

Invitae Corp
Form 10-Q
November 07, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

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 (I.R.S. Employer

Edgar Filing: Invitae Corp - Form 10-Q

incorporation or organization) 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)

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 November 2, 2018 was 74,617,232.

TABLE OF CONTENTS

Item No.	Page No.
<u>PART I: Financial Information</u>	
<u>Item 1. Financial Statements (Unaudited)</u>	
<u>Condensed Consolidated Balance Sheets</u>	1
<u>Condensed Consolidated Statements of Operations</u>	2
<u>Condensed Consolidated Statements of Comprehensive Loss</u>	3
<u>Condensed Consolidated Statements of Cash Flows</u>	4
<u>Notes to Condensed Consolidated Financial Statements</u>	5
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	31
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	44
<u>Item 4. Controls and Procedures</u>	44
<u>PART II: Other Information</u>	
<u>Item 1. Legal Proceedings</u>	45
<u>Item 1A. Risk Factors</u>	45
<u>Item 6. Exhibits</u>	65
<u>SIGNATURES</u>	66

PART I — Financial Information

ITEM 1. Financial Statements.

INVITAE CORPORATION

Condensed Consolidated Balance Sheets

(In thousands)

(Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 101,419	\$ 12,053
Marketable securities	27,760	52,607
Accounts receivable	25,488	10,422
Prepaid expenses and other current assets	12,659	11,599
Total current assets	167,326	86,681
Property and equipment, net	29,287	30,341
Restricted cash	5,006	5,406
Marketable securities, non-current	367	5,983
Intangible assets, net	31,725	35,516
Goodwill	47,233	46,575
Other assets	3,456	576
Total assets	\$ 284,400	\$ 211,078
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 8,044	\$ 8,606
Accrued liabilities	24,821	22,742
Capital lease obligation, current portion	1,857	2,039
Debt, current portion	8,135	—
Total current liabilities	42,857	33,387
Capital lease obligation, net of current portion	1,923	3,373
Debt, net of current portion	50,354	39,084
Other long-term liabilities	9,871	13,440
Total liabilities	105,005	89,284
Commitments and contingencies (Note 9)		
Stockholders' equity:		

Edgar Filing: Invitae Corp - Form 10-Q

Common stock	7	5
Accumulated other comprehensive loss	(46)	(171)
Additional paid-in capital	666,305	520,558
Accumulated deficit	(486,871)	(398,598)
Total stockholders' equity	179,395	121,794
Total liabilities and stockholders' equity	\$ 284,400	\$ 211,078

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2018	2017	September 30, 2018	2017
Revenue:				
Test revenue	\$36,611	\$17,310	\$100,014	\$40,597
Other revenue	755	838	2,329	2,225
Total revenue	37,366	18,148	102,343	42,822
Costs and operating expenses:				
Cost of test revenue	20,441	13,274	58,964	33,093
Research and development	15,776	11,502	46,926	32,864
Selling and marketing	17,591	13,246	55,222	37,338
General and administrative	13,668	11,102	37,884	25,915
Total costs and operating expenses	67,476	49,124	198,996	129,210
Loss from operations	(30,110)	(30,976)	(96,653)	(86,388)
Other income (expense), net	231	(56)	2,066	(596)
Interest expense	(1,844)	(1,128)	(4,927)	(2,517)
Net loss before taxes	(31,723)	(32,160)	(99,514)	(89,501)
Income tax benefit	—	(4,758)	—	(6,614)
Net loss	\$(31,723)	\$(27,402)	\$(99,514)	\$(82,887)
Net loss per share, basic and diluted	\$(0.45)	\$(0.57)	\$(1.56)	\$(1.86)
Shares used in computing net loss per share, basic and diluted	70,152,804	48,221,896	63,935,336	44,639,416

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	\$(31,723)	\$(27,402)	\$(99,514)	\$(82,887)
Other comprehensive income (loss):				
Unrealized income (loss) on available-for-sale marketable				
securities, net of tax	63	(19)	125	(57)
Comprehensive loss	\$(31,660)	\$(27,421)	\$(99,389)	\$(82,944)

See accompanying notes to unaudited condensed consolidated financial statements.

INVITAE CORPORATION

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$(99,514)	\$(82,887)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	10,268	5,876
Stock-based compensation	15,711	14,387
Amortization of debt issuance costs	681	326
Amortization of premium on marketable securities	9	108
Impairment losses	1,883	—
Loss on disposal of assets	—	268
Loss on sales of available-for-sale securities	24	—
Remeasurements of liabilities associated with business combinations	593	556
Benefit from income taxes	—	(6,614)
Changes in operating assets and liabilities net of effects of business combination:		
Accounts receivable	(4,483)	(1,801)
Prepaid expenses and other current assets	(1,060)	1,761
Other assets	(555)	(45)
Accounts payable	(1,226)	1,278
Accrued expenses and other liabilities	922	61
Net cash used in operating activities	(76,747)	(66,726)
Cash flows from investing activities:		
Purchases of marketable securities	(1,575)	(94,563)
Proceeds from sales of marketable securities	19,965	—
Proceeds from maturities of marketable securities	10,957	52,918
Acquisition of businesses, acquired cash	—	1,489
Purchases of property and equipment	(4,258)	(4,115)
Other	(500)	—
Net cash provided by (used in) in investing activities	24,589	(44,271)
Cash flows from financing activities:		
Proceeds from public offerings of common stock, net of issuance costs	112,480	—
Proceeds from issuance of common stock	10,732	71,687
Proceeds from loan and security agreement	19,544	39,661
Loan payments	—	(30,457)

Edgar Filing: Invitae Corp - Form 10-Q

Capital lease principal payments	(1,632)	(2,153)
Net cash provided by financing activities	141,124	78,738
Net increase (decrease) in cash, cash equivalents and restricted cash	88,966	(32,259)
Cash, cash equivalents and restricted cash at beginning of period	17,459	71,522
Cash, cash equivalents and restricted cash at end of period	\$106,425	\$39,263
Supplemental cash flow information of non-cash investing and financing activities:		
Equipment acquired through capital leases	\$—	\$4,849
Purchases of property and equipment in accounts payable and accrued liabilities	\$1,607	\$2,022
Amounts related to co-development agreement recognized in other assets	\$2,750	\$—
Amounts related to co-development agreement recognized in accrued liabilities	\$2,500	\$—
Warrants issued pursuant to loan and security agreement	\$383	\$740
Common stock issued for acquisition of businesses	\$6,443	\$22,876
Consideration payable for acquisition of businesses	\$—	\$12,436

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 (the “Company”) was incorporated in the State of Delaware on January 13, 2010, as Locus Development, Inc. and changed its name to Invitae Corporation in 2012. The Company utilizes an integrated portfolio of laboratory processes, software tools and informatics capabilities to process DNA-containing samples, analyze information about patient-specific genetic variation and generate test reports for clinicians and their patients. The Company’s headquarters and main production facility is located in San Francisco, California. The Company currently has more than 20,000 genes in production and provides a variety of diagnostic tests that can be used in multiple indications. The Company’s tests include genes associated with hereditary cancer, neurological disorders, cardiovascular disorders, pediatric disorders, metabolic disorders and other hereditary conditions. In addition, and as a result of the acquisitions of Good Start Genetics (“Good Start”) in August 2017 and CombiMatrix Corporation (“CombiMatrix”) in November 2017, the Company’s services also include screening and testing in reproductive health, including preimplantation and carrier screening for inherited disorders, prenatal diagnosis, miscarriage analysis and pediatric developmental disorders. The Company 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 the Company’s Annual Report on Form 10-K for the year ended December 31, 2017. The results for the three and nine months ended September 30, 2018 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

The unaudited condensed consolidated financial statements include the accounts of the Company and its 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 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. The Company believes judgment is involved in determining revenue recognition (See Note 3, "Revenue, accounts receivable and deferred revenue" for further information); the acquisition-date fair value of intangible assets; the fair value of contingent consideration associated with acquisitions; the recoverability of long-lived assets; impairment of goodwill and intangible assets; stock-based compensation expense; the fair value of its convertible notes; and income tax uncertainties. The Company bases these estimates on historical and anticipated results, trends and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. Actual results could differ materially from those estimates and assumptions.

Concentrations of credit risk and other risks and uncertainties

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

The Company's 10% or greater customers and their related revenue as a percentage of total revenue were as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Medicare	24.6%	*	19.7%	*
United Healthcare	10.0%	13.7%	*	*

* Less than 10% of total revenue

The Company's significant customers and their related accounts receivable balance as percentage of total accounts receivable were as follows:

	September 30,		December 31,	
	2018		2017	
Medicare	10.5	%	13.1	%

Accounts receivable

The Company receives payment for its tests from partners, patients, institutional customers and third-party payers. See Note 3, "Revenue, accounts receivable and deferred revenue" for further information.

Business combinations

The tangible and identifiable intangible assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. The Company bases the estimated fair value of identifiable intangible assets acquired in a business combination on independent valuations that use information and assumptions provided by management, which consider management's estimates of inputs and assumptions that a market participant would use. Any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed is recorded to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

In circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under FASB Accounting Standards Codification ("ASC") Topic 480, Distinguishing Liabilities from Equity, the Company recognizes a liability equal to the fair value of the contingent payments the Company expects to make as of the acquisition date. The Company remeasures this liability each reporting period and records changes in the fair value as a component of operating expenses.

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

Goodwill

In accordance with ASC 350, Intangibles-Goodwill and Other (“ASC 350”), the Company’s goodwill is not amortized but is tested for impairment on an annual basis or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. Under ASC 350, the Company performs annual impairment reviews of its goodwill balance during the fourth fiscal quarter. In testing for impairment, the Company compares the fair value of its reporting unit to its carrying value including the goodwill of that unit. If the carrying value, including goodwill, exceeds the reporting unit’s fair value, the Company will recognize an impairment loss for the amount by which the carrying amount exceeds the reporting unit’s fair value. The loss recognized cannot exceed the total amount of goodwill allocated to that reporting unit.

The Company did not incur any goodwill impairment losses in any of the periods presented.

Fair value of financial instruments

The Company’s financial instruments consist principally of cash and cash equivalents, marketable securities, accounts payable, accrued liabilities, capital leases and debt. 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 the Company, the carrying value of capital leases approximates fair value.

See Note 7, “Fair value measurements” for disclosure of the fair value of debt and further information on the fair value of the Company’s financial instruments.

Variable interest entity

The Company has a variable interest in a variable interest entity (“VIE”) through an investment in convertible notes issued by the VIE. The convertible notes do not provide the Company with voting rights in the VIE or with power to direct the activities of the VIE which most significantly affect its economic performance. The Company is not the VIE’s primary beneficiary and does not consolidate the VIE. The Company will continue to assess its investment and future commitments to the VIE. To the extent its relationship with the VIE changes, the Company may be required to consolidate the VIE in future periods.

See Note 7, “Fair value measurements” and Note 8, “Investment in privately held company” for additional disclosures related to the convertible notes, which are recorded as available-for-sale securities.

Revenue recognition

The Company recognizes revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration it expects to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers.

Test revenue is generated primarily from the sale of tests that provide analysis and associated interpretation of the sequencing of parts of the genome. Revenue associated with subsequent re-requisition services and family variant tests was de minimis for all periods presented.

Other revenue consists primarily of revenue from genome network subscription services which is recognized on a straight-line basis over the subscription term, and revenue from collaboration agreements.

Cost of test revenue

Cost of test revenue reflects the aggregate costs incurred in delivering the genetic testing results to clinicians and includes expenses for personnel-related costs including stock-based compensation, materials and supplies, equipment and infrastructure expenses associated with testing and allocated overhead including rent, equipment depreciation and utilities.

Net loss per common share

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

Recent accounting pronouncements

The Company evaluates 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 the Company's condensed consolidated financial statements.

Recently issued accounting pronouncements not yet adopted

In August 2018, the FASB issued ASU 2018-15, Intangibles - Goodwill and Other-Internal-Use Software, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This guidance is effective for interim and annual reporting periods beginning after December 15, 2019, and early adoption is permitted. The Company is currently evaluating the effect that adoption of this ASU will have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement - Disclosure Framework (Topic 820). The updated guidance improves the disclosure requirements on fair value measurements. The updated guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted for any removed or modified disclosures. The Company is currently evaluating the effect that adoption of this ASU will have on its consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. Under the new guidance, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU 2018-07 is effective for annual and interim periods beginning after December 15, 2018 and early adoption is permitted. The adoption of ASU 2018-07 is not expected to have a significant effect upon the Company's consolidated financial statements, related disclosures and ongoing financial reporting. The Company plans to implement ASU 2018-07 on January 1, 2019.

In February 2018, the FASB issued ASU 2018-02, Income Statement – Reporting Comprehensive Income (Topic 220). Under the new guidance, entities will be permitted to reclassify tax effects stranded in accumulated other comprehensive income as a result of tax reform to retained earnings. ASU 2018-02 is effective for annual and interim periods beginning after December 15, 2018 and early adoption is permitted. When adopted, ASU 2018-02 requires all entities to make new disclosures, regardless of whether they elect to reclassify stranded amounts. The Company is evaluating the effect that ASU 2018-02 will have on its consolidated financial statements, related disclosures and ongoing financial reporting. The Company has not yet selected an implementation date for ASU 2018-02.

In June 2016, FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326) which requires measurement and recognition of expected credit losses for financial assets. This guidance will become effective for the Company beginning in the first quarter of 2020 and must be adopted using a modified retrospective approach, with certain exceptions. The Company is currently evaluating the effect that adoption of this ASU will have on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) and in July 2018 issued ASU 2018-10, Codification Improvements to Topic 842, Leases and ASU 2018-11, Leases (Topic 842): Targeted Improvements (the foregoing ASUs collectively referred to as "Topic 842"). Under the new guidance, lessees will be required to recognize a lease liability and a right-of-use asset for all leases (with the exception of short-term leases) at the commencement date and also requires expanded disclosures about leasing arrangements. Topic 842 is effective for annual and interim periods beginning on or after December 15, 2018 and early adoption is permitted. Entities may initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

The Company is evaluating the effect that Topic 842 and related standards will have on its consolidated financial statements, related disclosures and ongoing financial reporting, but expects implementation of Topic 842 to result in the recognition of material right of use assets and corresponding lease liabilities in its consolidated balance sheets, principally relating to facilities leases. The Company plans to implement Topic 842 and related standards on January 1, 2019.

Recently adopted accounting pronouncements – Revenue recognition

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), designed to enable users of financial statements to better understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. On January 1, 2018, the Company adopted the provisions of Topic 606 using the modified retrospective method. From adoption to date, the Company has recognized all its revenue from contracts with customers within the scope of Topic 606. In connection with the adoption, the Company recognized the cumulative effect of initially applying this standard as an adjustment to retained earnings on the date of adoption. Comparative information prior to the date of adoption has not been restated and continues to be reported under the accounting standards in effect for those periods.

In connection with the adoption of Topic 606, the Company amended its revenue recognition policy to provide for the recognition of certain variable consideration related to diagnostic tests that was previously deferred pending cash

collection. Under Topic 606, the Company records variable consideration based on an estimate of the consideration to which it will be entitled.

Revenue recognition

Adoption of Topic 606, "Revenue from Contracts with Customers"

On January 1, 2018, the Company adopted Topic 606 using the modified retrospective transition method. The provisions of Topic 606 were applied to all customer contracts that were not completed as of the date of adoption. Prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for those periods.

The Company recognizes revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration it expects to be entitled to in exchange for those goods or services. All revenues are generated from contracts with customers.

Diagnostic tests

The majority of the Company's revenue is generated from genetic testing services that provide analysis and associated interpretation of the sequencing of parts of the genome. Test orders are placed under written requisitions signed by the patient and/or medical provider, and the Company often enters into contracts with institutions (e.g., hospitals and clinics) and insurance companies that include pricing provisions under which such tests are billed. Billing terms are generally net thirty days.

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

In connection with some diagnostic test orders, the Company offers limited re-requisition rights ("Re-Requisition Rights") that are considered distinct at contract inception, and therefore certain diagnostic test orders contain two performance obligations, the performance of the original test and the Re-Requisition Rights. When Re-Requisition Rights are granted, the Company allocates the transaction price to each performance obligation based on the relative estimated standalone selling prices. In order to comply with loss contract rules, the allocations are adjusted, if necessary, to ensure the amount deferred for Re-Requisition Rights is no less than the estimated cost of fulfilling the Company's related obligations.

The Company looks to transfer of control in assessing timing of recognition of revenue in connection with each performance obligation. In general, revenue in connection with diagnostic tests is recognized upon delivery of the underlying clinical report or when the report is made available on the Company's web portal. Outstanding performance obligations pertaining to orders received but for which the underlying report has not been issued are generally satisfied within a thirty-day period. Revenue in connection with Re-Requisition Rights is recognized as the rights are exercised or expire unexercised, which is generally within ninety days of initial deferral.

Other contracts

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

Amounts due under collaboration and genome network agreements are typically billable on net thirty-day terms.

Prior period reclassifications

Statement of cash flow amounts in prior periods have been reclassified to conform with current period presentation, which separates amortization of debt issuance costs from depreciation and amortization. Amortization of debt issuance costs in the nine months ended September 30, 2017 was \$0.3 million.

3. Revenue, accounts receivable and deferred revenue

As described in Note 2, the Company adopted Topic 606 effective January 1, 2018. In connection with the adoption the Company utilized the following practical expedients and exemptions:

• Certain information about remaining performance obligations is not disclosed because the underlying contracts have an original expected duration of one year or less.

• Sales commissions are expensed when incurred because the amortization period would have been one year or less. Commission costs are recorded as a component of sales and marketing expenses.

• No adjustments to promised consideration were made for financing as the Company expects, at contract inception, that the period between the transfer of a promised good or service and when the customer pays for that good or service will be one year or less.

The adoption of Topic 606 resulted in a cumulative-effect adjustment to accounts receivable and accumulated deficit of \$11.2 million as of January 1, 2018 primarily related to the recognition of uncollected diagnostic test variable consideration as of the date of adoption. Test revenue without adoption of Topic 606 for the three and nine months ended September 30, 2018 includes cash

collections related to accounts receivable recorded as of January 1, 2018 in connection with the Topic 606 cumulative-effect adjustment.

The effect of the adoption of Topic 606 on financial statement line items in the Company's condensed consolidated statement of operations for the three and nine months ended September 30, 2018, and the Company's condensed consolidated balance sheet as of September 30, 2018 was as follows (in thousands, except per share amounts):

Three Months Ended September 30, 2018			
	As Reported	Without Adoption of Topic 606	Effect of Adoption Higher/(Lower)
Test revenue	\$36,611	\$35,120	\$ 1,491
Net loss	\$(31,723)	\$(33,214)	\$ 1,491
Net loss per share, basic and diluted	\$(0.45)	\$(0.47)	\$ 0.02

Nine Months Ended September 30, 2018			
	As Reported	Without Adoption of Topic 606	Effect of Adoption Higher/(Lower)
Test revenue	\$100,014	\$98,631	\$ 1,383
Net loss	\$(99,514)	\$(100,897)	\$ 1,383
Net loss per share, basic and diluted	\$(1.56)	\$(1.58)	\$ 0.02

As of September 30, 2018			
	As Reported	Without Adoption of Topic 606	Effect of Adoption Higher/(Lower)
Accounts receivable, net	\$25,488	\$12,198	\$ 13,290
Accumulated deficit	\$(486,871)	\$(499,494)	\$ 12,623
Stockholders' equity	\$179,395	\$166,772	\$ 12,623

Disaggregation of revenue

Test revenue is generated from sales of diagnostic tests to three groups of customers: institutions, such as hospitals and clinics, patients who pay directly, and patients' insurance carriers. Amounts billed and collected, and the timing of collections, vary based on whether the payer is an institution, an insurance carrier or a patient. Accordingly, for

purposes of complying with the disclosure requirements of Topic 606, test revenue is disaggregated between these three payer groups. Further, other revenue, consisting principally of revenue recognized under collaboration and genome network agreements, is disaggregated from diagnostic test revenue.

The following table includes the Company's revenues as disaggregated by payer category (in thousands):

	Three Months Ended September 30, 2018		Nine Months Ended September 30, 2018	
	2017 ⁽¹⁾		2017 ⁽¹⁾	
Test revenue:				
Institutions	\$8,958	\$5,242	\$24,761	\$10,461
Patient - direct	3,280	1,762	9,705	3,368
Patient - insurance	24,373	10,306	65,548	26,768
Total test revenue	36,611	17,310	100,014	40,597
Other revenue	755	838	2,329	2,225
Total revenue	\$37,366	\$18,148	\$102,343	\$42,822

⁽¹⁾ As noted above, prior period amounts are presented as originally reported based upon the accounting standards in effect for those periods.

Included in revenue in the Company's condensed consolidated statement of operations for the nine months ended September 30, 2018 was \$0.3 million that was included in deferred revenue at January 1, 2018.

The Company recognizes revenue related to billings based on estimates of the amount that will ultimately be realized. The estimate of the transaction price of test revenue is based on many factors such as length of payer relationship, historical payment patterns, changes in contract provisions and insurance reimbursement policies. Cash collections for certain diagnostic tests delivered may differ from rates originally estimated. As a result of new information, the Company updated its estimate of the amounts to be recognized for previously delivered tests which resulted in an additional \$1.5 million and \$3.8 million of test revenue for the three and nine months ended September 30, 2018, respectively. These changes in estimates decreased the Company's loss from operations by \$1.5 million and \$3.8 million and decreased basic and diluted net loss per share by approximately \$0.02 and \$0.06 for the three and nine months ended September 30, 2018, respectively.

Accounts receivable, net

The majority of the Company's accounts receivable represents amounts billed to institutions (e.g., hospitals, clinics) and estimated amounts to be collected from third-party insurance payers for diagnostic test revenue recognized. Also included is amounts due under the terms of collaboration and genome network agreements for diagnostic testing and data aggregation reporting services provided and proprietary platform access rights transferred.

Deferred revenues

The Company records deferred revenues when cash payments are received or due in advance of its performance related to one or more performance obligations. The amounts deferred to date primarily consist of consideration received pertaining to the estimated exercise of certain Re-Requisition Rights. In order to comply with loss contract rules, the Company's Re-Requisition Rights revenue deferral is no less than the estimated cost of fulfilling its related obligations. The Company recognizes revenue related to Re-Requisition Rights as the rights are exercised or expire unexercised, which is generally within 90 days of initial deferral.

4. Business combinations

AltaVoice

On January 6, 2017, the Company acquired AltaVoice (formerly Patient Crossroads, Inc.), a privately owned patient-centered data company with a global platform for collecting, curating, coordinating and delivering safeguarded data from patients and clinicians. The acquisition, complemented by several other strategic partnerships, expands the Company's genome network, designed to connect patients, clinicians, advocacy organizations, researchers and therapeutic developers to accelerate the understanding, diagnosis and treatment of hereditary disease. Pursuant to the terms of the Stock Purchase Agreement entered into on January 6, 2017, the Company acquired all of the outstanding shares of AltaVoice for total purchase consideration of \$12.4 million, payable in the Company's common stock, as follows:

- (a) payment of \$5.5 million through the issuance of 641,126 shares of the Company's common stock;
- (b) payment of \$5.0 million in the Company's common stock, payable on March 31, 2018, with the common shares deliverable equal to \$5.0 million divided by the trailing average share price of the Company's common stock for the 30 days preceding March 31, 2018. This payment was made on April 2, 2018 through the issuance of 716,332

shares of the Company's common stock;

(c) payment of \$5.0 million in the Company's common stock, which was contingently payable on March 31, 2018 if a milestone based on a certain threshold of revenue was achieved during 2017, with the shares deliverable equal to \$5.0 million divided by the trailing average share price of the Company's common stock for the 30 days preceding March 31, 2018. As the foregoing milestone was not achieved, there is a new contingent milestone based on achieving a revenue target during 2017 and 2018. Should the new milestone revenue target be achieved, on March 31, 2019, a payment of up to \$5.0 million in the Company's common stock will be payable. The actual payout is dependent upon the 2017 and 2018 revenue target (capped at \$14.0 million) times 75% less \$5.5 million. This formula in effect caps the possible payout amount at \$5.0 million in the Company's common shares. The number of shares to be issued will be equal to the payout amount divided by the trailing average share price of the Company's common stock for the 30 days preceding March 31, 2019.

The first payment of \$5.5 million was classified as equity. The second payment was discounted to \$4.7 million as of the acquisition date, recorded as a liability, and was accreted to fair value at each reporting date until the extinguishment of the liability on April 2, 2018. The third payment, representing contingent consideration, was determined to have a fair value of \$2.2 million as of the acquisition date and was recorded as a liability. In accordance with ASC Topic 805, Business Combinations, the contingent consideration of \$2.2 million will be remeasured to fair value at each reporting date until the contingency is resolved, with changes in fair value recognized in earnings.

For the second payment, the acquisition-date fair value was \$4.7 million, and the Company recorded accretion gains (losses) of \$0.0 million and \$(0.1) million in other income (expense), net, for the three months ended September 30, 2018 and 2017, respectively and \$1.6 million and \$(0.2) million for the nine months ended September 30, 2018 and 2017, respectively. The accretion gains in 2018 resulted from an adjustment to the value of the second payment as of March 31, 2018, and principally reflected the difference between the value of the common shares deliverable, based upon the closing price of the Company's stock on March 29, 2018, and the value per share used to calculate the number of common shares deliverable. The accretion losses in 2017 resulted from adjustments to the discounted value of the second payment, reflecting the passage of time.

For the third payment, whose contingent acquisition-date fair value was \$2.2 million, the Company recorded remeasurement losses of \$0.1 million and \$0.1 million in operating expense for the three months ended September 30, 2018 and 2017, respectively and \$1.0 million and \$0.4 million in operating expense for the nine months ended September 30, 2018 and 2017, respectively. The remeasurement losses in 2018 reflect updated estimations of fair value of the third payment, based upon achieving a revenue target during 2017 and 2018, as the milestone based on a certain threshold of revenue to be achieved during 2017 was not met. The principal inputs affecting those estimations have been updates to the Company's revenue forecasts and the passage of time.

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its 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 at the date of acquisition (in thousands):

Cash	\$54
Accounts receivable	274
Prepaid expense and other assets	52
Non-compete agreement	286
Developed technology	570
Customer relationships	3,389
Total identifiable assets acquired	4,625
Accounts payable	(28)
Deferred revenue	(202)
Accrued expenses	(21)
Deferred tax liability	(1,422)
Total liabilities assumed	(1,673)
Net identifiable assets acquired	2,952
Goodwill	9,432
Net assets acquired	\$12,384

Acquisition-related intangibles included in the above table are finite-lived. Customer relationships are being amortized on an accelerated basis, utilizing free cash flows, over a period of ten years. All other 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, as follows (in thousands):

Gross	Estimated
-------	-----------

	Purchased	Useful
	Intangible	Life
	Assets	(in Years)
Non-compete agreement	\$ 286	5
Developed technology	570	6
Customer relationships	3,389	10
	\$ 4,245	

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of AltaVoice resulted in \$9.4 million of goodwill. The Company believes this goodwill consists principally of expected synergies to be realized by combining capabilities, technology and data to accelerate the use of genetic information for the diagnosis and treatment of hereditary diseases. In accordance with ASC 350, goodwill will not be amortized but will be tested for impairment at least annually. Goodwill created as a result of the acquisition is not deductible for tax purposes. Concurrent with the acquisition, the Company recorded additional goodwill of \$1.4 million relating to the tax consequence of recognizing the fair value of the acquisition-related intangibles, with an equal offset to deferred tax liability. The Company has finalized its assessment of fair value of the assets and liabilities assumed at the acquisition date.

Ommdom

On June 11, 2017, the Company acquired Ommdom, Inc. (“Ommdom”), a privately held company that develops, commercializes and sells hereditary risk assessment and management software, including CancerGene Connect, a cancer genetic counseling platform. The acquisition expands Invitae’s suite of genome management offerings designed to help patients and clinicians use genetic information as part of mainstream medical care. CancerGene Connect is a platform for collecting and managing genetic family histories. The platform uses a cloud-based, mobile friendly patient interface to gather family history information from patients prior to a clinician appointment. Then, analysis tools analyze patients’ predisposition to disease and provide actionable analysis to inform therapeutic decisions, such as genetic testing or treatment approaches. In addition, the platform provides clinicians with the ability to look beyond the individual to understand trends across all of their patients.

Pursuant to the terms of a Stock Exchange Agreement, the Company acquired all of the outstanding shares of Ommdom for consideration of \$6.1 million, payable entirely in the Company’s common stock. There was no cash consideration nor any contingent payments associated with the acquisition, other than a hold-back amount of \$0.6 million. Per the terms of the agreement, the Company was obligated to issue shares of its common stock as follows:

- (a) payment of \$5.5 million through the issuance of 600,108 shares of the Company’s common stock on the acquisition date; and
- (b) payment of \$0.6 million through the issuance of 66,582 shares of the Company’s common stock, representing a hold-back amount, and payable on the twelve-month anniversary of the acquisition date. This payment was made on June 11, 2018.

The first payment of \$5.5 million was classified as equity. The second payment of \$0.6 million was recorded as a stock payable liability on the acquisition date and was reclassified to equity upon the issuance of 66,582 shares of the Company’s common stock on June 11, 2018.

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its 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 at the date of acquisition (in thousands):

Cash	\$53
Accounts receivable	10
Prepaid expense and other assets	4
Trade name	13
Developed technology	2,335
Customer relationships	147
Total identifiable assets acquired	2,562
Accounts payable	(16)
Accrued expenses	(17)
Deferred tax liability	(434)
Total liabilities assumed	(467)
Net identifiable assets acquired	2,095
Goodwill	4,045
Net assets acquired	\$6,140

Edgar Filing: Invitae Corp - Form 10-Q

Finite-lived intangibles included in the above table 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, as follows (in thousands):

	Gross	Estimated
	Purchased	Useful
	Intangible	Life
	Assets	(in Years)
Trade name	\$ 13	5
Developed technology	2,335	5
Customer relationships	147	5
	\$ 2,495	

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of Ommdom resulted in the recognition of \$4.0 million of goodwill. The Company believes this goodwill consists

principally of expected synergies to be realized by expanding the Company's suite of genome management offerings designed to help patients and clinicians use genetic information as part of mainstream medical care. In accordance with ASC 350, goodwill will not be amortized but rather will be tested for impairment at least annually. Goodwill created as a result of the acquisition is not deductible for tax purposes. Concurrent with the acquisition, the Company recorded additional goodwill of \$0.4 million relating to the tax consequence of recognizing the fair value of the acquisition-related intangibles, with an equal offset to deferred tax liability. The Company has finalized its assessment of fair value of the assets and liabilities assumed at acquisition date.

Good Start Genetics

On August 4, 2017, the Company acquired 100% of the fully diluted equity of Good Start, a privately held molecular diagnostics company focused on preimplantation and carrier screening for inherited disorders. The acquisition of Good Start is intended to further Invitae's plan to create a comprehensive genetic information platform providing high-quality, affordable genetic information coupled with world-class clinical expertise to inform healthcare decisions throughout every stage of an individual's life. The purchase consideration for the Good Start acquisition consisted of the assumption of the net liabilities of Good Start of \$24.4 million at the acquisition date.

Immediately subsequent to the acquisition of Good Start, the Company paid \$18.4 million in cash to settle outstanding notes payable, accrued interest and related costs. In addition, and immediately subsequent to the acquisition, the Company settled outstanding convertible promissory notes payable through:

- (a) payment of \$11.9 million through the issuance of 1,148,283 shares of the Company's common stock; and
- (b) payment of \$3.6 million through the issuance of 343,986 shares of the Company's common stock, representing a hold-back amount payable on the one-year anniversary of the acquisition date. In September 2018, the Company issued 250,044 shares in partial payment of the hold-back amount payable. The remainder of the hold-back amount payable, approximately \$1.5 million, will be settled upon resolution of outstanding claims from Good Start customers.

Also in connection with the acquisition of Good Start and immediately subsequent to the acquisition, the Company paid bonuses to certain members of Good Start's management team through:

- (a) payment of \$0.9 million through the issuance of 83,025 shares of the Company's common stock; and
- (b) payment of \$0.4 million through the issuance of 37,406 shares of the Company's common stock, representing a hold-back amount payable on the one-year anniversary of the acquisition date.

These bonus payments were recorded as general and administrative expense.

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its 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.

At acquisition date, the Company also recorded \$4.8 million as a provisional amount for a deferred tax liability because certain information and analysis related to Good Start's historical net operating losses that could have affected the Company's initial valuation was still being obtained or reviewed at that time. This provisional amount for the deferred tax liability was subsequently reversed during the fourth quarter of 2017 based on the results of further analysis of Good Start's historical net operating losses.

The following table summarizes the fair values of assets acquired and liabilities assumed at the date of acquisition (in thousands):

Cash and restricted cash	\$ 1,381
Accounts receivable	2,246
Prepaid expense and other assets	1,579
Property and equipment	1,320
Trade name	460
Developed technology	5,896
Customer relationships	7,830
Total identifiable assets acquired	20,712
Accounts payable	(5,418)
Accrued expenses	(6,802)
Notes payable	(17,904)
Convertible promissory notes payable	(15,430)
Other liabilities	(222)
Total liabilities assumed	(45,776)
Net identifiable assets acquired	(25,064)
Goodwill	25,064
Net assets acquired	\$—

In March 2018, June 2018, and September 2018 the Company recorded adjustments to its accounting for the amount recorded as accounts receivable at acquisition. Accordingly, the fair value of accounts receivable was decreased by \$0.4 million on March 31, 2018, \$0.3 million on June 30, 2018, and \$0.1 million on September 30, 2018, with corresponding increases to goodwill.

Customer relationships are being amortized on an accelerated basis, utilizing free cash flows, over a period of eight years. All other finite-lived intangibles included in the above table 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, as follows (in thousands):

	Gross	Estimated
	Purchased	Useful
	Intangible	Life
	Assets	(in Years)
Trade name	\$ 460	3
Developed technology	5,896	5
Customer relationships	7,830	8
	\$ 14,186	

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of Good Start resulted in the recognition of \$25.1 million of goodwill. The Company believes this goodwill consists principally of expected synergies to be realized by expanding the Company's suite of genome management offerings designed to help patients and clinicians use genetic information as part of mainstream medical care. In accordance with ASC 350, goodwill will not be amortized but rather will be tested for impairment at least annually. Goodwill created as a result of the acquisition is not deductible for tax purposes. The Company has finalized its assessment of fair value of the assets and liabilities assumed at the acquisition date.

CombiMatrix

On November 14, 2017, the Company completed its acquisition of CombiMatrix in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of July 31, 2017 (the "Merger Agreement"), by and among the Company, Coronado Merger Sub, Inc., a wholly-owned subsidiary of the Company ("Merger Sub"), and CombiMatrix, pursuant to which Merger Sub merged with and into CombiMatrix, with CombiMatrix surviving as a wholly-owned subsidiary of the Company (the "Merger").

At the closing of the Merger, the Company issued shares of its common stock to (i) CombiMatrix's common stockholders, at an exchange ratio of 0.8692 of a share of the Company's common stock (the "Merger Exchange Ratio") for each share of CombiMatrix common stock outstanding immediately prior to the Merger, (ii) CombiMatrix's Series F preferred stockholders, at the Merger Exchange Ratio for each share of CombiMatrix common stock underlying Series F preferred stock outstanding immediately prior to the Merger, (iii) holders of outstanding and unexercised in-the-money CombiMatrix stock options, which were fully accelerated to the extent of any applicable vesting period and converted into the right to receive the number of shares of the Company's common stock equal to the Merger Exchange Ratio multiplied by the number of shares of CombiMatrix common stock issuable upon exercise of such

option, minus the number of shares of the Company's common stock determined by dividing the aggregate exercise price for such option by \$9.491 (the "Invitae Trailing Average Share Value"), and (iv) holders of outstanding and unsettled CombiMatrix restricted stock units, which were fully accelerated to the extent of any applicable vesting period and converted into the right to receive a number of shares of the Company's common stock determined by multiplying the number of shares of CombiMatrix common stock that were subject to such restricted stock unit by the Merger Exchange Ratio.

In addition, at the closing of the Merger, (a) all outstanding and unexercised out-of-the money CombiMatrix stock options were cancelled and terminated without the right to receive any consideration, (b) all CombiMatrix Series D Warrants and Series F Warrants outstanding and unexercised immediately prior to the closing of the Merger were assumed by the Company and converted into warrants to purchase the number of shares of the Company's common stock determined by multiplying the number of shares of CombiMatrix common stock subject to such warrants by the Merger Exchange Ratio, and with the exercise price adjusted by dividing the per share exercise price of the CombiMatrix common stock subject to such warrants by the Merger Exchange Ratio, and (c) certain entitlements under CombiMatrix's executive compensation transaction bonus plan (the "Transaction Bonus Plan") were paid in shares of the Company's common stock or RSUs to be settled in shares of the Company's common stock. All outstanding and unexercised CombiMatrix Series A, Series B, Series C, Series E, and PIPE warrants were repurchased by CombiMatrix prior to closing pursuant to that certain CombiMatrix Common Stock Purchase Warrants Repurchase Agreement dated July 11, 2016.

Pursuant to the Merger Agreement, the Company issued an aggregate of 2,703,389 shares of its common stock as follows:

- (a) payment of \$20.5 million through the issuance of 2,611,703 shares of the Company's common stock to holders of CombiMatrix common stock outstanding;
- (b) payment of \$0.7 million through the issuance of 85,219 shares of the Company's RSUs to holders of outstanding and unsettled CombiMatrix restricted stock units;
- (c) payment of \$0.1 million through the issuance of 3,323 shares of the Company's common stock to holders of outstanding and unexercised in-the-money CombiMatrix stock options; and
- (d) payment of \$0.1 million through the issuance of 3,144 shares of the Company's common stock to holders of CombiMatrix Series F preferred stock.

In addition, and pursuant to the Merger Agreement, the Company issued warrants to purchase an aggregate of 2,077,273 shares of its common stock as follows:

- (a) payment of \$7.4 million through the issuance of warrants to purchase a total of 1,739,689 shares of the Company's common stock in exchange for all outstanding CombiMatrix Series F warrants; and
- (b) payment of \$1,000 through the issuance of warrants to purchase a total of 337,584 shares of the Company's common stock in exchange for all outstanding CombiMatrix Series D warrants.

In connection with the acquisition of CombiMatrix, the Company paid bonuses to certain members of CombiMatrix's management team through:

- (a) payment of \$1.7 million through the issuance of common stock and RSUs totaling 214,976 shares of the Company's common stock to settle payments pursuant to CombiMatrix's executive compensation transaction bonus plan (the "Transaction Bonus Plan"), recorded as post-combination compensation expense and included in general and administrative expense; and
- (b) payment of \$0.2 million through the issuance of 22,966 shares of the Company's common stock to settle payments pursuant to the Transaction Bonus Plan, recorded as an assumed liability at the acquisition date.

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. The amount recorded as deferred tax liability, \$0 at December 31, 2017, is provisional because certain information and analysis related to CombiMatrix's tax attributes and ownership change history that may affect the Company's valuation is still being obtained or reviewed. Thus, the provisional measurement of fair value discussed above is subject to change. The Company expects to finalize the valuation as soon as practicable, but not later than one year from the acquisition date. While the Company believes that its 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 at the date of acquisition (in thousands):

Cash and restricted cash	\$1,333
Accounts receivable	4,118
Prepaid expense and other assets	1,299
Property and equipment	437
Other assets - non current	30
Favorable leases	247
Trade name	103
Patent licensing agreement	496
Developed technology	3,162
Customer relationships	12,397
Total identifiable assets acquired	23,622
Accounts payable	(276)
Accrued expenses	(3,925)
Other liabilities	(180)
Total liabilities assumed	(4,381)
Net identifiable assets acquired	19,241
Goodwill	8,692
Net assets acquired	\$27,933

Customer relationships are being amortized on an accelerated basis, utilizing free cash flows, over a period of 11 years. All other finite-lived intangibles included in the above table 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, as follows (in thousands):

	Gross	Estimated
	Purchased	Useful
	Intangible	Life
	Assets	(in Years)
Favorable leases	\$ 247	2
Trade name	103	1

Edgar Filing: Invitae Corp - Form 10-Q

Patent licensing agreement	496	15
Developed technology	3,162	4
Customer relationships	12,397	11
	\$ 16,405	

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The acquisition of CombiMatrix resulted in the recognition of \$8.7 million of goodwill. The Company believes this goodwill consists principally of expected synergies to be realized by expanding the Company's suite of genome management offerings designed to help patients and clinicians use genetic information as part of mainstream medical care. In accordance with ASC 350, goodwill will not be amortized but rather will be tested for impairment at least annually. Goodwill created as a result of the acquisition is not deductible for tax purposes.

5. Goodwill and intangible assets

Goodwill

Details of the Company's goodwill for the nine months ended September 30, 2018 are as follows (in thousands):

	AltaVoice	Ommdom	Good Start	CombiMatrix	Total
Balance as of December 31, 2017	\$ 9,432	\$ 4,045	\$24,406	\$ 8,692	\$46,575
Goodwill adjustment	—	—	658		658
Balance as of September 30, 2018	\$ 9,432	\$ 4,045	\$25,064	\$ 8,692	\$47,233

Intangible Assets

The following table presents details of the Company's finite-lived intangible assets as of September 30, 2018 (in thousands):

	Accumulated		Weighted Average Estimated Remaining Useful Life		Weighted Average Estimated Remaining Useful Life
	Cost	Amortization	Net	(in Years)	(in Years)
Customer relationships	\$23,763	\$ (2,262)	\$21,501	10.0	8.9
Developed technology	11,963	(2,847)	9,116	4.8	3.7
Non-compete agreement	286	(100)	186	5.0	3.3
Trade name	576	(273)	303	2.7	1.6
Patent licensing agreement	496	(29)	467	15.0	14.2
Favorable leases	247	(95)	152	2.0	1.3
	\$37,331	\$ (5,606)	\$31,725	8.2	7.1

Acquisition-related intangibles included in the above table are finite-lived and are being amortized on an accelerated basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are realized. Amortization expense was \$1.3 million and \$0.6 million for the three months ended September 30, 2018 and 2017, respectively, and \$3.8 million and \$0.8 million for the nine months ended September 30, 2018 and 2017, respectively. Intangible assets are carried at cost less accumulated amortization. Amortization expense is recorded to research and development, sales and marketing and general and administrative expense.

Edgar Filing: Invitae Corp - Form 10-Q

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of September 30, 2018 (in thousands):

	Amount
2018	\$ 1,262
2019	5,250
2020	5,525
2021	5,829
2022	4,123
Thereafter	9,736
Total estimated future amortization expense	\$ 31,725

6. Balance sheet components

Property and equipment, net

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

	September 30,	December 31,
	2018	2017
Leasehold improvements	\$ 12,984	\$ 12,623
Laboratory equipment	22,870	17,705
Equipment under capital lease	6,956	11,446
Computer equipment	4,251	4,023
Software	2,580	2,520
Furniture and fixtures	659	569
Automobiles	20	20
Construction-in-progress	3,012	965
Total property and equipment, gross	53,332	49,871
Accumulated depreciation and amortization	(24,045)	(19,530)
Total property and equipment, net	\$ 29,287	\$ 30,341

Depreciation expense was \$2.1 million and \$1.8 million for the three months ended September 30, 2018 and 2017, respectively, and \$6.5 million and \$5.1 million for the nine months ended September 30, 2018 and 2017, respectively.

Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30,	December 31,
	2018	2017
Accrued compensation and related expenses	\$ 6,498	\$ 7,406
Liabilities associated with business combinations	6,229	9,497
Liability associated with co-development agreement	2,500	—
Deferred revenue	869	307
Other	8,725	5,532
Total accrued liabilities	\$ 24,821	\$ 22,742

Other long-term liabilities

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

	September 30,	December 31,
	2018	2017
Lease incentive obligation, non-current	\$ 3,465	\$ 3,831
Deferred rent, non-current	5,441	5,153
Liabilities associated with business combination	—	3,779
Other non-current liabilities	965	677
Total other long-term liabilities	\$ 9,871	\$ 13,440

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 the Company's consolidated financial instruments that were measured at fair value on a recurring basis as of September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018			Estimated			
	Cost	Gain	Losses	Fair	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	\$91,840	\$ —	\$ —	\$91,840	\$91,840	\$ —	\$ —
Certificates of deposit	300	—	—	300	—	300	—
U.S. treasury notes	2,001	—	(3)	1,998	1,998	—	—
U.S. government agency securities	25,506	—	(43)	25,463	—	25,463	—
Convertible note	367	—	—	367	—	—	367
Total financial assets	\$120,014	\$ —	\$ (46)	\$119,968	\$93,838	\$25,763	\$367
Financial liabilities:							
Contingent consideration				\$4,767	\$ —	\$ —	\$4,767
Total financial liabilities				\$4,767	\$ —	\$ —	\$4,767
September 30, 2018							
Reported as:							
Cash equivalents					\$		86,835
Restricted cash							5,006
Marketable securities							28,127
Total cash equivalents, restricted cash, and marketable securities					\$		119,968
Accrued liabilities					\$		4,767

	December 31, 2017						
	Amortized	Unrealized		Estimated			
	Cost	Gains	Losses	Fair Value	Level 1	Level 2	Level 3
Financial assets:							
Money market funds	\$5,998	\$—	\$—	\$5,998	\$5,998	\$—	\$—
Certificates of deposit	300	—	—	300	—	300	—
U.S. treasury notes	12,010	—	(19)	11,991	11,991	—	—
U.S. government agency securities	46,451	—	(152)	46,299	—	46,299	—
Total financial assets	\$64,759	\$—	\$(171)	\$64,588	\$17,989	\$46,599	\$—
Financial liabilities:							
Contingent consideration				\$3,779	\$—	\$—	\$3,779
Total financial liabilities				\$3,779	\$—	\$—	\$3,779
						December 31, 2017	
Reported as:							
Cash equivalents						\$	592
Restricted cash							5,406
Marketable securities							58,590
Total cash equivalents, restricted cash, and marketable securities						\$	64,588
Accrued liabilities						\$	3,779

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented. The total fair value of investments with unrealized losses at September 30, 2018 was \$27.5 million. None of the available-for-sale securities held as of September 30, 2018 has been in a continuous unrealized loss position for more than one year. At September 30, 2018, unrealized losses on available-for-sale investments are not attributed to credit risk and are considered to be temporary. The Company believes it is more likely than not that investments in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. To date, the Company has not identified any other-than-temporary declines in market value and thus has not recorded any impairment charges on its financial assets other than on its convertible notes which are described in Note 8, "Investment in privately held company."

At September 30, 2018, the remaining contractual maturities of available-for-sale securities ranged from zero to five months.

The following tables present the Company's Level 3 financial instruments that are measured at fair value on a recurring basis (in thousands):

Level 3
Contingent

Consideration

	Liability
Balance as of December 31, 2017	\$ 3,779
Change in estimate of fair value	988
Balance as of September 30, 2018	\$ 4,767

Level 3
Convertible

	Note
Balance as of December 31, 2017	\$ —
Convertible note	367
Balance as of September 30, 2018	\$ 367

The Company's debt securities of U.S. government agency entities are classified as Level 2 as they are valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and

discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to benchmark yields, interest rate curves, reported trades, broker/dealer quotes and reference data.

The Company's convertible note receivable is classified as Level 3 as it is valued based upon market interest rates for similar debt instruments, estimates of the debtor's ability to repay the note and estimates of the likelihood of future events occurring which would trigger repayment of the note, all of which were significant inputs in the Level 3 measurement not supported by market activity.

As of September 30, 2018, the Company had a contingent obligation up to \$5.0 million payable in the Company's common stock to the former owners of AltaVoice in conjunction with the Company's acquisition of AltaVoice in January 2017. The amount of the contingent obligation is dependent upon future revenues attributable to AltaVoice. If revenue attributable to AltaVoice for the combined period of 2017 and 2018 is at least \$10 million, the Company will make a payment of up to \$5.0 million in the Company's common stock on March 31, 2019. The Company estimated the fair value of the contingent obligation at \$2.2 million at the acquisition date of January 6, 2017, based on a Monte Carlo simulation, as well as estimates of the 30-day trailing price of its stock at certain dates, its volatility assumptions and its revenue forecasts, all of which were significant inputs in the Level 3 measurement not supported by market activity. The value of the contingent obligation is remeasured to fair value at each reporting date. Changes to revenue forecasts can significantly affect the estimated fair value of the contingent obligation. Changes in estimated fair value are recorded quarterly as general and administrative expense until the contingent obligation is paid or expires. The total of changes in the fair value of the contingent obligation between the acquisition date and September 30, 2018 was an increase of \$2.6 million.

The fair value of the Company's outstanding debt is estimated using the net present value of future debt payments, discounted at an interest rate that is consistent with market interest rates, which is a Level 2 input. The carrying amount and the estimated fair value of the Company's outstanding debt at September 30, 2018 and December 31, 2017, are as follows (in thousands):

	September 30, 2018		December 31, 2017	
	Carrying	Fair	Carrying	Fair
	Amount	Value	Amount	Value
Debt	\$58,489	\$60,805	\$39,084	\$40,526

8. Investment in privately held company

On March 15, 2018, the Company entered into a collaboration agreement with KEW, Inc. ("KEW"), a privately held comprehensive genomic profiling company. The Company determined it has a variable interest in a VIE through its investment in a convertible note issued by KEW.

During the three and nine months ended September 30, 2018, the Company incurred losses relating to this collaboration agreement with KEW of \$1.9 million which were recognized in general and administrative expenses in the Company's consolidated statements of operations. As of September 30, 2018, the Company must continue to purchase incremental \$0.2 million convertible notes each month for three months and make monthly payments of \$0.2 million for the right of first refusal for three months.

9. Commitments and contingencies

Operating leases

In September 2015, the Company entered into a lease agreement for a headquarters and production facility in San Francisco, California. This lease expires in July 2026 and the Company may renew the lease for an additional ten years. The Company determined the lease term to be a ten-year period expiring in 2026. The lease term commenced when the Company took occupancy of the facility in February 2016. In connection with the execution of the lease, the Company provided a security deposit of approximately \$4.6 million which is included in restricted cash in the Company's condensed consolidated balance sheets. Minimum annual rent under the lease is subject to increases based on stated rental adjustment terms. In addition, per the terms of the lease, the Company received a \$5.2 million lease incentive in the form of reimbursement from the landlord for a portion of the costs of leasehold improvements the Company made to the facility. The assets purchased with the lease incentive are included in property and equipment, net, in the Company's condensed consolidated balance sheets and the lease incentive is recognized as a reduction of rental expense on a straight-line basis over the term of the lease. Aggregate future minimum lease payments for the San Francisco facility at September 30, 2018 were approximately \$59.4 million.

Future minimum payments under non-cancelable operating leases as of September 30, 2018 are as follows (in thousands):

	Amounts
2018 (remainder of year)	\$ 2,422
2019	9,690
2020	9,570
2021	9,787
2022	9,712
Thereafter	29,845
Total minimum lease payments	\$ 71,026

Rent expense was \$2.4 million and \$2.1 million for the three months ended September 30, 2018 and 2017, respectively and \$7.1 million and \$6.1 million for the nine months ended September 30, 2018 and 2017, respectively.

Debt financing

In July 2015, the Company entered into a Loan and Security Agreement (the “2015 Loan Agreement”) with a bank under which term loans were available for purchases of equipment up to an aggregate of \$15.0 million.

On March 15, 2017, the Company entered into a Loan and Security Agreement (the “2017 Loan Agreement”) with a lender pursuant to which the Company borrowed an initial term loan of \$40.0 million, and received net proceeds of approximately \$39.7 million. In connection with entering into the 2017 Loan Agreement, the Company terminated the 2015 Loan Agreement and repaid in full the balance of its obligations under that agreement, approximately \$12.1 million. The payment to the lender under the 2015 Loan Agreement included a prepayment premium of \$0.7 million, which was classified as extinguishment of debt and included in other income (expense), net.

Subject to certain conditions, the Company was eligible to borrow a second term loan pursuant to the 2017 Loan Agreement of \$20.0 million in the first quarter of 2018 and did so on March 12, 2018, receiving net proceeds of approximately \$19.8 million.

In February 2018 and June 2018, the Company entered into amendments to the 2017 Loan Agreement (the “2018 Amendments”) pursuant to which the Company, subject to certain conditions, is eligible to borrow a third term loan of \$20.0 million, during the period from April 2, 2018 to December 31, 2018. If the third term loan becomes available and is not fully drawn, a fee of 1% will be applied to the difference between \$20.0 million and the amount drawn. The 2018 Amendments added a quarterly covenant to achieve certain accession volumes. Substantially all other terms of the 2017 Loan Agreement as amended by the 2018 Amendments (the “Amended 2017 Loan Agreement”) are consistent with the terms of the 2017 Loan Agreement.

Term loans under the Amended 2017 Loan Agreement bear interest at a floating rate equal to an index rate plus 7.73%, where the index rate is the greater of 0.77% or the 30-day U.S. Dollar London Interbank Offered Rate (“LIBOR”) as reported in The Wall Street Journal, with the floating rate resetting monthly subject to a floor of 8.5%. The Company can make monthly interest-only payments until May 1, 2019 (or, subject to certain conditions, May 1, 2020), and thereafter monthly payments of principal and interest are required to fully amortize the borrowed amount by a final maturity date of March 1, 2022. A fee of 5% of each funded draw is due at the earlier of prepayment or loan maturity, a facility fee of 0.5% is due upon funding for each draw, and a prepayment fee of between 1% and 3% of the

outstanding balance will apply in the event of a prepayment. Concurrent with each term loan, the Company will grant to the lender a warrant to acquire shares of the Company's common stock equal to the quotient of 3% of the funded amount divided by a per share exercise price equal to the lower of the average closing price for the previous ten days of trading (calculated on the day prior to funding) or the closing price on the day prior to funding. In connection with the initial term loan, the Company granted the lender warrants to purchase 116,845 shares of common stock at an exercise price of \$10.27 per share. The Company classified these warrants as equity and determined their fair value to be \$0.7 million. In connection with the second term loan, the Company granted the lender warrants to purchase 85,482 shares of common stock at an exercise price of \$7.02 per share. The Company classified these warrants as equity and determined their fair value to be \$0.4 million. All warrants issued pursuant to the Amended 2017 Loan Agreement have a term of ten years from the date of issuance and include a cashless exercise provision.

The Company's obligations under the Amended 2017 Loan Agreement are subject to quarterly covenants to achieve certain revenue levels and accessioned test volumes as well as additional covenants, including limits on the Company's ability to dispose of assets, undergo a change in control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of its capital stock, repurchase stock and make investments, in each case subject to certain exceptions. At September 30, 2018, the Company was in compliance with all covenants under the Amended 2017 Loan Agreement. The Company's obligations under the Amended 2017 Loan Agreement are secured by a security interest on substantially all the Company's assets, excluding its intellectual property.

At September 30, 2018, obligations under the Amended 2017 Loan Agreement were \$60.0 million. Debt issuance costs related to the Amended 2017 Loan Agreement totaling \$0.6 million and the fair value of warrants totaling \$1.1 million were recorded as direct deductions from the debt liability and are being amortized to interest expense over the term of the Amended 2017 Loan Agreement. Future payments under the Amended 2017 Loan Agreement as of September 30, 2018 are as follows (in thousands):

	Amounts
2018 (remainder of year)	\$1,493
2019	19,302
2020	24,260
2021	22,196
2022	8,229
Thereafter	—
Total remaining debt payments	75,480
Less: amount representing debt discount	(1,511)
Less: amount representing interest	(15,480)
Present value of remaining debt payments	58,489
Less: current portion	(8,135)
Total non-current debt obligation	\$50,354

Interest expense related to the Amended 2017 Loan Agreement and the 2015 Loan Agreement totaled \$1.8 million and \$1.1 million for the three months ended September 30, 2018 and 2017, respectively and \$4.7 million and \$1.3 million for the nine months ended September 30, 2018 and 2017, respectively.

Capital leases

The Company has entered into various capital lease agreements to obtain laboratory equipment. The terms of the capital leases are typically three years and interest rates for capital leases outstanding at September 30, 2018 ranged from 5.2% to 8.8%. The capital leases are secured by the underlying equipment. The portion of the future payments designated as principal repayment was classified as a capital lease obligation on the condensed consolidated balance sheets.

Future payments under capital leases at September 30, 2018 are as follows (in thousands):

	Amounts
2018 (remainder of year)	\$ 522
2019	2,087
2020	1,394
2021	21
Total capital lease obligations	4,024
Less: amount representing interest	(244)
Present value of net minimum capital lease payments	3,780

Edgar Filing: Invitae Corp - Form 10-Q

Less: current portion	(1,857)
Total non-current capital lease obligations	\$ 1,923

Interest expense related to capital leases was \$0.1 million for the three months ended September 30, 2018 and 2017 and \$0.2 million and \$0.1 million for the nine months ended September 30, 2018 and 2017, respectively.

Property and equipment under capital leases was \$7.0 million and \$11.4 million as of September 30, 2018 and December 31, 2017, respectively. Accumulated depreciation on these assets was \$1.6 million and \$3.0 million at September 30, 2018 and December 31, 2017, respectively.

Other commitments

In the normal course of business, the Company enters into various purchase commitments primarily related to service agreements and laboratory supplies. At September 30, 2018, the Company's total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year were \$8.3 million.

At September 30, 2018, the Company was committed to make a minimum of three monthly payments of \$0.5 million relating to its collaboration agreement with KEW. (See Note 8, "Investment in privately held company" for further information.)

In September 2018, the Company entered into a co-development agreement with a privately held genetics testing company focused on single molecule digital array detection platforms. The co-development agreement grants the Company the right of first refusal to enter into an agreement for an acquisition of the entity in return for total fees of \$3.0 million over the term of the agreement, of which \$0.5 million has been paid by the Company as of September 30, 2018. The unpaid fees of \$2.5 million were recorded as an accrued liability in the Company's consolidated balance sheets as of September 30, 2018.

Guarantees and indemnifications

As permitted under Delaware law and in accordance with the Company's bylaws, the Company indemnifies its 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, the Company maintains director and officer liability insurance. This insurance allows the transfer of the risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company did not record any liabilities associated with these indemnification agreements at September 30, 2018 or December 31, 2017.

Contingencies

The Company was not a party to any material legal proceedings at September 30, 2018, or at the date of this report. The Company may from time to time become involved in various legal proceedings arising in the ordinary course of business, and the resolution of any such claims could be material.

10. Stockholders' equity

2018 Sales Agreement

On August 9, 2018, the Company entered into a Common Stock Sales Agreement (the "2018 Sales Agreement") with Cowen and Company, LLC ("Cowen"), under which the Company may offer and sell from time to time at its sole discretion shares of its common stock through Cowen as its sales agent, in an aggregate amount not to exceed \$75 million. Cowen may sell the shares by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including without limitation sales made directly on The New York Stock Exchange, and also may sell the shares in privately negotiated transactions, subject to the Company's prior approval. The Company will pay Cowen 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. For the three and nine months ended September 30, 2018, the Company sold a total of 4,325,134 shares of common stock under the 2018 Sales Agreement for aggregate gross proceeds of \$61.1 million and net proceeds of \$59.0 million.

Public offering

In April 2018, the Company sold, in an underwritten public offering, an aggregate of 12,777,777 shares of its common stock at a price of \$4.50 per share, for gross proceeds of \$57.5 million and net proceeds of \$53.5 million.

Warrant exercises

During the three and nine months ended September 30, 2018, the Company received \$3.3 million and \$6.5 million, respectively, from exercises of warrants issued pursuant the acquisition of CombiMatrix (See Note 4, "Business

combinations”).

11. Stock incentive plans

Stock incentive plans

In 2010, the Company 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 the Board of Directors. Under the terms of the 2010 Plan, options may be granted at an exercise price not less than fair market value. For employees holding more than 10% of the voting rights of all classes of stock, the exercise prices for incentive and nonstatutory stock options must be at least 110% of fair market of the common stock on the grant date, as determined by the Board of Directors. The terms of options granted under the 2010 Plan may not exceed ten years.

25

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

Options granted generally vest over a period of four years. Typically, the vesting schedule for options granted to newly hired employees provides that 1/4 of the award vests upon the first anniversary of the employee’s date of hire, with the remainder of the award vesting monthly thereafter at a rate of 1/48 of the total shares subject to the option. All other options typically vest in equal monthly installments over the four-year vesting schedule.

RSUs generally vest over a period of three years. Typically, the vesting schedule for RSUs provides that one third of the award vests upon each anniversary of the grant date.

In February 2016, the Company granted PRSUs under the 2015 Plan, which PRSUs could be earned based on the achievement of specified performance conditions measured over a period of approximately 12 months. In February 2017, upon the Audit Committee’s determination of the level of achievement, 352,045 fully vested stock units were awarded to holders of PRSUs.

Based on its evaluations of the probability of achieving performance conditions, the Company recorded stock-based compensation expense of \$0.4 million for the nine months ended September 30, 2018 and 2017 related to PRSUs. There was no stock-based compensation expense recorded for either three-month period ended September 30, 2018 or 2017 nor for the nine month period ended September 30, 2018 in relation to PRSUs.

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

	Shares	Stock	Weighted-Average	Weighted-Average	Aggregate
	Available	Options	Exercise	Remaining Contractual Life (years)	Intrinsic Value
	For Grant	Outstanding	Price		
Balances at December 31, 2017	2,397,234	4,114,874	\$ 8.51	7.63	\$ 5,128
Additional shares reserved	754,363	—			
Options granted	(260,000)	260,000	8.50		
Options cancelled	158,823	(158,823)	9.34		
Options exercised	—	(326,317)	7.85		
RSUs granted	(3,088,104)	—			
RSUs cancelled	319,226	—			

Edgar Filing: Invitae Corp - Form 10-Q

Balances at September 30, 2018	281,542	3,889,734	\$ 8.53	7.12	\$ 31,901
Options exercisable at September 30, 2018		2,579,154	\$ 8.16	6.66	\$ 22,097
Options vested and expected to vest at September 30, 2018		3,704,312	\$ 8.51	7.06	\$ 30,465

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

The weighted-average fair value of options to purchase common stock granted was \$4.87 and \$5.97 in the nine months ended September 30, 2018, and 2017, respectively. The weighted-average fair value of RSUs granted was \$6.99 and \$10.21 in the nine months ended September 30, 2018 and 2017, respectively.

The total grant-date fair value of options to purchase common stock vested was \$15.9 million and \$5.1 million in the nine months ended September 30, 2018 and 2017, respectively.

The intrinsic value of options to purchase common stock exercised was \$1.5 million and \$1.8 million in the nine months ended September 30, 2018 and 2017, respectively.

The following table summarizes RSU activity for the nine months ended September 30, 2018:

	Number of	Weighted- Average Grant Date Fair Value
	Shares	
Balance at December 31, 2017	2,387,120	\$ 9.91
RSUs granted	3,088,104	\$ 6.99
RSUs vested	(1,117,944)	\$ 8.84
RSUs cancelled	(319,226)	\$ 8.92
Balance at September 30, 2018	4,038,054	\$ 8.06

2015 employee stock purchase plan

In January 2015, the Company adopted the 2015 Employee Stock Purchase Plan (the “ESPP”), which became effective upon the closing of the IPO. Employees participating in the ESPP may purchase common stock at 85% of the lesser of the fair market value of common stock on the purchase date or last trading day preceding the offering date. At September 30, 2018, cash received from payroll deductions pursuant to the ESPP was \$1.4 million.

The ESPP provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 and continuing through January 1, 2025. At September 30, 2018, a total of 567,707 shares of common stock are reserved for issuance under the ESPP.

Stock-based compensation

The Company uses the grant date fair value of its common stock to value both employee and non-employee options when granted. The Company revalues non-employee options each reporting period using the fair market value of the Company’s common stock as of the last day of each reporting period.

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

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

Expected volatility—Because the Company was privately held until February 2015 and did not have any trading history for its common stock prior to its IPO, the expected volatility was estimated based on the average volatility for comparable publicly-traded life sciences companies, including molecular diagnostic companies, over a period equal to the expected term of the stock option grants. When selecting comparable companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies’ common stock during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

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

Dividend yield—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

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

	Three Months Ended September 30, 2018		Nine Months Ended September 30, 2017	
Expected term (in years)	6.00	—	6.00	6.03
Expected volatility	59.63%	—	59.58%	72.64%
Risk-free interest rate	2.82%	—	2.80%	2.01%

No stock options were granted in the three month period ended September 30, 2017.

Stock-based compensation related to stock options granted to non-employees is recognized as the stock options vest. The fair value of the stock options granted is calculated at each reporting date using the Black-Scholes option-pricing model based on the following assumptions:

	As of September 30, 2017
Expected term (in years)	—8.50 – 8.58
Expected volatility	—69.90 – 78.70%
Risk-free interest rate	—1.83 – 2.04%

No stock options granted to non-employees vested in the nine months ended September 30, 2018.

The following table summarizes stock-based compensation expense for the three and nine months ended September 30, 2018 and 2017 included in the condensed consolidated statements of operations (in thousands):

	Three Months Ended September 30, 2018 2017		Nine Months Ended September 30, 2018 2017	
Cost of revenue	\$747	\$404	\$2,320	\$1,606
Research and development	1,722	1,096	5,237	4,853
Selling and marketing	1,172	780	3,690	2,985
General and administrative	1,565	2,500	4,464	4,943
Total stock-based compensation expense	\$5,206	\$4,780	\$15,711	\$14,387

At September 30, 2018, unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was \$5.6 million, which the Company expects to recognize on a straight-line basis over a weighted-average period of 1.9 years. Unrecognized compensation expense related to RSUs at September 30, 2018, net of estimated forfeitures, was \$24.4 million, which the Company expects to recognize on a straight-line basis over a weighted-average period of 2.3 years. At September 30, 2018, there was no capitalized stock-based employee compensation.

12. Net loss per common share

Edgar Filing: Invitae Corp - Form 10-Q

The following table presents the calculation of basic and diluted net loss per share for the three and nine months ended September 30, 2018 and 2017 (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	\$(31,723)	\$(27,402)	\$(99,514)	\$(82,887)
Shares used in computing net loss per share, basic and diluted	70,152,804	48,221,896	63,935,336	44,639,416
Net loss per share, basic and diluted	\$(0.45)	\$(0.57)	\$(1.56)	\$(1.86)

The following common stock equivalents have been excluded from diluted net loss per share for the three and nine months ended September 30, 2018 and 2017 because their inclusion would be anti-dilutive:

	September 30,	
	2018	2017
Shares of common stock subject to outstanding options	3,889,734	4,264,222
Shares of common stock subject to outstanding warrants	949,328	116,845
Shares of common stock subject to outstanding RSUs	4,038,054	2,185,134
Shares of common stock pursuant to ESPP	250,410	142,947
Shares of common stock underlying Series A convertible preferred stock	3,458,823	3,458,823
Total shares of common stock equivalents	12,586,349	10,167,971

13. Geographic information

Revenue by country is determined based on the billing address of the customer. The following presents revenue by country for the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
United States	\$34,906	\$16,640	\$95,712	\$38,745
Canada	1,052	825	3,156	2,281
Rest of world	1,408	683	3,475	1,796
Total revenue	\$37,366	\$18,148	\$102,343	\$42,822

All long-lived assets at September 30, 2018 and December 31, 2017, were located in the United States.

14. Subsequent events

On November 6, 2018, the Company and certain of its subsidiaries, as guarantors, entered into a Note Purchase Agreement (the “Note Purchase Agreement”) with INN SA LLC, as collateral agent, and certain funds managed by Oberland Capital Management LLC, as purchasers (the “Oberland Funds” and, together with other purchasers party thereto from time to time, the “Purchasers”), pursuant to which the Company may sell to the Purchasers, and the Purchasers may buy from the Company, notes (the “Notes”) in an aggregate principal amount not to exceed \$200.0 million, consisting of:

- (i) an initial sale of \$75.0 million principal amount of Notes;
- (ii) at the option of the Company, a second sale of \$25.0 million principal amount of Notes, at any time through June 30, 2019;
- (iii) at the option of the Company, a third sale of up to \$50.0 million principal amount of Notes, in increments of \$25.0 million, to be borrowed at any time during the period beginning on July 1, 2019 and ending on December 31, 2019; and
- (iv) at the option of the Company, but subject to the approval of the Purchasers, a fourth sale of up to \$50.0 million principal amount of Notes, in no more than three increments of at least \$10.0 million, at any time through December 31, 2019, for certain permitted acquisitions and related expenses.

Pursuant to the Note Purchase Agreement, on November 6, 2018 (the “Closing Date”), the Company sold Notes in an aggregate principal amount of \$75.0 million, and received net proceeds of approximately \$10.3 million after terminating and repaying the balance of its obligations under the 2017 Loan Agreement of approximately \$64.7 million, but before payment of certain expenses payable by the Company.

The outstanding principal amount of the Notes bear interest at a rate of 8.75% annually, payable quarterly until the date which is 84 months after the Closing Date or the date on which all amounts owing to the Purchasers under the Note Purchase Agreement have been paid in full. In addition, beginning on January 1, 2020 and continuing until the

maturity date, the Purchasers will receive 0.50% of the annual net revenues of the Company, payable quarterly and subject to a maximum annual amount of such payments of \$1.625 million. The outstanding principal amount of the Notes, interest accrued thereon and any other amounts owing to the Purchasers under the Note Purchase Agreement will be due in full on the maturity date.

All of the Notes may be repaid prior to the full term at the option of the Company. Similarly, the Purchasers can demand repayment of the Notes prior to the full term in the event of a change of control of the Company or an event of default under the Note Purchase Agreement. If prepaid prior to the full term, the amount due will be: (a) 117.5% of the principal amount of the Notes if payment is made within 12 months after the Closing Date; (b) thereafter, 132.5% of the principal amount of the Notes if payment is made within 24 months after the Closing Date; (c) thereafter, 145.0% of the principal amount of the Notes if payment is made within 36 months after the Closing Date; and (d) thereafter, the amount necessary to generate an internal rate of return of 11.0% to the Purchasers, minus in the case of clause (a), (b) and (c) the sum of (i) all regularly scheduled interest paid prior to such date with respect to the Notes (excluding any default interest), plus (ii) all payments in respect of annual net revenues prior to such date, and calculated, in the case of clause (d), taking into account such sum.

The Company's Note Purchase Agreement contains quarterly covenants to achieve certain revenue levels as well as additional covenants, including limits on the Company's ability to dispose of assets, undergo a change of control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of its capital stock, repurchase stock and make investments, in each case subject to certain exceptions. The Company's obligations under the Note Purchase Agreement are secured by a security interest on substantially all of its and certain of its subsidiaries' assets.

In connection with the Note Purchase Agreement, on November 6, 2018, the Company entered into a Securities Purchase Agreement with the Oberland Funds, pursuant to which the Oberland Funds purchased 373,524 shares of the Company's common stock, \$0.0001 par value per share, at a price of \$13.386 per share.

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, 2017. 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 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;
- 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, including cost-savings and synergies, from our acquisitions;
- 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 assay to include additional genes;
- our expectations with respect to future hiring;
- the timing and results of studies with respect to our tests;
- developments and projections relating to our competitors and our industry;
- 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;
- our ability to obtain and maintain adequate reimbursement for our tests;
- regulatory developments in the United States and foreign countries;
- our ability to attract and retain key scientific or management personnel;
- our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- 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, judgements, estimates and assumptions on our financial results;
- our expectations regarding our future revenue, cost of revenue, operating expenses and capital expenditures, and our future capital requirements; and
- the impact of tax laws on our business.

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

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

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

Invitae and the Invitae logo are trademarks of Invitae Corporation. We also refer to trademarks of other companies and organizations in this report.

Mission and Strategy

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

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

- ✦ **Expanding our content offering.** We intend to continue steadily adding additional content to the Invitae platform, ultimately leading to affordable access to the personal molecular information relevant in enabling personalized medicine. The breadth and depth of our offering is a core and central contribution to an improved user experience.
- ✦ **Creating a unique user experience.** A state-of-the-art interactive platform will enhance our service offering, leverage the uniquely empowering characteristics of online sharing of genetic information and, we believe, enable a superior economic offering to clients. We intend to continue to expend substantial efforts developing, acquiring and implementing technology-driven enhancements to our customers’ experience. We believe that an enhanced user experience and the resulting benefits to our brand and reputation will help draw customers to us over and above our direct efforts to do so.
- ✦ **Driving volume.** We intend to increase our brand equity and visibility through excellent service and a variety of marketing and promotional techniques, including scientific publications and presentations, sales, marketing, public relations, social media and web technology vehicles. We believe that rapidly increasing volume 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 all of these strategic components will allow us to lower the cost of our service.
- ✦ **Lowering the costs and price of genetic information.** Our goal is to provide customers with a broad menu of genetic content at a reasonable price and rapid turn-around time in order to grow volume and further achieve economies of scale. As we do so and experience further cost savings, we expect that those cost savings will allow us to deliver still more comprehensive information at decreasing prices and further improve the customer experience, allowing us to experience cumulative benefits from all of the efforts outlined above.

Growth is core and central to the strategic approach to our business. In order to ensure genuine and lasting growth, we will prioritize, in order, the following in our decision-making processes:

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

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

Business overview

We offer high quality, comprehensive, affordable genetic testing across multiple clinical areas, including hereditary cancer, cardiology, neurology, pediatrics, metabolic conditions and rare diseases. To augment our offering and realize our mission, we have acquired multiple assets. We acquired four businesses in 2017 and in doing so expanded our suite of genome management offerings and completed our entry into prenatal and perinatal genetic testing.

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

We have experienced rapid growth. For the years ended December 31, 2017, 2016 and 2015, our revenue was \$68.2 million, \$25.0 million and \$8.4 million, respectively, and we incurred net losses of \$123.4 million, \$100.3 million and \$89.8 million, respectively. For the nine months ended September 30, 2018 and 2017, our revenue was \$102.3 million and \$42.8 million, respectively, and we incurred net losses of \$99.5 million and \$82.9 million, respectively. At September 30, 2018, our accumulated deficit was \$486.9 million. To meet the demands of scaling our business, we increased our number of employees to 723 at September 30, 2018 from 509 on September 30, 2017. We grew our sales force to 109 at September 30, 2018 from 77 at September 30, 2017. We expect headcount will continue to increase in 2018 as we add to the team to support anticipated growth.

Sales of our tests have grown significantly. In 2017, 2016 and 2015, we generated approximately 145,000, 57,000 and 19,000 billable tests, respectively. In the nine months ended September 30, 2018, we generated approximately 206,000 billable tests compared to approximately 86,500 billable tests in the same period in 2017. Approximately 28% of the billable tests we performed in the first nine months of 2018 were billable to institutions and patients, and the remainder were billable to third-party payers. Many of the gene tests on our assays are tests for which private 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 co-insurance or co-payment requirement from the patient which may result in further delay or decreased likelihood of collection.

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

We believe that the keys to our future growth will be to increase billable test volumes, achieve broad reimbursement coverage for our tests from third-party payers, consistently 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.

Factors affecting our performance

Number of billable tests

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

Success obtaining and maintaining reimbursement

Our ability to increase the number of billable tests and our revenue will depend in part on our success achieving broad reimbursement coverage and laboratory service contracts for our tests from third-party payers and agreements with institutions and partners. Reimbursement may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary and cost-effective, as well as whether we are in contract, where we get paid more consistently and at higher rates. Because each payer makes its own decision as to whether to establish a policy or enter into a contract to reimburse for our testing services, seeking these approvals is a time-consuming and costly process. In addition, clinicians 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. As of September 30, 2018, we have entered into contracts for laboratory services with payers covering approximately 262 million lives, comprised of Medicare, most national health plans, and Medicaid in 32 states, including California (Medi-Cal), our home state.

In cases where we have established reimbursement rates with third-party payers, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements may vary from payer to payer, and it may be time-consuming and require additional resources to meet these requirements. We may also experience delays in or denials of coverage if we do not adequately comply with these requirements. In addition, we have experienced, and may continue to experience, delays in reimbursement when we transition to being an in-network provider with a payer.

We expect to continue to focus our resources on increasing adoption of, and expanding coverage and reimbursement for, our current tests, tests provided by companies we acquire and any future tests we may develop. However, if we are not able to continue to obtain and maintain adequate reimbursement from third-party payers and institutions for our testing services and expand the base of clinicians ordering our tests, we may not be able to effectively increase the number of billable tests or our revenue.

Ability to lower the costs associated with performing our tests

Reducing the costs associated with performing our genetic tests is both a near-term 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, improving how we manage our materials, porting some tests onto a next generation sequencing platform and negotiating favorable terms for our materials purchases. We also intend to continue to design and implement hardware and software tools that will reduce personnel-related costs for both laboratory and clinical operations/medical interpretation by increasing personnel efficiency and thus lowering labor costs per test.

Ability to expand our genetic content

As we reduce our costs, we intend to continue to expand our test menus by steadily releasing additional genetic content for the same or lower prices per test, ultimately leading to affordable whole genome services. The breadth and flexibility of our offering will be a critical factor in our ability to address new markets for genetic testing services. Both of these will be critical to our ability to continue to grow the volume of billable tests we deliver.

Investment in our business and timing of expenses

We plan to continue to invest in our genetic testing and information management business. We deploy state-of-the-art and costly technologies in our genetic testing services, and we intend to continue to scale our infrastructure, including our testing capacity and information systems. We also expect to incur software development costs as we seek to further automate our laboratory processes and our genetic interpretation and report sign-out procedures, scale our customer service capabilities and expand the functionality of 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 facility in San Francisco to handle newly acquired tests and to accommodate growth. In addition, we expect to incur ongoing expenses as a result of operating as a public company. The expenses we incur may vary significantly by quarter, as we focus on building out different aspects of our business.

How we recognize revenue

From inception through December 31, 2017, we recognized revenue principally when cash was received. Effective January 1, 2018, we implemented Financial Accounting Standards Board Accounting Standards Codification, or ASC Topic 2014-09, Revenue from Contracts with Customers, or Topic 606, using the modified retrospective method. (See Note 3, “Revenue, accounts receivable and deferred revenue” in the Notes to Condensed Consolidated Financial Statements included elsewhere in this report.) Under Topic

606, 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 will be 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 co-payments, the existence of secondary payers and claims denials.

Financial overview

Revenue

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

Cost of test revenue

Cost of revenue reflects the aggregate costs incurred in delivering test results to clinicians and includes expenses for materials and supplies, personnel-related costs, equipment and infrastructure expenses associated with testing and allocated overhead including rent, equipment depreciation and utilities. Costs associated with performing our test are recorded as the patient's sample is processed. We expect cost of revenue to generally increase in line with the increase in the number of tests we perform. However, we expect that the cost per test will decrease over time due to the efficiencies we expect to gain as test volume increases and from automation and other cost reductions.

Operating expenses

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

Research and development

Research and development expenses represent costs incurred to develop our technology and future tests. These costs are principally for process development associated with our efforts to expand the number of genes we can evaluate in our tests and with our efforts to lower the cost of performing our test. In addition, we incur process development costs to further develop the software we use to operate our laboratory, analyze the data it generates, process customer orders, deliver reports and automate our business processes. These costs consist of personnel-related costs, laboratory supplies and equipment expenses, consulting costs and allocated overhead including rent, information technology, equipment depreciation and utilities.

We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses will increase as we continue our efforts to develop additional tests, port some of our acquired tests to our production facility, reduce testing costs and work on scaling the business.

Selling and marketing

Selling and marketing expenses consist of personnel-related costs, client service expenses, advertising and marketing expenses, educational and promotional expenses, market research and analysis, and allocated overhead including rent, information technology, equipment depreciation and utilities. We expect our selling expenses to be significantly higher as we expand our salesforce.

General and administrative

General and administrative expenses include executive, finance and accounting, billing and collections, legal and human resources functions. These expenses include personnel-related costs, audit and legal expenses, consulting costs, and allocated overhead including rent, information technology, equipment depreciation, utilities, and losses incurred in relation to our collaboration agreement with KEW. We expect our general and administrative expenses to increase as we support continued growth of operations.

Other income (expense), net

Other income (expense), net, primarily consists of interest income, offset by losses on extinguishment of debt, adjustments to fair value of acquisition liabilities, and losses on disposal of assets.

Interest expense

Interest expense is attributable to debt financing and capital leases. See Note 9 “Commitments and contingencies” in the Notes to Condensed Consolidated Financial Statements included elsewhere in this report.

Critical accounting policies and estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our condensed 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 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. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates.

Revenue recognition

We generate test revenue primarily from delivery of test reports generated from our assays. Other revenue consists primarily of revenue from genome network subscription services which we recognize on a straight-line basis over the subscription term, and from revenue from collaboration agreements.

Effective January 1, 2018, we adopted ASC Topic 606. Under Topic 606 we generally recognize revenue on an accrual basis, that is when a customer obtains control of the promised goods or services which for us is delivery of a test report. Accrual amounts recognized under Topic 606 are based on an estimate of the consideration that we expect to receive, and such estimates will be adjusted and subsequently recorded until fully settled. The estimate of the consideration that we expect to receive requires significant judgement by management and any adjustments may be material.

Business Combinations — Purchase Accounting

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

We account for acquisitions of entities that include inputs and processes and have the ability to create outputs as business combinations. The purchase prices of acquisitions are allocated to tangible assets, liabilities and identifiable

intangible assets acquired based on their estimated fair values. The excess of purchase prices over those fair values is recorded as goodwill. Acquisition-related expenses are expensed as incurred. While we use our best estimates and assumptions as a part of the process to accurately value assets acquired and liabilities assumed at the business combination date, these estimates and assumptions are inherently uncertain and subject to refinement. Our key assumptions used have included projected revenue, cost of goods sold and operating expenses for our acquired entities, as well as discount rates. As a result, during the measurement period, which may be up to one year from the business combination date, we may record adjustments to the assets acquired and liabilities assumed, with the corresponding offset to goodwill. After the measurement period, we record adjustments to assets acquired or liabilities assumed subsequent to the measurement period in our operating results in the period in which the adjustments were determined.

Goodwill

In accordance with ASC 350, Intangibles – Goodwill and Other, or ASC 350, we do not amortize goodwill or other intangible assets with indefinite lives but rather test them for impairment. ASC 350 requires us to perform an impairment review of our goodwill balance at least annually, which we do as of October 1 each year, and whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable.

Stock-based compensation

Stock-based compensation expense is measured at the date of grant and is based on the estimated fair value of the award. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and restricted stock unit, or RSU, awards and on an accelerated basis for performance-based restricted stock unit, or PRSU, awards. We recognize stock-based compensation expense associated with PRSU grants when we determine the achievement of performance conditions is probable. In determining the fair value of stock options and Employee Stock Purchase Plan, or ESPP, purchases, we estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. We estimate the grant date fair value of RSU and PRSU awards based on the grant date share price.

We account for stock-based compensation arrangements with non-employees using a fair value approach. The fair value of these options is measured using the Black-Scholes option-pricing model reflecting the same assumptions as applied to employee options in each of the reported periods, other than the expected life, which is assumed to be the remaining contractual life of the option. The compensation expenses of these arrangements are subject to remeasurement over the vesting terms as earned.

For the nine months ended September 30, 2018 and 2017, we recorded stock-based compensation expense of \$15.7 million, and \$14.4 million, respectively. At September 30, 2018, our unrecognized stock-based compensation expense related to unvested stock options, net of estimated forfeitures, was \$5.6 million, which we expect to recognize over a weighted-average period of 1.9 years. Unrecognized compensation expense related to RSUs at September 30, 2018 was \$24.4 million, which we expect to recognize on a straight-line basis over a weighted-average period of 2.3 years.

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

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

Expected volatility—Since we were privately held until our initial public offering in February 2015 and did not have any trading history for our common stock, we have estimated expected volatility based on the average volatility for comparable publicly traded life sciences companies, including molecular diagnostics companies, over a period equal to the expected term of stock option grants and RSUs. When selecting comparable publicly-traded biopharmaceutical companies, including molecular diagnostics companies, on which we based our expected stock price volatility, we have selected companies with comparable characteristics to us, including enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected life of the stock-based awards. We have computed historical volatility data using daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We estimate expected volatility for ESPP purchases using our own stock price volatility over the expected six-month term of the ESPP purchase period.

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

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

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

Results of operations

Comparison of the three months ended September 30, 2018 and 2017 (in thousands except for percentage changes)

	Three Months Ended				
	September 30, 2018	September 30, 2017	Dollar Change	% Change	
Revenue:					
Test revenue	\$36,611	\$17,310	\$19,301	112	%
Other revenue	755	838	(83)	(10)	%
Total revenue	37,366	18,148	19,218	106	%
Operating expenses:					
Cost of test revenue	20,441	13,274	7,167	54	%
Research and development	15,776	11,502	4,274	37	%
Selling and marketing	17,591	13,246	4,345	33	%
General and administrative	13,668	11,102	2,566	23	%
Total operating expenses	67,476	49,124	18,352	37	%
Loss from operations	(30,110)	(30,976)	866	(3)	%
Other income (expense), net	231	(56)	287	(513)	%
Interest expense	(1,844)	(1,128)	(716)	63	%
Net loss before taxes	(31,723)	(32,160)	437	(1)	%
Income tax benefit	—	(4,758)	4,758	(100)	%
Net loss	\$(31,723)	\$(27,402)	\$(4,321)	16	%

Comparison of the nine months ended September 30, 2018 and 2017 (in thousands except for percentage changes)

	Nine Months Ended				
	September 30, 2018	September 30, 2017	Dollar Change	% Change	
Revenue:					
Test revenue	\$100,014	\$40,597	\$59,417	146	%
Other revenue	2,329	2,225	104	5	%
Total revenue	102,343	42,822	59,521	139	%
Operating expenses:					
Cost of test revenue	58,964	33,093	25,871	78	%
Research and development	46,926	32,864	14,062	43	%
Selling and marketing	55,222	37,338	17,884	48	%
General and administrative	37,884	25,915	11,969	46	%
Total operating expenses	198,996	129,210	69,786	54	%
Loss from operations	(96,653)	(86,388)	(10,265)	12	%
Other income (expense), net	2,066	(596)	2,662	(447)	%
Interest expense	(4,927)	(2,517)	(2,410)	96	%
Net loss before taxes	(99,514)	(89,501)	(10,013)	11	%

Edgar Filing: Invitae Corp - Form 10-Q

Income tax benefit	—	(6,614)	6,614	(100)%
Net loss	\$(99,514)	\$(82,887)	\$(16,627)	20 %

Revenue

The increase in total revenue of \$19.2 million for the three months ended September 30, 2018 compared to the same period in 2017 was due primarily to increased test volume. Billable test volumes increased to approximately 75,000 in the three months ended September 30, 2018 compared to 39,000 in the same period of 2017. Average revenue per test increased to \$490 per test in the three months ended September 30, 2018 compared to \$442 per test in the comparable prior period.

The increase in total revenue of \$59.5 million for the nine months ended September 30, 2018 compared to the same period in 2017 was due primarily to increased test volume and the full effect of businesses acquired in 2017. Billable test volumes increased to approximately 206,000 in the nine months ended September 30, 2018 compared to 86,500 in the same period of 2017. In addition, test revenue for the nine months ended September 30, 2018 included a \$2.3 million adjustment relating to performance obligations satisfied in prior periods. This adjustment reflected a change in accounting estimate relating to notification from Medicare of approval for payment of deletion/duplication analysis under Current Procedure Terminology (CPT) code 84133 in conjunction with CPT code 81432, for tests completed during the second half of 2017. Average revenue per test increased to \$485 per test in the nine months ended September 30, 2018 compared to \$439 per test in the comparable prior period.

Cost of test revenue

The increase in the cost of test revenue of \$7.2 million for the three months ended September 30, 2018 compared to the same period in 2017 was primarily due to costs associated with increased test volume, partially offset by the effect of cost efficiencies. For the three months ended September 30, 2018, the number of samples accessioned increased to approximately 78,000 from approximately 40,000 for the same period in 2017. Cost per sample accessioned was \$262 in the three months ended September 30, 2018 compared to \$331 for the same period in 2017. The lower cost per sample accessioned in the current period was primarily attributable to increased volume, which together with automation efficiencies, resulted in lower per-sample costs for laboratory materials, labor and equipment depreciation. In addition, per-sample shipping costs were lower in the three months ended September 30, 2018 compared to the same period in 2017.

The increase in the cost of test revenue of \$25.9 million for the nine months ended September 30, 2018 compared to the same period in 2017 was primarily due to costs associated with increased test volume, partially offset by the effect of cost efficiencies. For the nine months ended September 30, 2018, the number of samples accessioned increased to approximately 216,000 from approximately 97,000 for the same period in 2017. Cost per sample accessioned was \$273 in the nine months ended September 30, 2018 compared to \$351 for the same period in 2017. The lower cost per sample accessioned in the nine months ended September 30, 2018 was primarily attributable to increased volume, which together with automation efficiencies resulted in lower per-sample costs for laboratory materials, labor and equipment depreciation. In addition, per-sample shipping costs were lower in the nine months ended September 30, 2018 compared to the same period in 2017.

Research and development

The increase in research and development expense of \$4.3 million for the three months ended September 30, 2018 compared to the same period in 2017 was due to the growth of the business and the effect of business acquisitions in 2017 and principally consisted of the following elements: personnel-related costs increased by \$6.1 million, principally reflecting increased headcount; laboratory expenses increased by \$1.0 million; allocated technology and facilities-related expenses increased by \$0.8 million; professional fees increased by \$0.4 million; and depreciation and amortization costs increased by \$0.3 million, principally due to amortization of intangible assets associated with business acquisitions.

These cost increases were partially offset by increased allocations of resources from research and development to cost of test revenue, resulting from increased test volumes, which reduced research and development expense by \$4.9 million.

The increase in research and development expense of \$14.1 million for the nine months ended September 30, 2018 compared to the same period in 2017 was due to the growth of the business and the effect of business acquisitions in 2017 and principally consisted of the following elements: personnel-related costs increased by \$16.2 million,

primarily reflecting increased headcount; laboratory expenses increased by \$4.1 million; allocated technology and facilities-related expenses increased by \$3.2 million; depreciation and amortization costs increased by \$1.9 million, principally due to amortization of intangible assets associated with business acquisitions; professional fees increased by \$1.7 million reflecting increased utilization of outside consultants; and information technology costs increased by \$1.0 million due principally to spending on networking equipment and software licenses.

These cost increases were partially offset by increased allocations of resources from research and development to cost of test revenue, resulting from increased test volumes, which reduced research and development expense by \$15.0 million.

Selling and marketing

The increase in selling and marketing expense of \$4.3 million for the three months ended September 30, 2018 compared to the same period in 2017 was due primarily to the growth of the business and the effect of business acquisitions in 2017 and principally consisted of the following elements: personnel-related costs increased by \$2.8 million primarily reflecting increased headcount; marketing costs, principally for branding initiatives, increased by \$0.5 million; headcount related costs, principally for travel, increased by \$0.4 million; and depreciation and amortization costs increased by \$0.4 million, principally due to amortization of intangible assets associated with business acquisitions.

The increase in selling and marketing expense of \$17.9 million for the nine months ended September 30, 2018 compared to the same period in 2017 was due primarily to the growth of the business and the effect of business acquisitions in 2017 and principally consisted of the following elements: personnel-related costs increased by \$10.7 million reflecting increased headcount; marketing costs, principally for branding initiatives, increased by \$2.4 million; headcount related costs, principally for travel, increased by \$2.0 million; depreciation and amortization costs increased by \$1.3 million, principally due to amortization of intangible assets associated with business acquisitions; professional fees increased by \$0.5 million reflecting increased utilization of outside consultants; and allocated technology and facilities-related expenses increased by \$0.5 million. The increase in personnel-related costs included commissions of \$2.5 million and severance costs of \$0.3 million.

General and administrative

The increase in general and administrative expense of \$2.6 million for the three months ended September 30, 2018 compared to the same period in 2017 was due primarily to the growth of the business and the effect of business acquisitions in 2017 and principally consisted of the following elements; personnel-related costs increased by \$1.9 million principally due to increased headcount, including an internal billings and collection team hired to replace third-party billings and collections contractors; \$1.9 million of losses related to our collaboration agreement with KEW during the three months ended September 30, 2018; right of first refusal payments relating to the collaboration agreement with KEW, Inc. and a separate co-development agreement with a different privately held genetics company increased by \$0.9 million (see Note 8, “Investment in privately held company,” and Note 9, “Commitments and contingencies,” in the Notes to Condensed Consolidated Financial Statements included elsewhere in this report for further details on these arrangements); occupancy costs increased by \$0.4 million, due principally to costs related to facilities acquired through business acquisitions; and professional fees increased by \$0.4 million principally due to the utilization of outside consultants to augment existing staff.

These cost increases were partially offset by a decrease of \$1.7 million for acquisition-related stock-based compensation expense, a decrease of \$0.7 million for acquisition-related transaction costs, and an increase of \$0.7 million in allocations of technology and facilities-related expenses to other functional areas.

The increase in general and administrative expense of \$12.0 million for the nine months ended September 30, 2018 compared to the same period in 2017 was due primarily to the growth of the business and the effect of business acquisitions in 2017 and principally consisted of the following elements: personnel-related costs increased by \$5.5 million principally due to increased headcount, including an internal billings and collection team hired to replace third-party billings and collections contractors; professional fees increased by \$2.2 million principally due to the utilization of outside consultants to augment existing staff; occupancy costs increased by \$1.9 million, due principally to costs related to facilities acquired through business acquisitions; \$1.9 million of losses related to our collaboration agreement with KEW during the three months ended September 30, 2018; right of first refusal payments relating to the collaboration agreement with KEW and a separate co-development agreement with a different privately held genetics company increased by \$1.8 million; (see Note 8, “Investment in privately held company,” and Note 9, “Commitments and contingencies,” in the Notes to Condensed Consolidated Financial Statements included elsewhere in this report for further details on these arrangements); information technology costs increased by \$1.2 million due to computer equipment and software purchases to support headcount growth; and headcount-related costs, principally travel related costs, increased by \$0.5 million. The increase in personnel-related costs included increases in severance and recruitment costs of \$1.0 million and \$0.6 million, respectively.

These cost increases were partially offset by an increase of \$3.7 million in allocations of technology and facilities-related expenses to other functional areas.

Other income (expense), net

The increase in other income (expense), net of \$0.3 million for the three months ended September 30, 2018 compared to the same period in 2017 was due to interest income generated on our cash equivalents and marketable securities.

The increase in other income (expense), net of \$2.7 million for the nine months ended September 30, 2018 compared to the same period in 2017 was principally due to a gain on remeasurement of an acquisition-related liability from AltaVoice of \$1.6 million in the nine months ended September 30, 2018 and to a loss on extinguishment of debt of \$0.7 million recorded in the nine months ended September 30, 2017.

Interest expense

Increases in interest expense of \$0.7 million for the three months ended September 30, 2018 compared to the same period in 2017 and \$2.4 million for the nine months ended September 30, 2018 compared to the same period in 2017, were due principally to borrowings under a loan and security agreement entered into in March 2017 and amended in February 2018 and June 2018 (the Amended 2017 Loan Agreement). See Note 9, "Commitments and contingencies" in the Notes to Condensed Consolidated Financial

Statements included elsewhere in this report. Pursuant to the Amended 2017 Loan Agreement, we borrowed \$40.0 million in March 2017 and an additional \$20.0 million in March 2018.

Income tax benefit

The income tax benefit of \$4.8 million and \$6.6 million recorded in the three and nine months ended September 30, 2017, respectively, were due to changes in our deferred income taxes and associated valuation allowances resulting from our acquisitions of Good Start of \$4.8 million in the three months ended September 30, 2017 and AltaVoice of \$1.4 million, Ommdom of \$0.4 million, and Good Start of \$4.8 million in the nine months ended September 30, 2017.

Liquidity and capital resources

Liquidity and capital expenditures

We have incurred net losses since our inception. For the nine months ended September 30, 2018 and 2017, we had net losses of \$99.5 million and \$82.9 million, respectively, and we expect to incur additional losses in the near term. At September 30, 2018, we had an accumulated deficit of \$486.9 million. 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 net proceeds of \$536.5 million from sales of our capital stock, including net proceeds of approximately \$112.5 million from the sale of common stock in public offerings that closed in April 2018 and August 2018.

From inception through September 30, 2018, we have entered into various capital lease agreements for an aggregate financing amount of \$14.9 million to obtain laboratory equipment. The terms of our capital leases are typically three years. Interest rates for currently outstanding capital leases range from 5.2% to 8.8% and the leases are secured by the underlying equipment.

In addition, in July 2015, we entered into a Loan and Security Agreement (the “2015 Loan Agreement”) with a bank pursuant to which term loans were available for purchases of equipment up to an aggregate of \$15.0 million.

In March 2017, we entered into a Loan and Security Agreement (the “2017 Loan Agreement”) with a lender pursuant to which we borrowed an initial term loan of \$40.0 million and received net proceeds of approximately \$39.7 million. In connection with entering into the 2017 Loan Agreement, we terminated the 2015 Loan Agreement and repaid in full the balance of our obligations under that agreement, approximately \$12.1 million.

Pursuant to the 2017 Loan Agreement and subject to certain conditions, we were eligible to borrow a second term loan of \$20.0 million in the first quarter of 2018 and did so in March 2018, receiving net proceeds of \$19.8 million.

In February 2018 and June 2018, we entered into amendments to the 2017 Loan Agreement (the “2018 Amendments”) pursuant to which we, subject to certain conditions, are eligible to borrow a third term loan of \$20.0 million during the remainder of 2018. If the third term loan becomes available and is not fully drawn, a fee of 1% will be applied to the difference between \$20.0 million and the amount drawn. The 2018 Amendments added a quarterly covenant to achieve certain accession volumes. Substantially all other terms of the 2017 Loan Agreement as amended by the 2018 Amendments (“the Amended 2017 Loan Agreement”) are consistent with the terms of the 2017 Loan Agreement.

Term loans under the Amended 2017 Loan Agreement bear interest at a floating rate equal to an index rate plus 7.73%, where the index rate is the greater of 0.77% or the 30-day U.S. Dollar London Interbank Offered Rate, or LIBOR, as reported in The Wall Street Journal, with the floating rate resetting monthly subject to a floor of 8.5%. We can make monthly interest-only payments until May 1, 2019 (or, subject to certain conditions, May 1, 2020), and thereafter monthly payments of principal and interest are required to fully amortize the borrowed amount by a final maturity date of March 1, 2022. A fee of 5% of each funded draw is due at the earlier of prepayment or loan maturity, a facility fee of 0.5% is due upon funding for each draw, and a prepayment fee of between 1% and 3% of the outstanding balance will apply in the event of a prepayment. Concurrent with each term loan, we will grant to the lender a warrant to acquire shares of our common stock equal to the quotient of 3% of the funded amount divided by a per share exercise price equal to the lower of the average closing price for the previous ten days of trading (calculated on the day prior to funding) or the closing price on the day prior to funding. In connection with the initial term loan, we granted the lender warrants to purchase a total of 116,845 shares of common stock at an exercise price of \$10.27 per share. In March 2018, in connection with the second term loan, we granted the lender warrants to purchase a total of 85,482 shares of common stock at an exercise price of \$7.02 per share. All warrants issued pursuant to the Amended 2017 Loan Agreement have a term of ten years from the date of issuance and include a cashless exercise provision.

Our obligations under the Amended 2017 Loan Agreement are subject to quarterly covenants to achieve certain revenue levels and accessioned test volumes as well as additional covenants, including limits on our ability to dispose of assets, undergo a change in control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock, repurchase stock and make investments, in each case subject to certain exceptions. At September 30, 2018, we were in compliance

with all covenants under the Amended 2017 Loan Agreement. Our obligations under the Amended 2017 Loan Agreement are secured by a security interest on substantially all of our assets, excluding our intellectual property.

During November 2018, we entered into the 2018 Loan Agreement pursuant to which we are able to borrow a total of \$200.0 million. For a detailed description, see “Subsequent Events,” in Notes to Condensed Consolidated Financial Statements (unaudited) in Part I, Item 1 of this Quarterly Report on Form 10-Q.

We estimate our capital expenditures for the full year 2018 will be \$6.0 million. We may finance our capital expenditures through capital leases or other means.

At September 30, 2018 and December 31, 2017, we had \$134.6 million and \$76.0 million, respectively, of cash, cash equivalents, restricted cash and marketable securities.

Our primary uses of cash are to fund our operations as we continue to grow our business, including through acquisitions. 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 our inception, and we expect to continue to incur operating losses in the near term. We believe our existing cash and cash equivalents as of September 30, 2018, revenue from sales of our tests and the amounts available to us under the 2018 Loan Agreement will be sufficient to meet our anticipated cash requirements for the 12-month period following the filing date of this report.

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

The following table summarizes our cash flows:

	Nine Months Ended	
	September 30, 2018	2017
	(in thousands)	
Cash used in operating activities	\$(76,747)	\$(66,726)
Cash provided by (used in) investing activities	24,589	(44,271)
Cash provided by financing activities	141,124	78,738

Cash flows from operating activities

For the nine months ended September 30, 2018, cash used in operating activities of \$76.7 million principally resulted from our net loss of \$99.5 million, partially offset by non-cash charges of \$15.7 million for stock-based compensation, \$10.3 million for depreciation and amortization, \$1.9 million of impairment losses related to our collaboration agreement with KEW, \$0.6 million for non-cash remeasurements of liabilities associated with business combinations and \$0.7 million for amortization of debt issuance costs. The net effect on cash of changes in net operating assets was a use of cash of \$6.4 million.

For the nine months ended September 30, 2017, cash used in operating activities of \$66.7 million principally resulted from our net loss of \$82.9 million, increased by \$6.6 million of income tax benefits associated with business combinations and offset by non-cash charges of \$14.4 million for stock-based compensation, \$6.0 million for depreciation and amortization and \$0.6 million for non-cash remeasurements of liabilities associated with business combinations. The net effect on cash of changes in net operating assets was a source of cash of \$1.5 million.

Cash flows from investing activities

For the nine months ended September 30, 2018, cash provided by investing activities of \$24.6 million was due to proceeds from maturities and sales of marketable securities of \$30.9 million offset by cash used for purchases of property and equipment of \$4.3 million, and purchases of convertible notes totaling \$1.6 million.

For the nine months ended September 30, 2017, cash used in investing activities of \$44.3 million was primarily due to purchases of marketable securities exceeding maturities of marketable securities by \$41.6 million. This was due to the application of net proceeds received from both the term loan under the 2017 Loan Agreement and the July 2017 private placement to purchase marketable securities. In addition, cash used for purchases of property and equipment was \$4.1 million.

Cash flows from financing activities

For the nine months ended September 30, 2018, cash provided by financing activities of \$141.1 million consisted of net proceeds from the public offerings of common stock of \$112.5 million, net proceeds of \$19.5 million from the second term loan under the Amended 2017 Loan Agreement and cash received from issuances of common stock totaling \$10.7 million, including \$6.5 million received from exercises of warrants issued pursuant to the acquisition of CombiMatrix. (See Note 4, “Business combinations,” in the Notes to Condensed Consolidated Financial Statements included elsewhere in this report), stock option exercises of \$2.6 million, and employee stock purchases of \$1.6 million. These cash inflows were partially offset by capital lease obligations payments of \$1.6 million.

For the nine months ended September 30, 2017, cash provided by financing activities of \$78.7 million consisted of net proceeds of \$68.9 million from the August 2017 private placement, net proceeds of \$39.7 million from an initial term loan under the 2017 Loan Agreement and cash received from exercises of stock options and employee stock plan purchases totaling \$2.3 million. These cash inflows were partially offset by a cash payment of \$18.4 million to settle loan obligations assumed in the Good Start acquisition, other loan payments of \$12.1 million and capital lease obligations payments of \$2.2 million.

Contractual obligations

The following table summarizes our contractual obligations, including interest, as of September 30, 2018 (in thousands):

	Remainder of			2023 and	
Contractual obligations:	2018	2019 and 2020	2021 and 2022	beyond	Total
Operating leases	\$ 2,422	\$ 19,260	\$ 19,499	\$29,845	\$71,026
Capital leases	522	3,481	21	—	4,024
Term loans	1,493	43,562	30,425	—	75,480
Co-development agreement obligation	500	2,000	—	—	2,500
Investment in privately held company	1,350	—	—	—	1,350
Total	\$ 6,287	\$ 68,303	\$ 49,945	\$29,845	\$154,380

In September 2015, we entered into a lease agreement for our production facility and headquarters in San Francisco, California, in which we commenced operations in January 2017. This lease expires in October 2026. Leases for other facilities in California, in Cambridge, Massachusetts and in Dallas, Texas expire at various dates from November 2018 through December 2022.

Aggregate future minimum lease payments for these facilities are included in the table above. See Note 9, “Commitments and contingencies” in the Notes to Condensed Consolidated Financial Statements included elsewhere in

this report.

In March 2017, we entered into the 2017 Loan Agreement pursuant to which we borrowed an initial term loan of \$40.0 million and received net proceeds of \$39.7 million. Subject to certain conditions, we were eligible to borrow a second term loan of \$20.0 million in the first quarter of 2018 and did so in March 2018, receiving net proceeds of approximately \$19.8 million. The amounts in the line item “Term loans” in the table above include principal and interest payments pertaining to the initial term loan of \$40.0 million and the second term loan of \$20.0 million. See Note 9, “Commitments and contingencies” in the Notes to Condensed Consolidated Financial Statements included elsewhere in this report.

In the normal course of business, we enter into various purchase commitments primarily related to service agreements and laboratory supplies. At September 30, 2018, total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year were \$8.3 million.

Off-balance sheet arrangements

We have not entered into any off-balance sheet arrangements. See Note 8, “Investment in privately held company” in the Notes to Condensed Consolidated Financial Statements included elsewhere in this report for a discussion of our holding in a variable interest entity.

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. We had loan obligations of \$60.0 million at September 30, 2018, which resulted from term loans pursuant to the Amended 2017 Loan Agreement. These loans are subject to a floating interest rate. We had capital lease obligations of \$3.8 million as of September 30, 2018, which result from various capital lease agreements to obtain laboratory equipment. Our capital lease obligations carry fixed rates of interest. Our cash, cash equivalents, marketable securities and restricted cash totaled \$134.6 million at September 30, 2018, and consisted primarily of bank deposits, money market funds, convertible note receivables, 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 short-term in duration, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. At September 30, 2018, a hypothetical 1% (100 basis points) increase or decrease in interest rates would not have resulted in a material change in the fair value of our cash equivalents and portfolio of marketable securities. Fluctuations in the value of our cash equivalents and portfolio of marketable securities caused by a change in interest rates (gains or losses on the carrying value) are recorded in other comprehensive gain (loss) and are realized only if we sell the underlying securities prior to maturity or declines in fair value are determined to be other-than-temporary.

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.

44

PART II — Other Information

ITEM 1. Legal Proceedings.

We are not a party to any material legal proceedings on the date of this report. We may from time to time become involved in legal proceedings arising in the ordinary course of business, and the resolution of any such claims could be material.

ITEM 1A. Risk Factors.

Risks related to our business and strategy

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

We have incurred substantial losses since our inception. For the nine months ended September 30, 2018, our net loss was \$99.5 million. For the years ended December 31, 2017, 2016 and 2015, our net losses were \$123.4 million, \$100.3 million and \$89.8 million, respectively. At September 30, 2018, our accumulated deficit was \$486.9 million. While our revenue has increased over time, we expect to continue to incur significant losses. In addition, these losses may increase as we focus on scaling our business and operations and expanding our testing capabilities, which may increase our operating expenses. In addition, as a result of the integration of acquired businesses, we may be subject to unforeseen or additional expenditures, costs or liabilities. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity, working capital and stock price. Our failure to achieve and sustain profitability in the future would negatively affect our business, financial condition, results of operations and cash flows, and could cause the market price of our common stock to decline.

We began operations in January 2010 and commercially launched our initial assay in late November 2013; accordingly, we have a relatively limited operating history upon which you can evaluate our business and prospects. Our limited commercial history makes it difficult to evaluate our current business and makes predictions about our future results, prospects or viability subject to significant uncertainty. Our prospects must be considered in light of the risks and difficulties frequently encountered by companies in their early stage of development, particularly companies in new and rapidly evolving markets such as ours. These risks include an evolving and unpredictable business model and the management of growth. To address these risks, we must, among other things, increase our customer base; implement and successfully execute our business and marketing strategy; identify, acquire and successfully integrate companies, assets or technologies in areas that are complementary to our business strategy; successfully enter into other strategic collaborations or relationships; obtain access to capital on acceptable terms and effectively utilize that capital; identify, hire and successfully integrate additional employees; continue to expand, automate and upgrade our laboratory, technology and data systems; obtain, maintain and expand coverage and reimbursement by healthcare payers; provide rapid test turnaround times with accurate results at low prices; provide superior customer service; respond to competitive developments; and attract, retain and motivate qualified personnel. 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.

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 may 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. As an organization, we have limited experience with respect to acquisitions as well as the formation of strategic alliances and joint ventures.

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

With respect to our acquired businesses and any acquisitions we may make in the future, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Furthermore, the loss of customers, payers, partners or suppliers following the completion of any acquisitions by us could harm our business. For example, we experienced a reduction in Good Start's sales as a result of the termination of a contract by a third-party laboratory that had performed expanded carrier screening for Good Start. 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. For example, we diverted resources from other projects in order to develop an expanded carrier screening test as a result of the termination of the third-party laboratory contract with Good Start. We may also need to divert cash from other uses in order to fund these integration activities. Ultimately, we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment, or these benefits may take longer to realize than we expected.

To finance any acquisitions or investments, we may choose to raise additional funds. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. In addition, our stockholders may experience substantial dilution as a result of additional securities we may issue for acquisitions. Open market sales of substantial amounts of our common stock issued to stockholders of companies we acquire could also depress our share price. Alternatively, it may be necessary for us to raise additional funds for our acquisition activities through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all. In addition, our Amended 2017 Loan Agreement limits our ability to merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock and make investments, in each case subject to certain exceptions.

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

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

Since each payer makes its own decision as to whether to establish a policy or enter into a contract to cover our tests, as well as the amount it will reimburse for a test, seeking these approvals is a time-consuming and costly process. In addition, the determination by a payer to cover and the amount it will reimburse for our tests will likely be made on an indication by indication basis. To date, we have obtained policy-level reimbursement approval or contractual reimbursement for some indications for our test from most of the large commercial third-party payers in the United States, and the Centers for Medicare and Medicaid Services, or CMS, provides reimbursement for our multi-gene tests for hereditary breast 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 co-insurance or co-payment requirement from the patient, which may result in further delay or decreased likelihood of collection.

In cases where we have established reimbursement rates with third-party payers, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements often vary from payer to payer,

and we have needed additional time and resources to comply with them. We have also experienced, and may continue to experience, delays in or denials of coverage if we do not adequately comply with these requirements. Our third-party payers may also, from time to time, request audits of the amounts paid to us. We are currently subject to several such audits. We could be adversely affected if we are required to repay these or 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. 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.

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 and research and development activities. We believe our existing cash and cash equivalents as of September 30, 2018, revenue from sales of our tests and available debt under our new note purchase agreement will be sufficient to

meet our anticipated cash requirements for our currently-planned operations for the 12-month period following the filing date of this report. We may need additional funding 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. 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. Our obligations under our new note purchase agreement are subject to covenants, including quarterly covenants to achieve certain volume and revenue levels as well as additional covenants, including limits on our ability to dispose of assets, undergo a change in control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock, repurchase stock and make investments, in each case subject to certain exceptions. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to tests we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. 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 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 inherited clinical genetics and gene sequencing, such as Ambry Genetics, Inc., a subsidiary of Konica Minolta Inc., Athena Diagnostics, a subsidiary of Quest Diagnostics Incorporated, Baylor Genetics, Blueprint Genetics, Inc., Centogene AC, Color Genomics, Inc., Cooper Surgical, Eurofins Scientific, GeneDx, a subsidiary of OPKO Health, Inc., MNG Laboratories, LLC, Myriad Genetics, Inc. (Myriad), Myriad Women's Health, Inc., a subsidiary of Myriad and formerly known as Counsyl, Inc., Natera, Inc., Perkin Elmer, Inc., PreventionGenetics, LLC, Progenity, Inc. and Sena4 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., who 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 believe the principal competitive factors in our market are:

- breadth and depth of content;

47

- 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 and selling and marketing capabilities, 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, or sell their tests at prices designed to win significant levels of market share. 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 third-party payers decide to reimburse only for tests that are FDA-approved or FDA-cleared, or if they are more likely to reimburse for such tests, we may not be able to compete effectively unless we obtain similar approval or clearance for our tests. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

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

Our expected future growth could create a strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand as it grows. We may need to continue expanding our sales force to facilitate our growth, and we may have difficulties locating, recruiting, training and retaining sales personnel. Our ability to manage our growth properly 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 will have a larger 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. 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. Future growth in our business could also make it

difficult for us to maintain our corporate culture.

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

In the ordinary course of our business, we collect and store sensitive data, including protected health information, personally identifiable 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 data center systems. We also communicate sensitive patient data through our Invitae Family History Tool, Patient Insights Network, or PIN, and CancerGene Connect platform. In addition to storing and transmitting sensitive personal

information that is subject to myriad legal protections, these applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure, inappropriate modification, and the risk of our being unable to adequately monitor and modify our controls over our critical information. Any technical problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions in our business and operations. These types of problems may be caused by a variety of factors, including infrastructure changes, human or software errors, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take what we believe to be reasonable and appropriate measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, altered, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under federal or state laws that protect the privacy of personal information, such as but not limited to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Health Information Technology for Economic and Clinical Health Act, or HITECH, state data security and data breach notification laws, and related regulatory penalties. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, our Invitae Family History Tool, PIN and CancerGene Connect platform are currently accessible through our online portal and/or through our mobile applications, and there is no guarantee we can protect our online portal or our mobile applications from breach. Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business) and damage our reputation, any of which could adversely affect our business.

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

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

There has been unprecedented activity in the development of data protection regulation around the world. As a result, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. For example, the European Union's forthcoming General

Data Protection Regulation, or GDPR, took effect in May 2018. While the text of the GDPR has been published, the European authorities have only begun to issue guidance and interpretations of the text, leaving companies in and outside of Europe to interpret the majority of the GDPR on their own. In addition, California passed the California Consumer Privacy Act of 2018, which will take effect in January 2020. With this new California law, as well as the GDPR and many others all over the world, it is possible that laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. We can provide no assurance that we are or will remain in compliance with diverse privacy and security requirements in all of the jurisdictions in which we do business. Failure to comply with privacy and security requirements could result in civil or criminal penalties, which could have a material adverse effect on our business.

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

Our performance, including our research and development programs and laboratory operations, largely depend on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization, including scientists, biostatisticians, technicians and software developers. Competition in our industry for qualified employees is intense, and we

may not be able to attract or retain qualified personnel in the future, including scientists, biostatisticians, technicians and software developers, due to the competition for qualified personnel among life science and technology businesses as well as universities and public and private research institutions, particularly in the San Francisco Bay Area. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to scale our business, support our research and development efforts and our clinical laboratory. We believe that our corporate culture fosters innovation, creativity and teamwork. However, as our organization grows, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

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

Our success depends in large part on our ability to extend our market position, to provide customers with high quality test reports quickly and at a lower price than our competitors, and to achieve sufficient test volume to realize economies of scale. In order to execute our business model, we intend to continue to invest heavily in order to significantly scale our infrastructure, including our testing capacity and information systems, expand our commercial operations, customer service, billing and systems processes and enhance our internal quality assurance program. We need to continue to hire and retain sufficient numbers of skilled personnel, including software developers, geneticists, biostatisticians, certified laboratory scientists and other scientific and technical personnel to process and interpret our genetic tests. In addition, we expect the need to expand our sales force with qualified and experienced personnel. 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 clinical adoption of our test to achieve sufficient volumes. Inasmuch as detailed genetic data from broad-based testing panels such as our tests have only recently become available at relatively affordable prices, the continued pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic testing that is specific to one or a few genes. Given the substantial amount of additional information available from a broad-based testing panel such as ours, there may be distrust as to the reliability of such information when compared with more limited and focused genetic tests. To generate further demand for our tests, we will need to continue to make clinicians aware of the benefits of our tests, including the price, the breadth of our testing options, and the benefits of having additional genetic data available from which to make treatment decisions. Because broad-based testing panels are relatively new, it may be more difficult or take more time for us to expand clinical adoption of our assay beyond our current customer base. In addition, clinicians in other areas of medicine may not adopt genetic testing for hereditary disease as readily as it has been adopted in hereditary cancer and our efforts to sell our tests to clinicians outside of oncology may not be

successful. A lack of or delay in clinical acceptance of broad-based panels such as our tests would negatively impact sales and market acceptance of our tests and limit our revenue growth and potential profitability. Genetic testing is expensive and many potential customers may be sensitive to pricing. In addition, potential customers may not adopt our tests if adequate reimbursement is not available, or if we are not able to maintain low prices relative to our competitors. If we are not able to generate demand for our tests at sufficient volume, or if it takes significantly more time to generate this demand than we anticipate, our business, prospects, financial condition and results of operations could be materially harmed.

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

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

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

The marketing, sale and use of our genetic tests could subject us to liability for errors in, misunderstandings of, or inappropriate reliance on, information we provide to clinicians or geneticists, 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, or if the ordering physician were to misinterpret test results or improperly rely on them when making a clinical decision. In addition, our recent entry into the reproductive health testing market exposes 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 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 effectively enough to drive demand sufficient to support our planned growth. We currently sell our tests in the United States through our internal sales force and outside the United States with the assistance of distributors. Historically, our sales efforts have been focused primarily on hereditary cancer and our efforts to sell our tests to clinicians outside of oncology may not be successful, or may be difficult to do successfully without significant additional selling and marketing efforts and expense. We significantly increased the size of our sales force in 2017 and early 2018, especially late in 2017 with the integration of the sales forces from our acquired companies and the hiring of new sales personnel. Our future sales will also 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 have limited experience implementing these types of alternative marketing efforts. We may not be able to drive sufficient levels of revenue using these sales and marketing methods and strategies necessary to support our planned growth, and our failure to do so could limit our revenue and potential profitability.

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

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

We record goodwill and intangible assets at fair value upon the acquisition of a business. Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired. Goodwill and indefinite-lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their

carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors that impact the fair value of a reporting unit could result in an impairment of goodwill or intangible assets and, in turn, a charge to net income. Any such charges could have a material adverse effect on our results of operations or financial condition.

We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our laboratory instruments and materials, 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 any short or long-term agreements with most of our suppliers, and our suppliers could cease supplying these materials and equipment at any time, or fail to provide us with sufficient quantities of materials or materials that meet our specifications. Our laboratory operations could be interrupted if we encounter delays or difficulties in securing these reagents, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers. Any disruption in Illumina's operations could impact our supply chain and laboratory operations as well as our ability to conduct our tests, and it could take a substantial amount of time to integrate replacement equipment into our laboratory operations.

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

If our laboratories in California and Massachusetts become inoperable due to disasters or for any other reason, we will be unable to perform our tests and our business will be harmed.

We perform all of our tests at our production facilities in San Francisco, California, Irvine, California and Cambridge, Massachusetts. Our laboratories and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use. Our laboratories may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding, fire and power outages, which may render it difficult or impossible for us to perform our tests for some period of time. This risk is especially high for us since we perform the substantial majority of our tests at our San Francisco laboratory, which is located in an active seismic region, and we do not have a redundant facility to perform the same tests in the event our San Francisco laboratory is inoperable. The inability to perform our tests or the backlog that could develop if our laboratories are inoperable for even a short period of time may result in the loss of customers or harm our reputation. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

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

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

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

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

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

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

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

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

Changes in financial accounting standards may cause adverse and unexpected revenue fluctuations and affect our reported results of operations.

We prepare our financial statements in accordance with U.S. GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting principles. Changes in these accounting standards or practices may have a significant effect on our results of operations. For example, in May 2014, the Financial Accounting Standards Boards, or FASB, issued Accounting Standards Update 2014-09, “Revenue from Contracts from Customers (Topic 606),” which superseded most existing revenue recognition guidance. We implemented Topic 606 effective January 1, 2018. Please see Note 2, “Summary of significant accounting policies” in the Notes to Condensed Consolidated Financial Statements for more information.

From inception through December 2017, we recognized revenue principally when cash was received. Under Topic 606 we now generally recognize revenue on an accrual basis. Accrual amounts are recognized based on estimates of the consideration that we expect to receive and such estimates will be updated and subsequently recorded until fully settled. Adjustments to these estimates may cause fluctuations in our revenue, and may have a material adverse effect on our revenue and our results of operations.

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, our Invitae Family History Tool, PIN, and CancerGene Connect platform. 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.

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

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

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

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

We currently have distribution arrangements in several countries 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 and transportation delays;
- limits on our ability to penetrate international markets if we do not to conduct our tests locally;
- natural disasters, 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.

Changes in U.S. tax laws could adversely impact us.

On December 22, 2017, President Trump signed The Tax Cuts and Jobs Act ,the Tax Act, into law. The Tax Act contains significant changes to U.S. federal corporate income taxation, including reduction of the corporate tax rate from 35% to 21% for U.S. taxable income, resulting in a one-time remeasurement of deferred taxes to reflect their value at a lower tax rate of 21%, limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, deemed repatriation, resulting in one-time taxation of offshore earnings at reduced rates, elimination of U.S. tax on foreign earnings (subject to certain exceptions), and immediate deductions for certain new investments instead of deductions for depreciation expense over time. Although the Tax Act is generally effective January 1, 2018, GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017. As a result of the lower corporate tax rate

enacted as part of the Tax Act, we recorded a provisional estimate to reduce deferred tax assets by \$48.8 million. The reduction in deferred tax assets was offset by a corresponding reduction in our valuation allowance resulting in no net impact to tax expense. We have determined that the adjustment to the deferred tax assets and valuation allowance recorded in connection with the remeasurement of certain deferred tax assets and liabilities is a reasonable estimate at December 31, 2017. Any subsequent adjustment to these amounts will be adjusted accordingly in the quarter of 2018 when the analysis is complete. Any such adjustment could adversely affect our tax positions, tax rate or results of operations.

Risks related to government regulation

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

We provide our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and state law, respectively).

Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. Subsequently, on January 13, 2017, the FDA published a "discussion paper" in which it outlined a substantially revised "possible approach" to the oversight of LDTs. In March 2017, a draft bill titled "The Diagnostics Accuracy and Innovation Act" was released for discussion. The draft bill proposes a risk-based approach to regulate LDTs and creates a new in vitro clinical test category of regulated products, which includes LDTs, and a regulatory structure under the FDA. As proposed, the draft bill grandfathers many existing tests and phases in FDA oversight over a period of years (e.g., companies would have two years from the date the FDA promulgates final implementing regulations before such regulations became effective). We cannot predict if this draft bill will be enacted in its current (or any other) form and cannot quantify the effect of this draft bill on our business.

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

If the FDA ultimately regulates certain LDTs as medical devices, 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 for medical devices 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 medical device requirements to our tests could materially and adversely affect our business, financial condition and results of operations.

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

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

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

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

We are also required to maintain licenses to conduct testing in California. California laws establish standards for day-to-day operation of our clinical reference laboratories in San Francisco and Irvine, including the training and skills required of personnel and quality control. We also maintain a Massachusetts clinical laboratory license to conduct testing at our laboratory in Cambridge, Massachusetts. We also maintain out-of-state laboratory licenses to conduct testing on specimens from Florida, Maryland, New York, Pennsylvania and Rhode Island, as well as California with respect to our laboratory in Cambridge.

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

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, and cancellation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certificate, 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 Irvine, San Francisco and Cambridge laboratories. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

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

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

- HIPAA, which established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions;
- amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators and expand vicarious liability, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual, for the furnishing of or arrangement for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering, arranging for, or

recommend purchasing, leasing or ordering, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program;

•the 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 laws, which impose 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 created new federal criminal statutes that prohibit, among other things, defrauding health care benefit programs, willfully obstructing a criminal investigation of a healthcare offense and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services;

- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payer, including private insurers;

- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;

- state laws that prohibit other specified practices, such as billing clinicians for testing that they order; waiving coinsurance, copayments, deductibles and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payers; and

- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

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

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

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other things, the Affordable Care Act requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, and applied to sales of taxable medical devices from January 1, 2013 through December 31, 2015. The medical device tax has been suspended for 2016 through 2019, but is scheduled to return beginning in 2020. It is unclear at this time when, or if, the provision of our LDTs will trigger the medical device tax if the FDA ends its policy of general enforcement discretion and regulates certain LDTs as medical devices. It is possible, however, that this tax will apply to some or all of our tests or tests that are in development.

Many of the Current Procedure Terminology, or CPT, procedure codes that we use to bill our tests were revised by the American Medical Association, effective January 1, 2013. Moreover, effective January 1, 2015, the AMA released several new codes to report genomic sequencing procedures. In a final determination under the Medicare Clinical Laboratory Fee Schedule, or CLFS, published in November 2014, CMS set the 2015 payment rate for these codes by the gap-fill process. Under the gap-fill process, local Medicare Administrative Contractors, or MACs, establish rates for those codes that each MAC believes meet the criteria for Medicare coverage and considering laboratory charges

and discounts to charges, resources, amounts paid by other payers for the tests, and amounts paid by the MAC for similar tests. In 2015, gap-filled payment rates were established for some, but not all, of the above-described codes. For those codes for which local gap-filled rate(s) were established in 2015, a national limitation amount for Medicare was established for 2016. Codes for which local gap-filled rates were not established in 2015 were priced by the local MACs in 2016 insofar as an individual MAC determines that such codes should be covered. Where available, the national limitation amount serves as a cap on the Medicare and Medicaid payment rates for a test procedure.

The AMA also released several CPT codes effective January 1, 2016 that may be appropriate to report certain of our tests. In a November 2015 final determination, CMS set the calendar year 2016 CLFS payment rate for these new codes by the gap-fill process. CMS and the local MACs went through the gap-fill process in 2016 and announced final gap-filled rates for 2017 on September 30, 2016. The calendar year 2017 national limitation amounts for certain codes were significantly less than the rates at which we have historically offered our tests.

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 will be paid under Medicare. Under the final rule that implements PAMA, which was promulgated by CMS in June 2016, clinical laboratories must report to CMS private payer rates beginning in 2017 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. 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 will be 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, similar to prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test. In April 2016, we announced that CMS had begun providing payments for our multi-gene tests for hereditary breast cancer-related disorders at an interim payment per test of \$622.53. On October 3, 2016, we announced that CMS had priced our multi-gene tests for hereditary breast cancer-related disorders at \$925.00 per test. The 2017 CLFS National Limitation Amount, or NLA, for this test was set at \$931.47.

In November 2017, CMS posted a “final” file that summarized the 2018 CLFS payment rates calculated under the PAMA final rule. This file indicates that the median of private payer rates reported to Medicare for the code used to report our multi-gene test for hereditary breast cancer-related disorders was \$136.47. The PAMA final rule caps the annual reduction in the calendar year 2018, 2019 and 2020 CLFS payment rates for any test to 10% of the previous year’s rates, so the proposed CLFS payment rate for this test will be substantially higher than the median for at least the next three years (i.e., \$838.33 in 2018, \$754.50 in 2019, and \$679.05 in 2020). The PAMA final rule also caps the annual percentage reduction in 2021, 2022 and 2023 rates to 15% of the previous year’s rate, further phasing-in any reduction required calculated using data reported during 2020. Nevertheless, we expect to experience 10% decreases in these Medicare reimbursement rates per test per year for at least the next three years.

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 it is unclear how these codes would apply to our tests.

In March 2018, CMS published a final national coverage determination, or NCD, for next generation sequencing, or NGS, tests for patients with advanced cancer. The final NCD establishes full coverage for FDA-approved or FDA-cleared NGS-based companion diagnostic assays 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 stages III or IV cancer) who have not have previously been tested with the same test for the same primary diagnosis of cancer or are seeking repeat testing for a new primary cancer diagnosis, and have decided to seek further cancer treatment. The final NCD also gives MACs the authority to establish local coverage for NGS-based assays that are not FDA-approved or FDA-cleared companion diagnostics when offered to patients meeting the above-referenced criteria. It is unclear, however, whether MACs retain the authority to establish local coverage for NGS-based tests provided for patients with cancer that do not meet the above-referenced criteria – e.g., patients with earlier stage cancers – or if such tests are nationally non-covered under the NCD. If CMS interprets the final NCD to exclude coverage for patients with earlier stage cancers, MACs will no longer have discretion to cover our current tests when offered to such patients, notwithstanding historical Medicare coverage for such tests. An interpretation of the NCD that results in Medicare non-coverage for our current and future assays would have

significant negative impact on our business, financial condition and results of operations.

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 eliminates the Affordable Care Act's "individual mandate" beginning in 2019, which may significantly impact the number of covered lives participating in exchange plans. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the clinical laboratory fee schedule, which would increase our billing and collecting costs and decrease our revenue.

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

Our activities currently require the use of hazardous chemicals and biological material. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. 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. Our reliance on independent distributors to sell our tests internationally demands a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

Risks related to our intellectual property

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

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

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

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

Although we view current U.S. Supreme Court precedent to be aligned with our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts (such as patient genetic data) and an understanding of that fact's implications (such as a patient's risk of disease associated with certain genetic variations) should not be patentable, it is possible that subsequent determinations by the U.S. Supreme Court or other federal courts could limit, alter or potentially overrule current law. Moreover, from time to time the U.S. Supreme Court, other federal courts, the United States 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.

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 that we did not incur as a private company, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC and the New York Stock Exchange, or NYSE, impose a number of requirements on public companies, including with respect to corporate governance practices. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In addition, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, enacted in 2010 includes significant corporate governance and executive-compensation-related provisions. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. If these requirements divert the attention of our management and personnel from other aspects of our business concerns, they could have a material adverse effect on our business, financial condition and results of operations. Moreover, these rules and regulations applicable to public companies substantially increase our legal, accounting and financial compliance costs, require that we hire additional personnel and make some activities more time-consuming and costly. It may also be more expensive for us to obtain director and officer liability insurance.

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

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

we are no longer an emerging growth company, as described below, our independent registered public accounting firm will be required to issue an attestation report on the effectiveness of our internal control over financial reporting. 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 when we are no longer an emerging growth company, 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.

We are an emerging growth company and have elected to comply with reduced public company reporting requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an emerging growth company, as defined under the Securities Act. We will remain an emerging growth company until December 31, 2020, although if our revenue exceeds \$1.07 billion in any fiscal year before that time, we would cease to be an

emerging growth company as of the end of that fiscal year. In addition, if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our second fiscal quarter of any fiscal year before the end of that five-year period, we would cease to be an emerging growth company as of December 31 of that year. As an emerging growth company, we have chosen to take advantage of exemptions from various reporting requirements applicable to certain other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced financial statement and financial-related disclosures, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirement of holding a nonbinding advisory vote on executive compensation and obtaining stockholder approval of any golden parachute payments not previously approved by our stockholders. We cannot predict whether investors will find our common stock less attractive because we have chosen to rely on any of these exemptions. If investors find our common stock less attractive as a result of any choices to reduce future disclosure we may make, there may be a less active trading market for our common stock and our stock price may be more volatile.

Risks related to our common stock

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

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

- actual or anticipated fluctuations in our operating results;
- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts or changed recommendations for our stock;
- our focus on long-term goals over short-term results;
- the timing 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 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.

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

At September 30, 2018, our total gross deferred tax assets were \$106.2 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Furthermore, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with completed acquisitions, or other future transactions in our stock, our ability to utilize NOLs and tax credit carryovers could be further limited by Section 382 of the Internal Revenue Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss and tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. In addition, the recently enacted Tax 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.

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, our loan agreement prohibits us from paying dividends on our common stock. 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.

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.

ITEM 6. Exhibits.

Exhibit

Number Description

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 XBRL Instance Document

101.SCH XBRL Taxonomy Extension Schema

101.CAL XBRL Taxonomy Extension Calculation Linkbase

101.DEF XBRL Taxonomy Extension Definition Linkbase

101.LAB XBRL Taxonomy Extension Label Linkbase

101.PRE XBRL Taxonomy Extension Presentation Linkbase

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

By: /s/ Shelly D. Guyer
Shelly D. Guyer
Chief Financial Officer
Principal Financial Officer

Date: November 7, 2018