal health care programs, to include private insurance;
- the federal physician self-referral law, known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity unless an exception applies, and prohibits an entity from billing for designated health services furnished pursuant to a prohibited referral;
- the federal false claims law, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the HIPAA fraud and abuse provisions, which create new federal criminal statutes that prohibit, among other things, defrauding health care benefit programs, willfully obstructing a criminal investigation of a healthcare offense and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payer, including private insurers;
- the 21st Century Cures Act information blocking prohibition, which prohibits covered actors from engaging in certain practices that are likely to interfere with the access, exchange, or use of electronic health information;
- the Physician Payments Sunshine Act and similar state laws that require reporting of certain payments and other transfers of value made by applicable manufacturers, directly or indirectly, to or on behalf of covered recipients including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- state laws that limit or prohibit the provision of certain payments and other transfers of value to certain covered healthcare providers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing clinicians for testing that they order; waiving coinsurance, copayments, deductibles and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payers; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

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

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

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

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA (as amended 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 (e.g., therapeutic chemotherapy). The NCD also gives MACs the authority to establish local coverage for NGS-based somatic cancer assays that are not FDA-approved or FDA-cleared companion diagnostics when offered to patients meeting the above-referenced criteria. It appears that NGS-based somatic cancer tests provided for patients with cancer that do not meet the above-referenced criteria, e.g., patients with earlier stage cancers, are currently nationally non-covered under the NCD.

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. Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the clinical laboratory fee schedule, which would increase our billing and collecting costs and decrease our revenue. Further, it is possible that additional governmental action be taken in response to the COVID-19 pandemic.

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

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

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

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

Risks related to our intellectual property

One of 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 acquisition of ArcherDX.

ArcherDX's AMP chemistry underlies all of its RUO 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. On October 13, 2020, the court issued an order denying ArcherDX's motion for dismissal of Natera's infringement claims against STRATAFIDE, PCM, and ArcherMET, and declined to enter judgment that U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, and U.S. Patent No. 10,590,482 are invalid. On January 12, 2021, the court issued an order granting Natera leave to amend its complaint to add Invitae as a co-defendant and plead allegations that ArcherDX and Invitae induce end-users to infringe the patents-in-suit. Natera filed its Second Amended Complaint on the same day and served Invitae on January 15, 2021. The litigations have now been consolidated for all purposes. A claim construction briefing order was issued on June 28, 2021. Discovery is ongoing, and trial has been scheduled for May 2022.

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

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 acquisition of ArcherDX, as well as our financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks related to being a public company

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

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

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

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

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

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

Risks related to our indebtedness

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

In October 2020, we entered into a credit agreement with Perceptive Credit Holdings II, LP, pursuant to which we borrowed an aggregate principal amount of $135.0 million, or the 2020 Term Loan. The 2020 Term Loan is secured by a first priority lien on all of our and our subsidiaries' assets (including our intellectual property) and is guaranteed by our subsidiaries, in each case, excluding certain excluded assets and immaterial subsidiaries. If the 2020 Term Loan is prepaid, we may be required to pay a prepayment fee of up to 6% and a make-whole fee, in each case depending on when the prepayment is made.

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

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

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

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

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

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

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

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

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

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

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

General risk factors

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

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

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

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

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

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

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

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, the terms of our credit agreement restrict our ability to pay dividends. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

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

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

- authorize our board of directors to issue, without further action by the stockholders, up to 20,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, our 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.

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

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of June 30, 2021, we had outstanding 203.0 million shares of our common stock, options to purchase 4.5 million shares of our common stock (of which 4.0 million were exercisable as of that date), outstanding restricted stock units, or RSUs, representing 8.3 million shares of our common stock (which includes an estimated number of RSUs, subject to certain employee's continued service with us, or time-based RSUs, and RSUs that are performance based RSUs, or PRSUs, granted in connection with an acquisition) and outstanding Series A convertible preferred stock convertible into 0.1 million shares of our common stock. The foregoing does not include shares that may be issuable in connection with indemnification hold-backs and contingent consideration related to our acquisitions other than ArcherDX, up to 8.0 million shares which may be issuable upon the achievement of certain milestones related to our acquisition of ArcherDX and 13.8 million shares issued in July 2021 related to the achievement of certain milestones related to our acquisition of ArcherDX, or shares that may be issuable in the future in connection with our convertible senior notes. Also not included are the shares issued or issuable in connection with acquisitions after June 30, 2021, including approximately 0.1 million shares of our common stock that we will register for resale following the filing of this report, or up to $400.0 million of our common stock that may be sold pursuant to the 2021 Sales Agreement. The sale or the availability for sale of a large number of shares of our common stock in the public market could cause the price of our common stock to decline.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds.

During the three months ended June 30, 2021, we issued an aggregate of 2,005,832 shares of our common stock upon the closing of the acquisition of Genosity. This issuance was in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933.

ITEM 6. Exhibits.

Exhibit Number	Description
4.1	Indenture, dated as of April 8, 2021, between Invitae Corporation and U.S. Bank National Association (including form of Note) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on April 8, 2021).
10.1	Investment Agreement, dated as of April 3, 2021, by and among Invitae Corporation and parties listed therein (including form of Indenture relating to 1.50% Convertible Senior Notes due 2028) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 5, 2021).
10.2	Amendment No. 1, dated as of April 3, 2021 , by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent, to Credit Agreement and Guaranty, dated as of October 2, 2020, by and among Invitae Corporation, the subsidiary guarantors from time to time party thereto, the lenders party thereto and Perceptive Credit Holdings III, LP, as the Administrative Agent (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on April 5, 2021).
10.3	Lease Agreement, dated as of April 20, 2021, by and between Invitae Corporation and APB Owned LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 23, 2021).
10.4#	Offer Letter, dated May 19, 2021, between Invitae Corporation and Roxi Wen (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 11, 2021).
10.5#	Change in Control and Severance Agreement, between Invitae Corporation and Sean George.
10.6#	Form of Change in Control and Severance Agreement, between Invitae Corporation and certain officers.
10.7	Sales Agreement, dated May 4, 2021, between Invitae Corporation and Cowen and Company, LLC (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed on May 5, 2021).
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).

# Indicates a management contract or compensatory plan or arrangement.

* 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/ Yafei (Roxi) Wen
Yafei (Roxi) Wen
Chief Financial Officer
Principal Financial Officer

Date: August 9, 2021

Exhibit 10.5

INVITAE CORPORATION

CHANGE OF CONTROL AND SEVERANCE AGREEMENT

This Change of Control Severance Agreement (this "Agreement") is made and entered into effective as of April 23, 2021 (the "Effective Date"), by and between Sean George ("Executive") and Invitae Corporation, a Delaware corporation (the "Company"). Certain capitalized terms used in this Agreement are defined in Section 1 below.

RECITALS

A. It is expected that the Company from time to time will consider the possibility of a Change of Control. The Board of Directors of the Company (the "Board") recognizes that such consideration can be a distraction to Executive and can cause Executive to consider alternative employment opportunities.

B. The Board believes that it is in the best interests of the Company and its shareholders to provide Executive with an incentive to continue Executive's employment and to maximize the value of the Company upon a Change of Control for the benefit of its shareholders.

C. In order to provide Executive with enhanced financial security and sufficient encouragement to remain with the Company notwithstanding the possibility of a Change of Control, the Board believes that it is imperative to provide Executive with certain severance and other benefits upon Executive's termination of employment in connection with a Change of Control.

D. The Board also believes it is in the best interests of the Company and its shareholders to provide Executive with severance upon an involuntary termination other than in connection with a Change of Control.

AGREEMENT

In consideration of the mutual covenants herein contained and the continued employment of Executive by the Company, the parties agree as follows:

1. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) Cause. "Cause" shall mean Executive's (i) commission of a felony, an act involving moral turpitude, or an act constituting common law fraud, and which has an adverse effect on the business or affairs of the Company or its affiliates or stockholders; (ii) intentional or willful misconduct or refusal to follow the lawful instructions of the Board that is not cured within thirty (30) days following written notice from the Board; (iii) commission of any violation of a company policy that has a material adverse effect on the business or reputation of the Company or (iv) intentional breach of Company confidential information obligations which has

an adverse effect on the Company or its affiliates or stockholders. For these purposes, no act or failure to act shall be considered "intentional or willful" unless it is done, or omitted to be done, in bad faith without a reasonable belief that the action or omission is in the best interests of the Company.

(b) Change of Control. "Change of Control" shall mean the occurrence of any of the following events:

(i) A change in the composition of the Board occurs, as a result of which fewer than one-half of the incumbent directors are directors who either:

(A) had been directors of the Company on the "look-back date" (as defined below) (the "original directors"); or

(B) were elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the aggregate of the original directors who were still in office at the time of the election or nomination and the directors whose election or nomination was previously so approved (the "continuing directors");

provided, however, that for this purpose, the "original directors" and "continuing directors" shall not include any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or

(ii) Any "person" (as defined below) who by the acquisition or aggregation of securities, is or becomes the "beneficial owner" (as defined in Rule 13d-3 under the Securities Exchange Act of 1934 (the "Exchange Act")), directly or indirectly, of securities of the Company representing 50% or more of the combined voting power of the Company's then outstanding securities ordinarily (and apart from rights accruing under special circumstances) having the right to vote at elections of directors (the "Base Capital Stock"); except that any change in the relative beneficial ownership of the Company's securities by any person resulting solely from a reduction in the aggregate number of outstanding shares of Base Capital Stock, and any decrease thereafter in such person's ownership of securities, shall be disregarded until such person increases in any manner, directly or indirectly, such person's beneficial ownership of any securities of the Company; or

(iii) the consummation of a merger or consolidation of the Company or a Subsidiary of the Company with or into another entity or any other corporate reorganization, if persons who were not stockholders of the Company immediately prior to such merger, consolidation or other reorganization own immediately after such merger, consolidation or other reorganization 50% or more of the voting power of the outstanding securities of each of:

(A) the Company (or its successor) and

(B) any direct or indirect parent corporation of the Company (or its successor); or

(iv) The sale, transfer or other disposition of all or substantially all of the Company's assets.

For purposes of subsection 1(b)(i) above, the term "look-back date" shall mean the date 24 months prior to the date of the event that may constitute a Change of Control.
For purposes of subsection 1(b)(ii)) above, the term "person" shall have the same meaning as when used in Sections 13(d) and 14(d) of the Exchange Act but shall exclude (1) a trustee or other fiduciary holding securities under an employee benefit plan maintained by the Company or a parent or subsidiary and (2) a corporation owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of the stock.

Any other provision of this Section 1(b) notwithstanding, a transaction shall not constitute a Change of Control if its sole purpose is to change the state of the Company's incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction, and a Change of Control shall not be deemed to occur if the Company files a registration statement with the United States Securities and Exchange Commission for the initial or secondary public offering of securities or debt of the Company to the public.

(c) Disability. "Disability" shall mean "disability" within the meaning of Section 22(e)(3) of the Code

(d) Equity Award. "Equity Award" shall mean Executive's awards of options, stock appreciation rights, restricted shares or stock units with respect to the Company or its successor, or the direct or indirect parent of either, or of any deferred compensation into which such stock options, stock appreciation rights, restricted shares or stock units were converted upon or prior to a Change of Control.

(e) Involuntary Termination. "Involuntary Termination" shall mean:

(i) a material reduction in Executive's title, duties, authorities or responsibilities as the Chief Executive Officer of the Company without the Executive's consent;

(ii) without Executive's express written consent, a reduction by the Company of Executive's base compensation of more than ten percent (10%), unless such reduction in base compensation is part of a general reduction in compensation applicable to senior executives of the Company;

(iii) without Executive's express written consent, the relocation of Executive's principal place of employment to a facility or a location more than fifty (50) miles from its location as of the Effective Date or, on or following a Change of Control, from its location immediately prior to such Change of Control;

(iv) any termination of Executive by the Company which is not effected for Cause; or

(v) the failure of the Company to obtain the assumption of this Agreement or any other agreement between the Company and Executive by any successors contemplated in Section 10 below.

A termination shall not be considered an "Involuntary Termination" unless Executive provides notice to the Company of the existence of the condition described in subsections (i), (ii), (iii) or (iv) above within ninety (90) days of the initial existence of such condition, the Company fails to remedy the condition within thirty (30) days following the receipt of such notice, and Executive terminates employment within one-hundred eighty (180) days following the initial existence of such condition. A termination due to death or disability shall not be considered an Involuntary Termination.

(f) Termination Date. "Termination Date" shall mean Executive's "separation from service" within the meaning of that term under Section 409A of the Internal Revenue Code of 1986, as amended (the "Code").

2. Term of Agreement. This Agreement shall terminate on the third anniversary of the Effective Date, unless mutually renewed by the parties.

3. At-Will Employment. The Company and Executive acknowledge that Executive's employment is and shall continue to be at-will, as defined under applicable law.

4. Change of Control Related Benefits

(a) Effect of Change of Control on Performance-Based Equity Awards. If Executive is either employed at the time of a Change of Control or Executive's employment with the Company terminates as a result of an Involuntary Termination on or within three (3) months prior to a Change of Control, and provided that in the case of such Involuntary Termination the Executive signs and does not revoke a release in a form approved by the Company (a "Release") that has become irrevocable within sixty (60) days following the later of the Change of Control or the Termination Date, then all of Executive's Equity Awards subject to vesting based on performance shall have their performance criteria deemed satisfied at 100% of target for any unfinished performance period and such Equity Awards will convert to time-based vesting on such vesting schedule as specified in the applicable Equity Award agreement, subject to the provisions of Section 4(b). The portion of any performance-based Equity Award for which the performance condition is not deemed satisfied pursuant to this Section 4(a) (if any) will be forfeited. The effective date of the foregoing vesting credit and forfeiture will be the date of the Change of Control.

(b) Involuntary Termination in Connection with a Change of Control. If Executive's employment with the Company terminates as a result of an Involuntary Termination either on or at any time within twelve months (12) months after a Change of Control, or within three (3) months prior to a Change of Control, and Executive signs and does not revoke a Release that has become irrevocable within sixty (60) days following the later of the Change of Control or the Termination Date, then Executive shall be entitled to the following severance benefits, subject to Section 9 below:

(i) 150% of Executive's annual base salary (as in effect prior to any reduction that constitutes a basis for Involuntary Termination pursuant to this Agreement), payable in a lump sum on the sixtieth (60th) day following the later of the Termination Date or the Change of Control;

(ii) any earned but unpaid annual bonus for any annual bonus period which had ended prior to the Termination Date, which amount shall be paid at such time as annual bonuses are paid to other senior executives of the Company;

(iii) all of Executive's outstanding Equity Awards subject to time-based vesting (including any Equity Awards converted to time-based vesting pursuant to Section 4(a)) will become fully vested and exercisable; provided, however, that notwithstanding any contrary term of the Equity Award agreement, if Executive is entitled to accelerated vesting under this Section 4(b) as a result of an Involuntary Termination within three (3) months prior to a Change of Control: (1) the portion of the Equity Award subject to such accelerated vesting shall not be forfeited or terminated upon the Termination Date pending the Change of Control, (2) the accelerated vesting shall be deemed to take place immediately prior to the effective date of the Change of Control, and (3) the period within which the Equity Award may be exercised following the Termination Date, if applicable, will expire no less than one (1) month following the effective date of the Change of Control (but no later than the expiration of the term of the Equity Award); and

(iv) a lump sum payment equal to eighteen (18) months of premiums under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or corresponding provision of state law ("COBRA") for health insurance coverage for Executive and Executive's eligible dependents, at the same level and for the same eligible dependents covered as of Executive's Termination Date. If Executive is eligible and chooses to continue health coverage through COBRA, Executive is solely responsible for timely electing COBRA continuing coverage and for making all COBRA premium payments.

5. Involuntary Termination Apart from a Change of Control. If Executive's employment with the Company terminates as a result of an Involuntary Termination that occurs more than three (3) months prior to or twelve (12) months after a Change of Control, and Executive signs and does not revoke a Release that has become irrevocable within sixty (60) days following the Termination Date, then Executive shall be entitled to the following severance benefits, subject to Section 9 below:

(a) 150% of Executive's annual base salary (as in effect prior to any reduction that constitutes a basis for Involuntary Termination pursuant to this Agreement), payable in a lump sum on the sixtieth (60th) day following the Termination Date;

(b) any earned but unpaid annual bonus for any annual bonus period which had ended prior to the Termination Date, which amount shall be paid at such time as annual bonuses are paid to other senior executives of the Company; and

(c) a lump sum payment equal to eighteen (18) months of premiums under COBRA for health insurance coverage for Executive and Executive's eligible dependents, at the same level and for the same eligible dependents covered as of Executive's Termination Date. If Executive is eligible and chooses to continue health coverage through COBRA, Executive is solely responsible for timely electing COBRA continuing coverage and for making all COBRA premium payments.

6. Mutually Exclusive Benefits. For the avoidance of doubt, the benefits afforded under Sections 4(b) and 5 are mutually exclusive. If Executive has an Involuntary Termination within three (3) months prior to a Change of Control and becomes entitled to cash severance pursuant to Section 4(b), but already received cash severance pursuant to Section 5, the amount of the cash severance payable pursuant to Section 4(b) shall be offset by the amount already paid, subject to compliance with Section 409A of the Code.

7. Accrued Wages and Vacation; Expenses. If Executive's employment with the Company terminates, without regard to the reason for, or the timing of, Executive's termination of employment, then (i) the Company shall pay Executive any unpaid wages due for periods prior to the Termination Date; (ii) the Company shall pay Executive all of Executive's accrued and unused vacation through the Termination Date; and (iii) following submission of proper expense reports by Executive, the Company shall reimburse Executive for all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the Termination Date. These payments shall be made promptly upon termination and within the period of time mandated by law.

8. Limitation on Payments. In the event that the severance and other benefits provided for in this Agreement or otherwise payable to Executive (i) constitute "parachute payments" within the meaning of Section 280G of the Code and (ii) would be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then Executive's benefits under this Agreement shall be either:

(a) delivered in full or

(b) delivered as to such lesser extent which would result in no portion of such benefits being subject to the Excise Tax,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by Executive on an after-tax basis, of the greatest amount of benefits, notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code.

Unless the Company and Executive otherwise agree in writing, any determination required under this Section 8 shall be made in writing by the Company's independent public accountants (the "Accountants"), whose determination shall be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required by this Section 8, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning

the application of Sections 280G and 4999 of the Code. The Company and Executive shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section 8. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section 8. In the event that a reduction is required, the reduction shall be applied first to any benefits that are not subject to Section 409A of the Code, and then shall be applied to benefits (if any) that are subject to Section 409A of the Code, with the benefits payable latest in time subject to reduction first.

9. Section 409A; Delayed Commencement of Benefits. The parties intend that any amounts payable hereunder comply with or are exempt from Section 409A of the Code ("Section 409A"), and this Agreement shall be administered accordingly. In the event that any changes to this Agreement or any additional terms are required to ensure that a payment is either exempt from or complies with Section 409A so that the penalty taxes under Section 409A(a)(1)(B) are not applied, you hereby agree that the Company may make such change or incorporate such terms (by reference or otherwise) without your consent. Each payment contemplated by this Agreement will be treated as a separate payment for purposes of Section 409A. Notwithstanding anything herein to the contrary, the Company shall have no liability to the Executive or to any other person if the payments and benefits provided in this Agreement that are intended to be exempt from or compliant with Section 409A are not so exempt or compliant, as applicable.

10. Successors.

(a) Company's Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the Company's obligations under this Agreement and agree expressly to perform the Company's obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets which executes and delivers the assumption agreement described in this subsection (a) or which becomes bound by the terms of this Agreement by operation of law.

(b) Executive's Successors. Without the written consent of the Company, Executive shall not assign or transfer this Agreement or any right or obligation under this Agreement to any other person or entity. Notwithstanding the foregoing, the terms of this Agreement and all rights of Executive hereunder shall inure to the benefit of, and be enforceable by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

11. Notices.

(a) General. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. In the case of Executive, mailed notices shall be addressed to Executive at the

home address which he most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

(b) Notice of Termination. Any termination by the Company for Cause or by Executive as a result of an Involuntary Termination shall be communicated by a notice of termination to the other party hereto given in accordance with this Section 11. Such notice shall indicate the specific termination provision in this Agreement relied upon, shall set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision so indicated, and shall specify the Termination Date (which shall be not more than thirty (30) days after the giving of such notice). The failure by Executive to include in the notice any fact or circumstance which contributes to a showing of Involuntary Termination shall not waive any right of Executive hereunder or preclude Executive from asserting such fact or circumstance in enforcing Executive's rights hereunder, subject to the requirements of Section 1(e).

12. Arbitration. Any controversy involving the construction or application of any terms, covenants or conditions of this Agreement, or any claims arising out of any alleged breach of this Agreement, will be governed by the rules of the American Arbitration Association and submitted to and settled by final and binding arbitration in San Francisco, California, except that any alleged breach of Executive's confidential information obligations shall not be submitted to arbitration and instead the Company may seek all legal and equitable remedies, including without limitation, injunctive relief.

13. Miscellaneous Provisions.

(a) No Duty to Mitigate. Executive shall not be required to mitigate the amount of any payment contemplated by this Agreement, nor shall any such payment be reduced by any earnings that Executive may receive from any other source.

(b) Waiver. No provision of this Agreement may be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Integration. This Agreement supersedes and replaces any prior agreements, representation or understandings, whether written, oral, express or implied, between Executive and the Company and constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof.

(d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the internal substantive laws, but not the conflicts of law rules, of the State of California.

(e) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(f) Employment Taxes. All payments made pursuant to this Agreement shall be subject to withholding of applicable income and employment taxes.

(g) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

COMPANY:

INVITAE CORPORATION
By: /s/ Tom Brida
Name: Tom Brida
Title: General Counsel

EXECUTIVE:

/s/ Sean George
Signature
Sean George
Printed Name: Sean George
Title: President & CEO

Exhibit 10.6

INVITAE CORPORATION

CHANGE OF CONTROL AND SEVERANCE AGREEMENT

This Change of Control Severance Agreement (this "Agreement") is made and entered into effective as of _____ (the "Effective Date"), by and between _____ ("Executive") and Invitae Corporation, a Delaware corporation (the "Company"). Certain capitalized terms used in this Agreement are defined in Section 1 below.

RECITALS

A. It is expected that the Company from time to time will consider the possibility of a Change of Control. The Board of Directors of the Company (the "Board") recognizes that such consideration can be a distraction to Executive and can cause Executive to consider alternative employment opportunities.

B. The Board believes that it is in the best interests of the Company and its shareholders to provide Executive with an incentive to continue Executive's employment and to maximize the value of the Company upon a Change of Control for the benefit of its shareholders.

C. In order to provide Executive with enhanced financial security and sufficient encouragement to remain with the Company notwithstanding the possibility of a Change of Control, the Board believes that it is imperative to provide Executive with certain severance and other benefits upon Executive's termination of employment in connection with a Change of Control.

D. The Board also believes it is in the best interests of the Company and its shareholders to provide Executive with severance upon an involuntary termination other than in connection with a Change of Control.

AGREEMENT

In consideration of the mutual covenants herein contained and the continued employment of Executive by the Company, the parties agree as follows:

1. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) Cause. "Cause" shall mean Executive's (i) commission of a felony, an act involving moral turpitude, or an act constituting common law fraud, and which has an adverse effect on the business or affairs of the Company or its affiliates or stockholders; (ii) intentional or willful misconduct or refusal to follow the lawful instructions of the Board or the Chief Executive Officer that is not cured within thirty (30) days following written notice from the Board or the Chief Executive Officer; (iii) commission of any violation of a company policy that has a material adverse effect on the business or reputation of the Company or (iv) intentional

breach of Company confidential information obligations which has an adverse effect on the Company or its affiliates or stockholders. For these purposes, no act or failure to act shall be considered "intentional or willful" unless it is done, or omitted to be done, in bad faith without a reasonable belief that the action or omission is in the best interests of the Company.

(b) Change of Control. "Change of Control" shall mean the occurrence of any of the following events:

(i) A change in the composition of the Board occurs, as a result of which fewer than one-half of the incumbent directors are directors who either:

(A) had been directors of the Company on the "look-back date" (as defined below) (the "original directors"); or

(B) were elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the aggregate of the original directors who were still in office at the time of the election or nomination and the directors whose election or nomination was previously so approved (the "continuing directors");

provided, however, that for this purpose, the "original directors" and "continuing directors" shall not include any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or

(ii) Any "person" (as defined below) who by the acquisition or aggregation of securities, is or becomes the "beneficial owner" (as defined in Rule 13d-3 under the Securities Exchange Act of 1934 (the "Exchange Act")), directly or indirectly, of securities of the Company representing 50% or more of the combined voting power of the Company's then outstanding securities ordinarily (and apart from rights accruing under special circumstances) having the right to vote at elections of directors (the "Base Capital Stock"); except that any change in the relative beneficial ownership of the Company's securities by any person resulting solely from a reduction in the aggregate number of outstanding shares of Base Capital Stock, and any decrease thereafter in such person's ownership of securities, shall be disregarded until such person increases in any manner, directly or indirectly, such person's beneficial ownership of any securities of the Company; or

(iii) the consummation of a merger or consolidation of the Company or a Subsidiary of the Company with or into another entity or any other corporate reorganization, if persons who were not stockholders of the Company immediately prior to such merger, consolidation or other reorganization own immediately after such merger, consolidation or other reorganization 50% or more of the voting power of the outstanding securities of each of:

(A) the Company (or its successor) and

(B) any direct or indirect parent corporation of the Company (or its successor); or

(iv) The sale, transfer or other disposition of all or substantially all of the Company's assets.

For purposes of subsection 1(b)(i) above, the term "look-back date" shall mean the date 24 months prior to the date of the event that may constitute a Change of Control.
For purposes of subsection 1(b)(ii)) above, the term "person" shall have the same meaning as when used in Sections 13(d) and 14(d) of the Exchange Act but shall exclude (1) a trustee or other fiduciary holding securities under an employee benefit plan maintained by the Company or a parent or subsidiary and (2) a corporation owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of the stock.

Any other provision of this Section 1(b) notwithstanding, a transaction shall not constitute a Change of Control if its sole purpose is to change the state of the Company's incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction, and a Change of Control shall not be deemed to occur if the Company files a registration statement with the United States Securities and Exchange Commission for the initial or secondary public offering of securities or debt of the Company to the public.

(c) Disability. "Disability" shall mean "disability" within the meaning of Section 22(e)(3) of the Code

(d) Equity Award. "Equity Award" shall mean Executive's awards of options, stock appreciation rights, restricted shares or stock units with respect to the Company or its successor, or the direct or indirect parent of either, or of any deferred compensation into which such stock options, stock appreciation rights, restricted shares or stock units were converted upon or prior to a Change of Control.

(e) Involuntary Termination. "Involuntary Termination" shall mean:

(i) a material reduction in Executive's title, duties, authorities or responsibilities relative to Executive's title, duties, authorities, or responsibilities as of the Effective Date without the Executive's consent;

(ii) without Executive's express written consent, a reduction by the Company of Executive's base compensation of more than ten percent (10%), unless such reduction in base compensation is part of a general reduction in compensation applicable to senior executives of the Company;

(iii) without Executive's express written consent, the relocation of Executive's principal place of employment to a facility or a location more than fifty (50) miles from its location as of the Effective Date or, on or following a Change of Control, from its location immediately prior to such Change of Control;

(iv) any termination of Executive by the Company which is not effected for Cause; or

(v) the failure of the Company to obtain the assumption of this Agreement or any other agreement between the Company and Executive by any successors contemplated in Section 10 below.

A termination shall not be considered an "Involuntary Termination" unless Executive provides notice to the Company of the existence of the condition described in subsections (i), (ii), (iii) or (iv) above within ninety (90) days of the initial existence of such condition, the Company fails to remedy the condition within thirty (30) days following the receipt of such notice, and Executive terminates employment within one-hundred eighty (180) days following the initial existence of such condition. A termination due to death or disability shall not be considered an Involuntary Termination.

(f) Termination Date. "Termination Date" shall mean Executive's "separation from service" within the meaning of that term under Section 409A of the Internal Revenue Code of 1986, as amended (the "Code").

2. Term of Agreement. This Agreement shall terminate on the third anniversary of the Effective Date, unless mutually renewed by the parties.

3. At-Will Employment. The Company and Executive acknowledge that Executive's employment is and shall continue to be at-will, as defined under applicable law.

4. Change of Control Related Benefits

(a) Effect of Change of Control on Performance-Based Equity Awards. If Executive is either employed at the time of a Change of Control or Executive's employment with the Company terminates as a result of an Involuntary Termination on or within three (3) months prior to a Change of Control, and provided that in the case of such Involuntary Termination the Executive signs and does not revoke a release in a form approved by the Company (a "Release") that has become irrevocable within sixty (60) days following the later of the Change of Control or the Termination Date, then all of Executive's Equity Awards subject to vesting based on performance shall have their performance criteria deemed satisfied at 100% of target for any unfinished performance period and such Equity Awards will convert to time-based vesting on such vesting schedule as specified in the applicable Equity Award agreement, subject to the provisions of Section 4(b). The portion of any performance-based Equity Award for which the performance condition is not deemed satisfied pursuant to this Section 4(a) (if any) will be forfeited. The effective date of the foregoing vesting credit and forfeiture will be the date of the Change of Control.

(b) Involuntary Termination in Connection with a Change of Control. If Executive's employment with the Company terminates as a result of an Involuntary Termination either on or at any time within twelve months (12) months after a Change of Control, or within three (3) months prior to a Change of Control, and Executive signs and does not revoke a

Release that has become irrevocable within sixty (60) days following the later of the Change of Control or the Termination Date, then Executive shall be entitled to the following severance benefits, subject to Section 9 below:

(i) 100% of Executive's annual base salary (as in effect prior to any reduction that constitutes a basis for Involuntary Termination pursuant to this Agreement), payable in a lump sum on the sixtieth (60th) day following the later of the Termination Date or the Change of Control;

(ii) any earned but unpaid annual bonus for any annual bonus period which had ended prior to the Termination Date, which amount shall be paid at such time as annual bonuses are paid to other senior executives of the Company;

(iii) all of Executive's outstanding Equity Awards subject to time-based vesting (including any Equity Awards converted to time-based vesting pursuant to Section 4(a)) will become fully vested and exercisable; provided, however, that notwithstanding any contrary term of the Equity Award agreement, if Executive is entitled to accelerated vesting under this Section 4(b) as a result of an Involuntary Termination within three (3) months prior to a Change of Control: (1) the portion of the Equity Award subject to such accelerated vesting shall not be forfeited or terminated upon the Termination Date pending the Change of Control, (2) the accelerated vesting shall be deemed to take place immediately prior to the effective date of the Change of Control, and (3) the period within which the Equity Award may be exercised following the Termination Date, if applicable, will expire no less than one (1) month following the effective date of the Change of Control (but no later than the expiration of the term of the Equity Award); and

(iv) a lump sum payment equal to twelve (12) months of premiums under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or corresponding provision of state law ("COBRA") for health insurance coverage for Executive and Executive's eligible dependents, at the same level and for the same eligible dependents covered as of Executive's Termination Date. If Executive is eligible and chooses to continue health coverage through COBRA, Executive is solely responsible for timely electing COBRA continuing coverage and for making all COBRA premium payments.

5. Involuntary Termination Apart from a Change of Control. If Executive's employment with the Company terminates as a result of an Involuntary Termination that occurs more than three (3) months prior to or twelve (12) months after a Change of Control, and Executive signs and does not revoke a Release that has become irrevocable within sixty (60) days following the Termination Date, then Executive shall be entitled to the following severance benefits, subject to Section 9 below:

(a) 100% of Executive's annual base salary (as in effect prior to any reduction that constitutes a basis for Involuntary Termination pursuant to this Agreement), payable in a lump sum on the sixtieth (60th) day following the Termination Date;

(b) any earned but unpaid annual bonus for any annual bonus period which had ended prior to the Termination Date, which amount shall be paid at such time as annual bonuses are paid to other senior executives of the Company; and

(c) a lump sum payment equal to twelve (12) months of premiums under COBRA for health insurance coverage for Executive and Executive's eligible dependents, at the same level and for the same eligible dependents covered as of Executive's Termination Date. If Executive is eligible and chooses to continue health coverage through COBRA, Executive is solely responsible for timely electing COBRA continuing coverage and for making all COBRA premium payments.

6. Mutually Exclusive Benefits. For the avoidance of doubt, the benefits afforded under Sections 4(b) and 5 are mutually exclusive. If Executive has an Involuntary Termination within three (3) months prior to a Change of Control and becomes entitled to cash severance pursuant to Section 4(b), but already received cash severance pursuant to Section 5, the amount of the cash severance payable pursuant to Section 4(b) shall be offset by the amount already paid, subject to compliance with Section 409A of the Code.

7. Accrued Wages and Vacation; Expenses. If Executive's employment with the Company terminates, without regard to the reason for, or the timing of, Executive's termination of employment, then (i) the Company shall pay Executive any unpaid wages due for periods prior to the Termination Date; (ii) the Company shall pay Executive all of Executive's accrued and unused vacation through the Termination Date; and (iii) following submission of proper expense reports by Executive, the Company shall reimburse Executive for all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the Termination Date. These payments shall be made promptly upon termination and within the period of time mandated by law.

8. Limitation on Payments. In the event that the severance and other benefits provided for in this Agreement or otherwise payable to Executive (i) constitute "parachute payments" within the meaning of Section 280G of the Code and (ii) would be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then Executive's benefits under this Agreement shall be either:

(a) delivered in full or

(b) delivered as to such lesser extent which would result in no portion of such benefits being subject to the Excise Tax,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by Executive on an after-tax basis, of the greatest amount of benefits, notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code.

Unless the Company and Executive otherwise agree in writing, any determination required under this Section 8 shall be made in writing by the Company's independent public

accountants (the "Accountants"), whose determination shall be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required by this Section 8, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Executive shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section 8. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section 8. In the event that a reduction is required, the reduction shall be applied first to any benefits that are not subject to Section 409A of the Code, and then shall be applied to benefits (if any) that are subject to Section 409A of the Code, with the benefits payable latest in time subject to reduction first.

9. Section 409A; Delayed Commencement of Benefits. The parties intend that any amounts payable hereunder comply with or are exempt from Section 409A of the Code ("Section 409A"), and this Agreement shall be administered accordingly. In the event that any changes to this Agreement or any additional terms are required to ensure that a payment is either exempt from or complies with Section 409A so that the penalty taxes under Section 409A(a)(1)(B) are not applied, you hereby agree that the Company may make such change or incorporate such terms (by reference or otherwise) without your consent. Each payment contemplated by this Agreement will be treated as a separate payment for purposes of Section 409A. Notwithstanding anything herein to the contrary, the Company shall have no liability to the Executive or to any other person if the payments and benefits provided in this Agreement that are intended to be exempt from or compliant with Section 409A are not so exempt or compliant, as applicable.

10. Successors.

(a) Company's Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the Company's obligations under this Agreement and agree expressly to perform the Company's obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets which executes and delivers the assumption agreement described in this subsection (a) or which becomes bound by the terms of this Agreement by operation of law.

(b) Executive's Successors. Without the written consent of the Company, Executive shall not assign or transfer this Agreement or any right or obligation under this Agreement to any other person or entity. Notwithstanding the foregoing, the terms of this Agreement and all rights of Executive hereunder shall inure to the benefit of, and be enforceable by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

11. Notices.

(a) General. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. In the case of Executive, mailed notices shall be addressed to Executive at the home address which he most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

(b) Notice of Termination. Any termination by the Company for Cause or by Executive as a result of an Involuntary Termination shall be communicated by a notice of termination to the other party hereto given in accordance with this Section 11. Such notice shall indicate the specific termination provision in this Agreement relied upon, shall set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision so indicated, and shall specify the Termination Date (which shall be not more than thirty (30) days after the giving of such notice). The failure by Executive to include in the notice any fact or circumstance which contributes to a showing of Involuntary Termination shall not waive any right of Executive hereunder or preclude Executive from asserting such fact or circumstance in enforcing Executive's rights hereunder, subject to the requirements of Section 1(e).

12. Arbitration. Any controversy involving the construction or application of any terms, covenants or conditions of this Agreement, or any claims arising out of any alleged breach of this Agreement, will be governed by the rules of the American Arbitration Association and submitted to and settled by final and binding arbitration in San Francisco, California, except that any alleged breach of Executive's confidential information obligations shall not be submitted to arbitration and instead the Company may seek all legal and equitable remedies, including without limitation, injunctive relief.

13. Miscellaneous Provisions.

(a) No Duty to Mitigate. Executive shall not be required to mitigate the amount of any payment contemplated by this Agreement, nor shall any such payment be reduced by any earnings that Executive may receive from any other source.

(b) Waiver. No provision of this Agreement may be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Integration. This Agreement supersedes and replaces any prior agreements, representation or understandings, whether written, oral, express or implied, between

Executive and the Company and constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof.

(d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the internal substantive laws, but not the conflicts of law rules, of the State of California.

(e) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(f) Employment Taxes. All payments made pursuant to this Agreement shall be subject to withholding of applicable income and employment taxes.

(g) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

COMPANY: INVITAE CORPORATION

By: _____

Name: _____

Title: _____

EXECUTIVE:

Signature

Printed Name:

Title:

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 June 30, 2021;

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: August 9, 2021

/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, Yafei (Roxi) Wen, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Invitae Corporation for the period ended June 30, 2021;

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: August 9, 2021

/s/ Yafei (Roxi) Wen

Yafei (Roxi) Wen
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the quarterly report of Invitae Corporation (the "Company") on Form 10-Q for the period ended June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

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

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

Dated: August 9, 2021

/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 June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

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

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

Dated: August 9, 2021

/s/ Yafei (Roxi) Wen
Yafei (Roxi) Wen
Chief Financial Officer
(Principal Financial Officer)