Invitae Corp
Form 10-Q
May 15, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015

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

For the transition period from to

Commission File No. 001-36847

Invitae Corporation

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

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

458 Brannan Street, San Francisco, California 94107

(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 x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company o

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

The number of shares of the registrant s Common Stock outstanding as of April 30, 2015 was 31,819,289.

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PART I Financial Information

ITEM 1. Financial Statements.

INVITAE CORPORATION

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	March 31, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 68,264	$ 107,027
Prepaid expenses and other current assets	3,889	2,616
Marketable securities	116,069	
Total current assets	188,222	109,643
Property and equipment, net	18,180	15,672
Restricted cash	150	150
Marketable securities, noncurrent	10,181	
Other assets	1,482	3,313
Total assets	$ 218,215	$ 128,778
Liabilities, convertible preferred stock, and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,123	$ 2,862
Accrued liabilities	7,102	3,237
Capital lease obligation, current portion	1,428	1,524
Total current liabilities	9,653	7,623
Capital lease obligation, net of current portion	1,780	2,011
Other long-term liabilities	412	401
Liabilities related to early exercise of stock options	11	14
Total liabilities	11,856	10,049
Commitments and contingencies (Note 5)		
Convertible preferred stock, $0.0001 par value; 0 and 141,131,524 shares authorized, 0 and 141,131,524 shares issued and outstanding as of March 31, 2015 and December 31, 2014, respectively		202,305
Stockholders equity (deficit):		
Preferred stock, $0.0001 par value; 20,000,000 and 0 shares authorized, no shares issued and outstanding as of March 31, 2015 and December 31, 2014		
Common stock, $0.0001 par value; 400,000,000 and 160,131,524 shares authorized, 31,803,345 and 944,581 shares issued and outstanding as of March 31, 2015 and December 31, 2014, respectively	3	

Accumulated other comprehensive loss		(26)		
Additional paid-in capital		310,199		1,604
Accumulated deficit		(103,817)		(85,180)
Total stockholders equity (deficit)		206,359		(83,576)
Total liabilities, convertible preferred stock, and stockholders equity (deficit)	$	218,215	$	128,778

See accompanying notes to unaudited condensed consolidated financial statements.

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INVITAE CORPORATION

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Revenue	$ 1,229	$ 118
Costs and operating expenses:		
Cost of revenue	3,199	611
Research and development	8,455	4,965
Selling and marketing	4,740	1,666
General and administrative	3,440	1,895
Total costs and operating expenses	19,834	9,137
Loss from operations	(18,605)	(9,019)
Interest and other income (expense), net	(4)	3
Interest expense	(28)	(17)
Net loss	$ (18,637)	$ (9,033)
Net loss per share, basic and diluted	$ (1.09)	$ (12.06)
Shares used in computing net loss per share, basic and diluted	17,063,463	749,048

See accompanying notes to unaudited condensed consolidated financial statements.

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INVITAE CORPORATION

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Net loss	$ (18,637)	$ (9,033)
Other comprehensive loss:		
Unrealized loss on available-for-sale marketable securities, net of tax	(26)	
Comprehensive loss	$ (18,663)	$ (9,033)

See accompanying notes to unaudited condensed consolidated financial statements.

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INVITAE CORPORATION

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (18,637)	$ (9,033)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,017	471
Stock-based compensation	538	132
Amortization of premium on marketable securities	65	
Loss on disposal of assets	15	
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,273)	(229)
Other assets	380	(191)
Accounts payable	(1,775)	326
Accrued expenses and other liabilities	1,487	327
Net cash used in operating activities	(18,183)	(8,197)
Cash flows from investing activities:		
Purchase of marketable securities	(130,841)	
Proceeds from maturities of marketable securities	4,500	
Purchases of property and equipment	(1,116)	(867)
Net cash used in investing activities	(127,457)	(867)
Cash flows from financing activities:		
Proceeds from issuance of common stock upon initial public offering, net of issuance costs	107,147	
Proceeds from exercise of stock options	57	19
Capital lease principal payments	(327)	(185)
Net cash provided by (used in) financing activities	106,877	(166)
Net decrease in cash and cash equivalents	(38,763)	(9,230)
Cash and cash equivalents at beginning of period	107,027	43,070
Cash and cash equivalents at end of period	$ 68,264	$ 33,840
Supplemental cash flow information:		
Interest paid	$ 27	$ 16
Supplemental cash flow information of non-cash investing and financing activities:		

Conversion of convertible preferred stock to common stock	$	202,305	$	
Purchases of property and equipment in accounts payable and accrued liabilities	$	2,424	$	49

See accompanying notes to unaudited condensed consolidated financial statements.

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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 physicians and their patients. The Company has two laboratories: one in San Francisco, California and a second in Santiago, Chile. The Company s current product is an assay of 221 genes that can be used for multiple indications. The test includes multiple genes associated with hereditary cancer, neurological disorders, cardiovascular disorders and other hereditary conditions. The Company operates in one segment.

Reverse stock split

In January 2015, the Company s board of directors approved an amendment to the Company s amended and restated certificate of incorporation to effect a reverse split of the Company s issued and outstanding common stock at a 1-for-6 ratio, which was effected on February 9, 2015. The par value and authorized shares of common stock and convertible preferred stock were not adjusted as a result of the reverse split. All issued and outstanding common stock, options to purchase common stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect the reverse stock split for all periods presented. The financial statements have also been retroactively adjusted to reflect a proportional adjustment to the conversion ratio for each series of preferred stock that will be effected in connection with the reverse stock split.

Initial public offering

In February 2015, the Company completed an initial public offering (IPO) of its common stock. In connection with its IPO, the Company sold 7,302,500 shares of common stock at $16.00 per share for aggregate net proceeds of $105.7 million after underwriting discounts and commissions and offering expenses payable by the Company. This includes the exercise in full by the underwriters of their option to purchase up to 952,500 additional shares of common stock at the same price to cover over-allotments. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into 23,521,889 shares of common stock.

Upon the effectiveness of the Amended and Restated Certificate of Incorporation of the Company on February 12, 2015, the number of shares of capital stock the Company is authorized to issue was increased to 420,000,000 shares, of which 400,000,000 shares are common stock and 20,000,000 shares are preferred stock. Both the common stock and preferred stock have a par value of $0.0001 per share. There are no shares of preferred stock outstanding at March 31, 2015.

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. general 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, 2014. The results for the three months ended March 31, 2015 are not necessarily indicative of the results expected for the full fiscal year or any other periods.

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2. Summary of significant accounting policies

Principles of consolidation

The Company s unaudited condensed consolidated financial statements have been prepared in conformity with U.S. GAAP. 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; the recoverability of long-lived assets; the fair value of the Company s common stock; stock-based compensation expense; 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.

Customer concentration

Significant customers are those which represent 10% or more of the Company s total revenue for each period presented in the condensed consolidated statements of operations. For each significant customer, revenue as a percentage of total revenue was follows:

	Three Months Ended March 31,	
Customers	**2015**	**2014**
Customer A	14%	20%
Customer B	*	12%
Customer C		11%

* Less than 10% of total revenue

Cash equivalents

The Company considers all highly liquid marketable securities with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market funds and U.S government agency securities.

Marketable securities

All marketable securities, have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its marketable securities in debt securities at the time of purchase and reevaluates such designation as of each balance sheet date. Short-term marketable securities have maturities less than 365 days as of the balance sheet date. Long-term marketable securities have maturities greater than 365 days as of the balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive income (loss). Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in other income (expense), net. The cost of securities sold is based on the specific-identification method. Interest on marketable securities is included in interest income.

Restricted cash

Restricted cash consists of money market funds that serves as collateral for a credit card agreement at one of the Company s financial institutions.

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Internal-use software

The Company capitalizes third-party costs incurred in the application development stage to design and implement the software used in its tests and Invitae Family History Tool mobile application. Costs incurred in the application development stage of the software and mobile application are capitalized and will be amortized over an estimated useful life of three years on a straight line basis.

During the three months ended March 31, 2015 and 2014, the Company capitalized $750,000 and $150,000, respectively, of software development costs.

Deferred offering costs

Deferred offering costs, which primarily consist of direct incremental legal, accounting and printer fees relating to the IPO, were initially capitalized. The deferred offering costs were subsequently offset against IPO proceeds upon the closing of the offering in February 2015. As of December 31, 2014, the Company capitalized $1.9 million of deferred offering costs in other assets on the consolidated balance sheets.

Fair value of financial instruments

The Company s financial instruments consist principally of cash and cash equivalents, marketable securities, and accounts payable. The carrying amounts of certain of these financial instruments, including cash and cash equivalents, and accounts payable, approximate fair value due to their short maturities.

See Note 4, Fair value measurements for further information on the fair value of the Company s financial instruments.

Revenue recognition

Revenue is generated 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 was de minimis for all periods presented.

Revenue is recognized when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured. The criterion for whether the fee is fixed or determinable and whether collectability is reasonably assured are based on management s judgments. When evaluating collectability, in situations where contracted reimbursement coverage does not exist, the Company considers whether the Company has sufficient history to reliably estimate a payor s individual payment

patterns. The Company reviews the number of tests paid against the number of tests billed and the payor s outstanding balance for unpaid tests to determine whether payments are being made at a consistently high percentage of tests billed and at appropriate amounts given the amount billed. The Company has not been able to demonstrate a predictable pattern of collectability, and therefore recognizes revenue when payment is received.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering the genetic testing results to physicians and includes expenses for personnel costs including stock-based compensation, materials and supplies, equipment and infrastructure expenses associated with testing and allocated overhead including rent, equipment depreciation and utilities. Costs associated with performing the Company s test are recorded as the test is processed regardless of whether and when revenue is recognized with respect to that test.

Foreign currency transactions

The Company uses the U.S. dollar as its functional currency for its subsidiary in Chile. Foreign currency assets and liabilities are remeasured into U.S. dollars using the end of period exchange rates except for nonmonetary assets and liabilities, which are remeasured using historical exchange rates. Expenses are remeasured using an average exchange rate for the respective period. No revenue has been recorded in Chile for the periods presented. Gains or losses from foreign currency transactions are included in interest income and other income (expense), net, in the condensed consolidated statements of operations. Foreign currency transaction gains and losses have not been significant to the condensed consolidated financial statements for all periods presented.

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Net loss per common share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per common share in the periods presented is the same as basic net loss per common share, since the effects of potentially dilutive securities are antidilutive. Common shares subject to repurchase are excluded from the weighted-average shares. At March 31, 2015 and 2014, 17,907 and 48,439 shares subject to repurchase, respectively, are excluded from basic net loss per share calculation.

Recent accounting pronouncements

On May 28, 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard will become effective for the Company on January 1, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In August 2014, the FASB issued ASU No. 2014-15 (Subtopic 205- 40), *Presentation of Financial Statements Going Concern: Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern* (ASU 2014-15), which provides guidance about management s responsibility to evaluate whether there is substantial doubt about the Company s ability to continue as a going concern and to provide related footnote disclosure. ASU 2014-15 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early application is permitted. The adoption of this standard is not expected to have an impact on the Company s consolidated financial statements.

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3. Balance sheet components

Cash equivalents and marketable securities

The following is a summary of cash equivalents and marketable securities (in thousands).

	March 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 24,430	$	$	$ 24,430
U.S. treasury notes	2,033			2,033
U.S. government agency securities	163,376	1	(27)	163,350
	$ 189,839	$ 1	$ (27)	$ 189,813
Reported as:				
Cash equivalents				$ 63,413
Restricted cash				150
Marketable securities				116,069
Marketable securities, non-current				10,181
Total cash equivalents, restricted cash and marketable securities				$ 189,813

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 15,167	$	$	$ 15,167
	$ 15,167	$	$	$ 15,167
Reported as:				
Cash equivalents				$ 15,017
Restricted cash				150
Total cash equivalents and restricted cash				$ 15,167

At March 31, 2015, the remaining contractual maturities of available-for-sale securities were less than 1.5 years. For the three months ended March 31, 2015, there were no realized gains or losses on the available-for-sale securities. There were no available-for-sale marketable securities held by the Company at December 31, 2014.

Property and equipment, net

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

	March 31, 2015	December 31, 2014
Leasehold improvements	$ 2,123	$ 1,914
Laboratory equipment	8,196	6,528
Equipment under capital lease	6,585	3,735
Computer equipment	1,349	1,156
Internal-use software	1,551	800
Software	45	31
Furniture and fixtures	158	158
Automobiles	20	
Construction-in-progress	2,617	4,853
Total property and equipment, gross	22,644	19,175
Accumulated depreciation and amortization	(4,464)	(3,503)
Total property and equipment, net	$ 18,180	$ 15,672

Included in the construction-in-progress balance as of December 31, 2014 was $2.9 million of capital lease equipment that had not been placed in service. This capital lease equipment was placed in service as of March 31, 2015.

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Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2015	December 31, 2014
Accrued compensation and related expenses	$ 1,929	$ 1,439
Accrued costs of equipment	2,313	
Accrued professional services	909	1,030
Accrued costs for construction-in-progress	75	32
Other	1,876	736
Total accrued liabilities	$ 7,102	$ 3,237

4. 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 briefly 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 March 31, 2015 and December 31, 2014 (in thousands):

	March 31, 2015			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 24,430	$	$	$ 24,430
U.S. treasury notes	2,033			2,033
U.S. government agency securities		163,350		163,350
Total financial assets	$ 26,463	$ 163,350	$	$ 189,813

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 15,167	$	$	$ 15,167
Total financial assets	$ 15,167	$	$	$ 15,167

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 movements 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.

There were no transfers between Level 1 and Level 2 during the periods presented.

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5. Commitments and contingencies

New Leases

In March 2015, the Company leased additional space in San Francisco and Oakland, California. The leases expire in April and June 2017, respectively, and aggregate future minimum lease payments for these facilities are approximately $2.4 million.

Contingencies

On November 25, 2013, the University of Utah Research Foundation, the Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership, Endorecherche, Inc. and Myriad Genetics, Inc. (collectively, the Myriad Plaintiffs) filed a complaint in the District of Utah (the Utah Action), alleging that certain of the Company s genetic testing services infringe certain claims of various U.S. Patents (collectively, the Myriad Patents). On November 26, 2013, the Company filed a complaint for declaratory judgment in the Northern District of California (the California Action), asserting that the Myriad Patents are invalid and the Company does not infringe them, and the Myriad Plaintiffs counterclaimed alleging that the Company infringes the Myriad Patents. Although the Utah Action was dismissed, on February 19, 2014, the Judicial Panel on Multidistrict Litigation granted the Myriad Plaintiffs motion to consolidate for pre-trial proceedings all actions concerning the Myriad Patents (the MDL Proceedings), with the MDL Proceedings taking place in the District of Utah. On January 23, 2015, the Myriad Plaintiffs stipulated to the dismissal with prejudice of all of their claims and granted the Company a covenant not to sue for all of the patents they had asserted against the Company. On January 26, 2015, the court issued an order dismissing the California Action with prejudice, thereby ending the litigation.

The Company may become party to various other claims and complaints arising in the ordinary course of business. Management does not believe that any ultimate liability resulting from any of these claims will have a material adverse effect on its results of operations, financial condition, or liquidity. However, management cannot give any assurance regarding the ultimate outcome of these claims, and their resolution could be material to operating results for any particular period, depending upon the level of income for the period.

6. 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.

In January 2015, the Company adopted the 2015 Stock Incentive Plan, or the 2015 Plan, which became effective upon the closing of the IPO. The 2015 Plan had 4,370,452 shares of common stock reserved for future issuance at the time of its effectiveness, which included 120,452 shares under the 2010 Plan which 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.

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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 grant vests upon the first anniversary of the employee s date of hire, with the remainder of the shares 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.

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. A total of 325,000 shares of common stock are reserved for issuance under the ESPP. Eligible employees 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. The ESPP provides for automatic annual increases in shares available for grant, beginning on January 1, 2016 through January 1, 2025. The Company has not determined the date on which the initial purchase period will commence under the ESPP.

Summary of option activity

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

	Shares available for grant	Stock options outstanding	Weighted-average exercise price	Weighted-average remaining contractual life (years)	Aggregate intrinsic value
Balances at December 31, 2014	276,805	1,923,332	$ 4.37	8.90	$ 15,946
Additional shares reserved	4,370,452				
Granted	(144,070)	144,070	$ 13.98		
Cancelled	41,613	(41,613)	$ 5.41		
Exercised		(28,379)	$ 1.99		
Balances at March 31, 2015	4,544,800	1,997,410	$ 5.07	8.74	$ 23,341
Options exercisable at March 31, 2015		546,810	$ 2.01	7.94	$ 8,063
Options vested and expected to vest at March 31, 2015		1,947,699	$ 5.03	8.73	$ 22,852

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 $10.78 and $2.89 per share in the three months ended March 31, 2015 and 2014, respectively.

The fair value of options to purchase common stock vested was $484,000 and $62,000 in the three months ended March 31, 2015 and 2014, respectively.

The intrinsic value of options to purchase common stock exercised was $364,000 and $88,000 in the three months ended March 31, 2015 and 2014, respectively.

Early exercise of stock options

The 2010 Plan allows for the granting of options that may be exercised before the options have vested. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser s employment or services, at the price paid by the purchaser, and are not deemed to be issued for accounting purposes until those related shares vest. The amounts received in exchange for these shares have been recorded as a liability on the accompanying balance sheets and will be reclassified into common stock and additional paid-in-capital as the shares vest. The Company s right to repurchase these shares generally lapses 1/4 after a one-year cliff then at a monthly rate of 1/48 thereafter.

At March 31, 2015 and December 31, 2014, there were 17,907 and 23,903 shares of common stock outstanding, respectively, subject to the Company s right of repurchase at prices ranging from $0.30 to $1.26 per share. At March 31, 2015 and December 31, 2014, the Company recorded $11,000 and $14,000, respectively, as liabilities associated with shares issued with repurchase rights.

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Stock-based compensation

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

	Three Months Ended March 31,	
	2015	**2014**
Expected term (in years)	6.03	6.03
Expected volatility	83.8%	86.6%
Risk-free interest rate	1.28%	1.75 - 1.91%
Dividend yield		

Stock-based compensation related to stock options granted to non- employees is recognized as the stock options are earned. The fair value of the stock options granted is calculated at each reporting date using the Black- Scholes option pricing model with the following assumptions: expected life is equal to the remaining contractual term of the award as of the measurement date ranging from 8.00 years to 9.12 years as of March 31, 2015, and 9.00 years to 9.35 years as of March 31, 2014, respectively; risk free rate is based on the U.S. Treasury Constant Maturity rate with a term similar to the expected life of the option at the measurement date; expected dividend yield of 0%; and volatility of 83.8% as of March 31, 2015, and 86.63% as of March 31, 2014, respectively.

The following table summarizes stock-based compensation expense related to stock options for the three months ended March 31, 2015 and 2014 included in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended March 31,	
	2015	**2014**
Cost of revenue	$ 76	$ 6
Research and development	213	62
Selling and marketing	124	19
General and administrative	125	45
Total stock-based compensation expense	$ 538	$ 132

As of March 31, 2015, unrecognized compensation expense related to unvested options, net of estimated forfeitures, was $6.2 million, which the Company expects to recognize on a straight-line basis over a weighted- average period of 3.3 years.

7. Net loss per common share

The following table presents the calculation of basic and diluted net loss per share for the three months ended March 31, 2015 and 2014 (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2015	2014
Net loss	$ (18,637)	$ (9,033)
Shares used in computing net loss per share, basic and diluted	17,063,463	749,048
Net loss per share, basic and diluted	$ (1.09)	$ (12.06)

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The following outstanding common stock equivalents have been excluded from diluted net loss per share for the three months ended March 31, 2015 and 2014 because their inclusion would be anti-dilutive:

	Three Months Ended March 31,	
	2015	2014
Shares of common stock subject to outstanding options	1,997,410	1,615,581
Shares of common stock subject to conversion from convertible preferred stock		13,521,900
Shares of common stock subject to unvested early exercise of outstanding options subject to repurchase	17,907	48,439
Total common stock equivalents	2,015,317	15,185,920

8. Geographic information

Revenue by country is determined based on the billing address of the customer. The following presents revenue by country for the three months ended March 31, 2015 and 2014 (in thousands):

	Three Months Ended March 31,	
	2015	2014
United States	$ 974	$ 97
Canada	125	13
Rest of world	130	8
Total revenue	$ 1,229	$ 118

Long-lived assets, net, by location are summarized as follows (in thousands):

	March 31, 2015	December 31, 2014
United States	$ 16,451	$ 13,858
Chile	1,729	1,814
Total long-lived assets, net	$ 18,180	$ 15,672

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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 financial statements and the related notes included in our Annual Report on Form 10-K for the year ended December 31, 2014. Historic results are not necessarily indicative of future results.

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

- our views regarding the future of genetic testing and its role in mainstream medical practice;
- strategic plans for our business, products and technology, including our ability to expand our assay and develop new assays while maintaining attractive pricing, further enhance our genetic testing process and the related user experience, build interest in and demand for our tests (including by driving traffic to our website) and attract potential partners;
- the implementation of our business model;
- 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 current 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 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;

- our financial performance; and

- our expectations regarding our future revenue, cost of revenue, operating expenses and capital expenditures, and our future capital requirements.

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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 corporations and organizations in this report.

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Business Overview

Our mission is to bring comprehensive genetic information into mainstream medical practice to improve the quality of healthcare for billions of people. Our goal is to aggregate most of the world s genetic tests into a single service with higher quality, faster turnaround time and lower price than many single gene tests today. By aggregating large numbers of currently available genetic tests into a single service, we can achieve great economies of scale that allow us to not only provide primary single gene or multi-gene tests but also to generate and store additional genetic information on behalf of the patient for future use. We refer to the service of managing genetic information over the course of disease or the lifetime of a patient as genome management. In addition, as more individuals gain access to their genetic information, we believe that sharing genetic information will provide an economic opportunity for patients and us to participate in advancing the understanding and treatment of disease.

We launched our first commercial offering in late November 2013, an assay of 216 genes comprising 85 different genetic disorders and 17 targeted panels, and began selling and marketing our panels with a focused effort on hereditary cancers, including breast, colon and pancreatic cancer. We charge $1,500 per sample in most cases, which allows our clients to receive test results on any or all genes in a specific indication or multi-gene panel. On May 12, 2015, we announced changes to our pricing. Effective immediately, the price for contracted in-network third-party payors is $950 per indication. In addition, effective June 1, 2015, we expect to offer our test at $475 per indication where patients are paying. We also currently offer a free re-requisition of additional data within the same indication when ordered within 90 days of the date of service. In addition, clients may obtain test results on genes that are in other indications or panels, or genes within the same indication or panel more than 90 days after the date of initial service, for an additional fee. Importantly, we are providing turnaround time of less than three weeks for the substantial majority of our tests. Since our initial launch, we have marketed additional panels based on the same assay of 216 genes.

In the first quarter of 2015, we introduced a substantial improvement to our genetic testing platform which allows us to sequence certain genes with features that are more difficult to analyze and to include additional genes in our offering, which increased the size of our assay to 221 genes. This important addition to our test menu is the result of a series of process improvements that we believe will enable us to further expand our test menu throughout the course of the year while maintaining our strategy of lowering the cost of genetic testing. In addition, we plan to introduce in the second half of 2015 an expansion of our current offering to over 500 genes. This expanded offering would double the amount of genetic content we are able to provide at a fixed cost, which would further drive down the cost per reportable gene.

We have experienced rapid growth in recent periods. Our revenue increased $1.1 million, or 942%, from $0.1 million for the three months ended March 31, 2014 to $1.2 million for the three months ended March 31, 2015. For the three months ended March 31, 2015 and 2014, we incurred a net loss of $18.6 million and $9.0 million, respectively. As of March 31, 2015, we had an accumulated deficit of $103.8 million. We also increased our number of employees to 207 at March 31, 2015 from 104 on March 31, 2014. Our sales force grew to 14 people in the first quarter of 2015 from six people in the first quarter of 2014.

Since our commercial launch, we have delivered more than 6,200 billable tests as of March 31, 2015. Sales of our tests have grown significantly from 206 billable tests in the three months ended March 31, 2014 to more than 2,200 billable tests in the three months ended March 31, 2015, which we believe is evidence that our value proposition is attractive to our clients. We estimate that the U.S. market for hereditary cancer tests is greater than $650.0 million per year and thus represents a key growth opportunity for us. On a historical basis through March 31, 2015, approximately 34% of the billable tests we performed have been billable to institutions and patients, and the remainder have been billable to third-party payors. Many of the gene tests on our assay are tests for which private insurers reimburse. However, because we do not have reimbursement policies or contracts with very many private insurers, our claims for reimbursement from them 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 achieving reimbursement, we may be paid at lower rates than if we were under contract with the third-party payor. 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 intend to continue to invest aggressively in our business and we expect to continue to incur additional expenditures as a public company. As a result of these and other factors, we expect to incur operating losses for the foreseeable 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 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, increase the number of partners working with us to add value for our clients and consistently drive down the price per gene for genetic analysis and interpretation.

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Factors affecting our performance

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 assay and laboratory processes, modifying our platform-agnostic assay and laboratory processes to use materials and technologies that provide equal or greater quality at lower cost, improving how we manage our inventory and negotiating favorable terms for our materials purchases. We also intend to design and implement hardware and software tools that will reduce personnel cost for both laboratory and clinical operations 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.

Number of billable tests

The growth in our genetic testing business is tied to the number of tests for which we bill third-party payors, institutions or patients, which we refer to as billable tests. We 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 an important indicator of the growth in our business.

Success obtaining third party reimbursement

Our ability to increase the number of billable tests and our revenue will depend in part on our success achieving broad reimbursement coverage for our tests from third-party payors. Reimbursement may depend on a number of factors, including a payor s determination that a test is appropriate, medically necessary and cost-effective. Because each payor 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, physicians 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 physicians. We believe that establishing coverage from third-party payors, including the Center for Medicare and Medicaid Services, or CMS, is an important factor in gaining adoption by ordering physicians. We have received approval as a Medicare provider, which allows us to bill for our services to Medicare patients. Further we have entered into reimbursement contracts with Blue Shield of California, SelectHealth, Capital Health Plan of Florida and Ohio State Plan. If we are not able to obtain and maintain adequate reimbursement from third-party payors for our

testing services and expand the base of physicians ordering our tests, we may not be able to effectively increase the number of billable tests or our revenue.

Investment in our business and timing of expenses

We plan to continue to invest significantly in our genetic testing, genome management and genome network business. We deploy state-of-the-art and costly technologies in our genetic testing services, and we intend to significantly 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 genetic interpretation and report sign-out procedures, conduct ongoing research and development activities, scale our customer service capabilities and expand the functionality of our website. As part of our growth, we also plan to hire additional personnel, including software engineers, sales and marketing personnel, research and development personnel, medical specialists, biostatisticians and geneticists. In addition, we expect to incur additional expenses as a result of operating as a public company. The expenses we incur may vary significantly by quarter depending, for example, on when large equipment purchases are made or significant hiring takes place, and as we focus on building out different aspects of our business.

How we recognize revenue

Our historical revenue has been recognized when cash is received. We do not expect to recognize significant amounts of revenue on an accrual basis for some period of time. Until we achieve and maintain a predictable pattern of collection at a consistent payment amount from a large number of payors, we will continue to recognize the substantial majority of our revenue when cash is received. Additionally, as we commercialize new test offerings, we will need to achieve a predictable pattern of collection at a consistent payment amount for each payor for each new product offering prior to being able to recognize the related test revenue on an accrual basis. Because the timing and amount of cash payments received from payors is difficult to predict, we expect that our revenue will fluctuate significantly in any given quarter.

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For the three months ended March 31, 2015 and 2014, amounts billed for tests delivered totaled $3.2 million and $0.3 million, respectively. As of March 31, 2015, we had recognized revenue of $0.3 million related to amounts billed for tests delivered during the three months ended March 31, 2015 and $0.9 million related to amounts billed for tests delivered during the year ended December 31, 2014. It is difficult to predict future revenue from previously delivered but unpaid tests. Accordingly, we cannot provide any assurance as to when, if ever, or to what extent any of these amounts will be collected. Because we are in the early stages of commercializing our tests, we have had limited payment and collection history. Notwithstanding our efforts to obtain payment for these tests, payors may deny our claims, in whole or in part, and we may never receive revenue from any previously delivered but unpaid tests. Revenue from these tests, if any, may not be equal to the billed amount due to a number of factors, including differences in reimbursement rates, the amounts of patient co-payments, the existence of secondary payors and claims denials.

We incur and recognize expenses for tests in the period in which the test is conducted and recognize revenue for tests in the period in which our revenue recognition criteria are met. Accordingly, any revenue that we receive in respect of previously delivered but unpaid tests will favorably impact our liquidity and results of operations in future periods.

Financial overview

Revenue

We 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. As we do not have sufficient history of collection and are not yet able to determine a predictable pattern of collection, we currently recognize revenue when cash is received. Our ability to increase our revenue will depend on our ability to increase our market penetration, obtain contracted reimbursement coverage from third-party payors and increase the rate at which we are paid for tests performed.

Cost of revenue

Cost of revenue reflects the aggregate costs incurred in delivering test results to physicians and includes expenses for materials and supplies, personnel 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 regardless of when the test is billed or when revenue is recognized with respect to that test. As a result, our cost of revenue as percentage of revenue may vary significantly from period to period because we generally do not recognize revenue in the period in which costs are incurred. 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 may 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 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, including costs associated with our efforts to expand the number of genes we can evaluate in our tests. These costs consist of personnel 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 substantially increase in absolute dollars in future periods as we continue to invest in research and development activities related to developing additional tests. We expect that in the next 12 months the substantial increase in research and development expenses will be for the continued development and support of our assay of 221 genes and other new testing services and programs under development.

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Selling and marketing

Selling and marketing expenses consist of personnel costs, client service expenses, direct 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 and marketing expenses to substantially increase over the next 12 months, primarily driven by the cost of hiring additional account executives and business development personnel associated with efforts to further penetrate the domestic market.

General and administrative

General and administrative expenses include executive, finance and accounting, 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 and utilities. We expect our general and administrative expenses will increase as we scale our operations. We also expect to incur additional general and administrative expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and the New York Stock Exchange, additional insurance expenses, investor relations activities and other administration and professional services.

Interest income and other income (expense), net

Interest income and other income (expense), net, primarily consists of interest income and the net exchange gain/loss on foreign currency transactions related to the operations of our subsidiary in Chile.

Interest expense

Interest expense is attributable to our financing obligation under our capital lease agreements in connection with the purchase of laboratory equipment.

Critical accounting policies and estimates

Management s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make 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.

There have been no material changes in our critical accounting policies during the three months ended March 31, 2015, as compared to those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

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Results of operations

Comparison of the three months ended March 31, 2015 and 2014

	Three Months Ended March 31,		Dollar Change	% Change
	2015	2014		
	(In thousands)			
Revenue	$ 1,229	$ 118	$ 1,111	942%
Operating expenses:				
Cost of revenue	3,199	611	2,588	424%
Research and development	8,455	4,965	3,490	70%
Selling and marketing	4,740	1,666	3,074	185%
General and administrative	3,440	1,895	1,545	82%
Total operating expenses	19,834	9,137	10,697	117%
Loss from operations	(18,605)	(9,019)	(9,586)	106%
Interest income and other income (expense), net	(4)	3	(7)	(233)%
Interest expense	(28)	(17)	(11)	65%
Net loss	$ (18,637)	(9,033)	$ (9,604)	106%

Revenue

Revenue increased $1.1 million, or 942%, in the three months ended March 31, 2015 compared to the same period in 2014. The increase is due to an increase in the adoption of our test, which resulted in an increase in cash collections. The increase is also driven by our more aggressive collection activities in the first quarter of 2015, as we hired a third-party to assist with collections.

Cost of revenue

Cost of revenue increased $2.6 million, or 424%, in the three months ended March 31, 2015 compared to the same period in 2014. This increase was primarily due to a $1.2 million increase in costs of reagents and laboratory materials, a $1.0 million increase in personnel costs related to the increase in headcount and a $0.3 million increase in costs of facilities and equipment associated with increased tests performed and the purchase and use of equipment during 2014. The number of billed test results delivered increased to more than 2,200 for the three months ended March 31, 2015 from 206 for the same period in 2014.

Research and development

Research and development expenses increased $3.5 million, or 70%, for the three months ended March 31, 2015 compared to the same period in 2014. The increase was primarily driven by a $1.3 million increase in personnel costs related to the increase in headcount and consultant costs, a $1.3 million increase in allocated facilities-related expenses due to the expansion of our operations, and a $0.7 million increase in costs of

laboratory materials and laboratory equipment maintenance.

Selling and marketing

Selling and marketing expenses increased $3.1 million, or 185%, for the three months ended March 31, 2015, compared to the same period in 2014. The increase was due to a $1.6 million increase in personnel costs and travel related expenses due to the increase in headcount and consultant costs, a $0.7 million increase related to an increase in allocated technology and facilities related expenses as the result of our office expansion, and a $0.7 million increase in conferences, marketing activities and trade show-related expenses.

General and administrative

General and administrative expenses increased $1.5 million, or 82%, for the three months ended March 31, 2015 compared to the same period in 2014. The increase was due to a $1.3 million increase in professional services to support our growing infrastructure as we expanded our operations and began operating as a public company, a $0.9 million increase in personnel costs resulting from an increase in headcount, offset by a $0.6 million decrease in allocated technology and facilities related expenses as additional costs were allocated to research and development expenses in 2015 due to the increase in headcount, and $0.1 million decrease in legal costs primarily related to the Myriad litigation, which was dismissed during the three months ended March 31, 2015.

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Liquidity and capital resources

Liquidity and capital expenditures

We have incurred net losses since our inception. For the three months ended March 31, 2015 and 2014, we had a net loss of $18.6 million and $9.0 million, respectively, and we expect to incur additional losses in the foreseeable future. As of March 31, 2015, we had an accumulated deficit of $103.8 million. To date, we have generated only limited revenue, and we may never achieve revenue sufficient to offset our expenses.

Since inception, our operations have been financed primarily by net proceeds of $202.3 million from sales of our convertible preferred stock and net proceeds of approximately $105.7 million from our initial public offering. In addition, we have entered into various capital lease agreements for an aggregate financing amount of $6.6 million from inception through March 31, 2015 to obtain laboratory equipment. The terms of the capital leases are typically three years with interest rates ranging from 3.5% to 18.9%. The leases are secured by the underlying equipment. As of March 31, 2015 and December 31, 2014, we had $194.5 million and $107.0 million, respectively, of cash, cash equivalents, and marketable securities.

Our primary uses of cash are to fund our operations as we continue to grow our business. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We believe that our existing cash and cash equivalents as of March 31, 2015, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. However, management may in the future elect to finance operations by selling equity or debt securities. If we raise funds by issuing 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. 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, or that we will generate sufficient cash from operations to adequately fund our operating needs or sustain profitability. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, 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.

The following table summarizes our cash flows for the three months ended March 31, 2015 and 2014:

	Three Months Ended March 31,	
	2015	2014
	(in thousands)	
Cash used in operating activities	$ (18,183)	$ (8,197)
Cash used in investing activities	(127,457)	(867)
Cash provided by (used in) financing activities	106,877	(166)

Cash flows from operating activities

For the three months ended March 31, 2015, cash used in operating activities was $18.2 million. The net cash outflow from operations primarily resulted from our net loss of $18.6 million offset by non-cash charges of $1.1 million for depreciation and amortization, and $0.5 million for stock-based compensation. The change in net operating assets of $1.2 million was primarily due to a decrease in accounts payable of $1.8 million due to timing of payments to our vendors and an increase in prepaid expenses and other current assets of $1.3 million related to increases in prepaid director and officer insurance cost and interest receivables related to our marketable securities placed in the first quarter of 2015. This was offset by an increase in accrued expenses and other liabilities of $1.5 million due to the growth in our business and a decrease in other assets of $0.4 million.

For the three months ended March 31, 2014, cash used in operating activities of $8.2 million primarily resulted from our net loss of $9.0 million offset by $0.5 million for depreciation and amortization and non-cash charges of $0.1 million for stock-based compensation. The change in net operating assets of $0.2 million was primarily due to the $0.7 million increase in payables to suppliers and partially offset by an increase in prepaid and other current assets of $0.2 million and an increase in other assets of $0.2 million primarily related to security deposits on our new office leases.

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Cash flows from investing activities

For the three months ended March 31, 2015, cash used in investing activities was primarily for the purchases of marketable securities of $130.8 million and property and equipment of $1.1 million, offset by proceeds from maturities of our marketable securities of $4.5 million.

For the three months ended March 31, 2014, cash used in investing activities is related to the acquisition of property and equipment of $0.9 million.

Cash flows from financing activities

Cash provided by financing activities for the three months ended March 31, 2015 was primarily from $107.1 million of net proceeds from our initial public offering completed in February 2015, offset by payments of $0.3 million on our capital lease obligations.

Cash used in financing activities for the three months ended March 31, 2014 was primarily from payments of $0.2 million on our capital lease obligations.

Contractual obligations

During the three months ended March 31, 2015, there were no material changes to our contractual obligations and commitments described under Management s Discussion and Analysis of Financial Condition and Results of Operations in our Form 10-K.

Off-balance sheet arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

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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 capital lease obligations of $3.2 million as of March 31, 2015, which result from various capital lease agreements to obtain laboratory equipment. We had cash, cash equivalents, and marketable securities of $194.5 million as of March 31, 2015, which consisted of bank deposits, money market funds, U.S treasury notes, and U.S. government agency securities. Such interest-bearing instruments carry a degree of risk; however because our investments are primarily 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. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

We face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars (Chilean peso). Due to the uncertain timing of expected payments in foreign currencies, we do not utilize any forward exchange contracts. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made. An adverse movement in foreign exchange rates could have a material effect on payments made to foreign suppliers and for license agreements. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our financial statements.

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 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.

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PART II Other Information

ITEM 1. Legal Proceedings.

We were 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.

As previously reported, on November 25, 2013, the University of Utah Research Foundation, the Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership, Endorecherche, Inc. and Myriad (referred to collectively as the Myriad Plaintiffs) filed a complaint in the U.S. District Court in the District of Utah (referred to as the Utah Action), alleging that certain of our genetic testing services infringe certain claims of U.S. Patent Nos. 7,753,441; 6,951,721; 7,250,497; 6,033,857; 6,051,379; 7,470,510; 7,622,258; and 7,838,237 (referred to collectively as the Myriad Patents). On November 26, 2013, we filed a complaint for declaratory judgment in the U.S. District Court in the Northern District of California (referred to as the California Action), asserting that the Myriad Patents are invalid and we do not infringe them, and the Myriad Plaintiffs counterclaimed alleging that we infringe the Myriad Patents. Although the Utah Action was dismissed, on February 19, 2014, the Judicial Panel on Multidistrict Litigation granted the Myriad Plaintiffs motion to consolidate for pre-trial proceedings all actions concerning the Myriad Patents (referred to as the MDL Proceedings), with the MDL Proceedings taking place in the District of Utah. On January 23, 2015, the Myriad Plaintiffs stipulated to the dismissal with prejudice of all of their claims in the California Action and granted us a covenant not to sue for all of the patents they had asserted against us, and on January 26, 2015, the court issued an order dismissing the California Action with prejudice thereby ending our involvement in the MDL Proceedings.

ITEM 1A. Risk Factors.

Risks related to our business and strategy

We are an early-stage company with a history of losses, we expect to incur significant losses for the foreseeable future, and we may not be able to achieve or sustain profitability.

We have incurred substantial losses since our inception. For the three months ended March 31, 2015, we had a net loss of $18.6 million. As of March 31, 2015, we had an accumulated deficit of $103.8 million. To date, we have generated limited revenue, and we may never achieve revenue sufficient to offset our expenses. In addition, we expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we focus on scaling our business and operations. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders equity and working capital. 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 we have only a limited operating history upon which you can evaluate our business and prospects. We commercially launched our assay of 216 genes in late November 2013. 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, continue to expand, automate and upgrade our laboratory, technology and data systems, obtain coverage and reimbursement by healthcare payors such as Medicare and private health insurers, 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.

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We will 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 will depend 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 invest heavily in order to significantly scale our infrastructure, including our testing capacity and information systems, expand our customer service, billing and systems processes and enhance our internal quality assurance program. We will also need to hire and retain sufficient numbers of skilled personnel, including geneticists, biostatisticians, certified laboratory scientists and other scientific and technical personnel to process and interpret our genetic tests. 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 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 driving 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 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 demand for our tests, we will need to continue to make physicians 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 a relatively small number of early adopters. In addition, physicians 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 physicians 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.

If third-party payors, including managed care organizations, private health insurers and government health plans do not provide coverage and adequate reimbursement for our tests, 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 broad reimbursement for our tests from third-party payors. Physicians may not order our tests unless third-party payors, such as managed care organizations, private health insurers and government healthcare programs, such as Medicare and Medicaid, cover and provide adequate reimbursement for a substantial portion of the price of our tests. Reimbursement by a payor may depend on a number of factors, including a payor s determination that a test is appropriate, medically necessary, and cost-effective.

Since each payor 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 payor 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 a small number of commercial third-party payors, and have not obtained coverage from Medicare or any state Medicaid program. Further, we believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from commercial payors 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.

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We expect to continue to focus substantial resources on increasing adoption of, and coverage and reimbursement for, our current tests and any future tests we may develop. We believe it may take several years to achieve coverage and adequate contracted reimbursement with a majority of third-party payors. However, we cannot predict whether, under what circumstances, or at what payment levels payors will reimburse for our tests. If we fail to establish 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 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, including if our tests fail to detect genomic variants with high accuracy, or mistakes, including if we fail to or incompletely or incorrectly identify the significance of gene variants, 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 physicians and geneticists ordering our tests around 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 physicians or geneticists, and lead to claims against us if someone were to allege that our 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. 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 our 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 business, reputation and results of operations.

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 Myriad Genetics, Inc., or Myriad, Ambry Genetics, Inc. and GeneDx, Inc., a subsidiary of Bio- Reference Laboratories, Inc.;

- 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.

Hospitals, academic medical centers and eventually physician practice groups and individual physicians 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.

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Participants in closely related markets such as prenatal testing and 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:

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

- quality of website content; and

- reliability.

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 payors. 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 payors 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. 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.

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.

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We have limited experience in marketing and selling our tests, and our success will depend in part on our ability to generate sales using a relatively small internal sales team and through alternative marketing strategies.

We have limited experience marketing and selling our tests, which we began selling in late 2013. 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 a relatively small 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 physicians outside of oncology may not be successful, or may be difficult to do successfully without significant additional selling and marketing efforts and expense. As part of our strategy to reduce the cost of genetic testing, we will need to maintain our selling and marketing expenses at levels that are lower than many of our competitors through the use of focused sales efforts. Our future sales will depend in large part on our ability to develop and substantially expand awareness of our company and our tests through alternative strategies including through education of key opinion leaders, through social media-related and online outreach, education and marketing efforts, and through focused channel partner strategies designed to drive demand for our tests. We 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 and intend to continue to use distributors to assist with sales, logistics, education, and customer support. Identifying, qualifying, and engaging distributors with local industry experience and knowledge will be necessary to effectively market and sell our tests outside the United States. We may not be successful in finding, attracting and retaining additional distributors, or we may not be able to enter into additional distribution arrangements on favorable terms. 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 materially and adversely impact our business operations.

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 Agilent Technologies, Inc., Illumina, Inc., Integrated DNA Technologies Incorporated, Qiagen N.V., and Roche Holdings Ltd. 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 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.

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If our laboratory in San Francisco becomes inoperable due to an earthquake 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 laboratory in San Francisco, California. Our laboratory 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 laboratory 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. The inability to perform our tests or the backlog that could develop if our laboratory is 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.

We currently have a second laboratory established in Santiago, Chile, however this laboratory has not been used for the performance of our tests in significant volume. The use of such laboratory as a back-up facility for our laboratory operations in San Francisco would require substantial lead time, including to obtain CLIA certification, as well as to secure the necessary equipment, labor and other resources. In addition, a number of third-party payors, including Medicare, do not reimburse for tests performed outside of the United States.

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 and our third-party billing and collections provider collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payors, 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. 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.

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 measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider, 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, 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 the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Health Information Technology for Economic and Clinical Heath Act, or HITECH, and 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 is currently accessible through our online portal and 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 payors 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.

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.

In addition, 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. It is possible that these 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.

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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. 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. 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. In addition, we plan to hire a chief medical officer, as well as add additional geneticists, biostatisticians, certified laboratory scientists and other scientific and technical personnel. 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.

The loss of any member 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 or long-term equity incentives in place with our chief executive officer.

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 and technicians. 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 and technicians, due to the competition for qualified personnel among life science 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.

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.

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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.

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

We currently have a laboratory in Chile and distribution arrangements in several countries, and our business strategy contemplates significant international expansion. We plan to enter into additional distribution relationships to conduct physician outreach activities and to develop and expand payor relationships 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 payor reimbursement regimes, government payors, or patient self-pay systems;

- logistics and regulations associated with shipping blood samples, including infrastructure conditions and transportation delays;

- limits on our ability to penetrate international markets if we do not to conduct our tests locally;

- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial conditions on demand and payment for our tests, and exposure to foreign currency exchange rate fluctuations;

- 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 future international expansion and 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 blood 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.

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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. The proceeds from our initial public offering will not be sufficient to fully fund our business and growth strategy. 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. 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 may 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 may 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. If we make any acquisitions 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 future 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. Integration of an acquired company or business also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment.

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. Once we become a public company, if the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

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

We depend on information technology and telecommunications systems for significant elements of our operations, including our laboratory information management system, our bioinformatics analytical software systems, our database of information relating to genetic variations and their role in disease process and drug metabolism, our clinical report optimization systems, our customer- facing web-based software, our customer reporting, and our family history and risk assessment tools. 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. In addition, our third-party billing and collections provider depends upon technology and telecommunications systems provided by outside vendors.

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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 physicians, billing payors, processing reimbursement appeals, handling physician or patient inquiries, conducting research and development activities, and managing the administrative 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.

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.

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. The Centers for Medicare and Medicaid Services, or 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 U.S. Food and Drug Administration, or FDA, has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency s requirements for medical devices (e.g., establishment registration, device listing, quality 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. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. It is unclear at this time when, or if, the draft guidance documents will be finalized, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance (in as little as 12 months after the draft guidance is finalized for certain high-priority LDTs). Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time.

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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 final guidance, final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA s requirements 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 payors, for our tests. We have a current CLIA certificate to conduct our tests at our laboratory in San Francisco. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratory.

We are also required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operation of our clinical reference laboratory in San Francisco, including the training and skills required of personnel and quality control. We also maintain licenses to conduct testing in Florida, Maryland, Pennsylvania and Rhode Island. Our clinical reference laboratories are required to be licensed on a test- specific basis by New York State as an out of state laboratory and our products, as LDTs, must be approved by the New York State Department of Health, or NYDOH, before they are performed on specimens from New York. Once approved, we would also be subject to periodic inspection by the NYDOH and required to demonstrate ongoing compliance with NYDOH regulations and standards. Because our laboratories are not licensed by New York, we are currently prohibited from testing samples from New York. Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of human blood 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.

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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. Designed to go well beyond regulatory compliance, CAP asserts that the program 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. In November 2014, we obtained CAP accreditation for our San Francisco laboratory. 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, 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, in return for or to induce such person to refer an individual, or to purchase, lease, order, arrange for, or recommend purchasing, leasing or ordering, any good, facility, item or service that is reimbursable, in whole or in part, under a federal healthcare program;

- the federal Stark physician self-referral law, which prohibits a physician from making a referral 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 providing the designated health services, and prohibits that entity from billing or presenting a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies;

- 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 healthcare 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 payor, including private insurers;

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- 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 physicians 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 payors; 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.

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

We are also 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.

Healthcare policy changes, including recently enacted 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 began to apply to sales of taxable medical devices after December 31, 2012. 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 which are in development.

- mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule of 1.75% for the years 2011 through 2015. In addition, a multi-factor productivity adjustment is made to the fee schedule payment amount.

- establishes an Independent Payment Advisory Board to reduce the per capita rate of growth in Medicare spending. The Independent Payment Advisory Board has broad discretion to propose policies, which may have a negative impact on payment rates for our tests beginning in 2016.

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The Medicare Physician Fee Schedule rates for diagnostic tests are updated annually under the current statutory formula. For the past several years, the application of the statutory formula would have resulted in substantial payment reductions to all items and services reimbursed under the Physician Fee Schedule if Congress had failed to intervene. In the past, Congress has passed interim legislation to prevent the decreases, with the most current legislation postponing the payment reductions through March 31, 2015. If Congress fails to pass legislation to prevent application of the sustainable growth rate payment reductions beginning April 1, 2015, or for any future deadline, the resulting decrease in payment could materially adversely impact our revenue for services reimbursed under the Medicare Physician Fee Schedule, *e.g.*, physician interpretation of molecular testing.

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, the AMA recently released new codes to report genomic sequencing procedures, and in November 2014, CMS published a final determination that sets the price for these codes for purposes of calendar year 2015 via the gap-filling methodology, where Medicare contractors establish jurisdiction-specific payment amounts for these tests, from which national limits may be set under Medicare for 2016. We do not yet know how our tests may fit under these new codes, but if we are required to report our tests under these codes, we cannot assure you that Medicare or its contractors will set adequate reimbursement rates for these new codes.

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 PAMA, clinical laboratories must report to Medicare private payor rates beginning in 2016 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. An advanced diagnostic laboratory test is a clinical diagnostic laboratory test covered under Medicare that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria: (1) the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result; (2) the test is cleared or approved by the FDA; or (3) the test meets other similar criteria established by the Secretary of Health and Human Services (no criteria have been established by the Secretary as of October 2014).

We do not believe that our tests meet the current definition of advanced diagnostic laboratory tests, but in the event that our tests are determined by CMS to meet these criteria or new criteria developed by CMS, we would be required to report private payor data for those tests annually. Otherwise, we will be required to report private payor rates for our tests on an every three years basis. Laboratories that fail to report the required payment information may be subject to substantial civil money penalties.

For tests furnished on or after January 1, 2017, Medicare payments for clinical diagnostic laboratory tests will be paid based upon these reported private payor rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests will be assigned by the cross-walk or gap-fill methodology, as under prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test. The impact of the new payment system on rates for our tests, including any current or future clinical diagnostic laboratory tests or advanced diagnostic laboratory tests we develop, is not clear at this time.

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 payors 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. 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.

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Risks related to our intellectual property

Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation have and may continue to 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. Our activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties. Numerous U.S. and foreign patents and pending patent applications exist in the genetic testing market and are owned 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. In the event of a successful claim of infringement against us by a third party, we may have to (1) pay substantial damages, 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 (4) redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure.

On November 26, 2013, in response to infringement allegations by Myriad we sued Myriad in the Northern District of California for declaratory judgment that certain of its U.S. patents are invalid and not infringed by our tests. This case was consolidated for pre-trial proceedings with actions for infringement by Myriad together with certain of its licensors, the Myriad Plaintiffs, against six other companies. See Item 1 Legal proceedings in Part II of this Report. The Myriad Plaintiffs counterclaimed against us, alleging that our tests infringe those patents and alleging that we are willfully infringing those patents. On January 23, 2015, the Myriad Plaintiffs stipulated to the dismissal with prejudice of all of their claims and granted us a covenant not to sue for all of the patents they had asserted against us, and on January 26, 2015, the court issued an order dismissing the case with prejudice thereby ending the litigation.

As we continue to commercialize our tests in their current or an updated form, launch different and expanded tests, and enter new markets, other 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. If such a suit were brought, regardless of merit, we could incur substantial costs and diversion of the attention of our management and technical personnel in defending ourselves against such claims. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our cash position and stock price. Furthermore, parties making claims against us may seek and thereby potentially obtain injunctive or other relief, which could block our ability to commercialize our tests, and could result in the award of substantial damages against us. In the event of a successful claim of infringement or misappropriation against us, we may be required to pay damages and obtain one or more licenses from third parties, or be prohibited from commercializing certain tests, 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.

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

We believe that naturally occurring DNA sequences should not be patentable, and we do not currently have any patents or patent applications directed to such sequences nor have we in-licensed such patents rights of any third party. In this regard, a few key cases involving diagnostic method claims and gene patents have recently been decided by the U.S. Supreme Court. On March 20, 2012, the U.S. Supreme Court issued a decision in *Mayo Collaborative v. Prometheus Laboratories*, or *Mayo*, a case involving patent claims directed to optimizing on a patient-specific basis the dosage of a certain drug by measuring its metabolites in a patient. In *Mayo*, the U.S. Supreme Court determined that patent claims directed at detection of natural correlations, such as the correlation between drug metabolite levels in a patient and that drug s optimal dosage for such patient, are not eligible for patent protection. The *Mayo* Court held that claims based on this type of comparison between an observed fact and an understanding of that fact s implications represent attempts to patent a natural law and, moreover, when the processes for making the comparison are not themselves sufficiently inventive, claims to such processes are similarly patent-ineligible. On June 13, 2013, the U.S. Supreme Court decided *Association for Molecular Pathology v. Myriad Genetics*, or *Myriad*, a case brought by multiple plaintiffs challenging the validity of certain patent claims held by Myriad relating to the breast cancer susceptibility genes BRCA1 and BRCA2. In *Myriad*, the U.S. Supreme Court held that genomic DNAs that have been isolated from, or have the same sequence as, naturally occurring samples, such as the DNA constituting the BRCA1 and BRCA2 genes or fragments thereof, are not eligible for patent protection. Instead, the *Myriad* Court held that only those complementary DNAs, or cDNAs, which have a sequence that differs from a naturally occurring fragment of genomic DNA may be patent eligible. Because it will be applied by other courts to all gene patents, the holding in *Myriad* also invalidates patent claims to other genes and gene variants. On June 19, 2014, the U.S. Supreme Court decided *Alice Corporation v. CLS Bank (2014), or Alice*, where it amplified its *Mayo* and *Myriad* decisions and clarified the analytical framework for distinguishing between patents that claim laws of nature, natural phenomena and abstract ideas and those that claim patent-eligible applications of such concepts. According to the *Alice* Court, the analysis depends on whether a patent claim directed to a law of nature, a natural phenomenon or an abstract idea contains additional elements, an inventive concept, that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself&!#cs; (citing *Mayo*).

Although we view the *Mayo, Myriad* and *Alice* cases as aligned with our belief that naturally occurring DNA sequences 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 the holdings of such cases. 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 should not be patentable.

We cannot fully predict what impact the U.S. Supreme Court s decisions in *Mayo, Myriad* and *Alice* may have on the ability of various third parties, including competitors with substantial resources, to obtain or enforce patents relating to genes, genomic discoveries or genetic testing services currently or in the future. The *Mayo, Myriad* and *Alice* decisions are relatively new, and the precise contours of patent eligibility with respect to claims to laws of nature, natural phenomena or abstract ideas are not yet fully settled and may take many years to develop, including through further interpretation in the courts. There are many patents claiming testing methods based on similar or related correlations that issued before *Mayo*, and although some or many of these patents may be invalid under the standard set forth in *Mayo*, until successfully challenged, these patents may be entitled to a presumption of validity and enforceability in litigation, and certain third parties could allege that we infringe, or request that we obtain a license to, these patents. Whether based on patents issued prior to or after *Mayo*, we could have to defend ourselves against claims of patent infringement, or choose to license rights, if available, under patents claiming such methods. Moreover, although the U.S. Supreme Court has held in *Myriad* that isolated genomic DNA is not patent-eligible subject matter, certain third parties could allege that activities that we may undertake infringe other classes of gene-related patent claims, and we could have to defend ourselves against these claims by asserting non-infringement or invalidity positions, or pay to obtain a license to these claims. In any of the foregoing or in other situations involving third-party intellectual property rights, if we are unsuccessful in defending against claims of patent infringement, we could be forced to pay damages or be subjected to an injunction that would prevent us from utilizing the patented subject matter in question if we are unable to obtain a license on reasonable terms. Such outcomes could materially affect our ability to offer our tests and have a material adverse impact on our business. Even if we are able to obtain a license or successfully defend against claims of patent infringement, the cost and distraction associated with the defense or settlement of these claims could have a material adverse impact on our business.

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With respect to our own patent protection, recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of any patent applications and the enforcement or defense of any patents that issue. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a first-to-invent system to a first-to-file system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO has developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, including in particular the first-to-file provisions, became effective on March 16, 2013. Among other changes to the patent laws are features that limit where a patentee may file a patent infringement suit and that provide opportunities for third parties to challenge any issued patent in the USPTO. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents that issue, all of which could harm our business and financial condition. In addition, further patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of patent applications and any patents we may obtain.

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 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,

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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 will 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 will 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 July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive-compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Our management and other personnel will 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 will substantially increase our legal, accounting and financial compliance costs, require that we hire additional personnel and make some activities more time-consuming and costly. We also expect that it will be more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to comply with these requirements.

If we are unable to implement and 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 will be required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our annual report for the year ending December 31, 2015, 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 are in the process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion.

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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, 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 may elect 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 of 1933, or the Securities Act. We will remain an emerging growth company until December 31, 2020, although if our revenue exceeds $1 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 may choose 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 if we choose 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 may be volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

Prior to our initial public offering in February 2015, there was no public market for our common stock, and an active and liquid public market for our stock may not develop or be sustained. In addition, the trading price of our common stock is likely to be highly 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;

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- 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 payors; and
- general economic and market conditions.

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 or 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.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale resulting from our recent initial public offering, the trading price of our common stock could decline. On March 31, 2015, 31,803,345 shares of common stock were outstanding. Of these shares, 7,302,500 are freely tradable, without restriction, in the public market. Each of our directors and officers and substantially all of our other stockholders has entered into a lock-up agreement with the underwriters of our initial public offering that restricts their ability to sell or transfer their shares. The lock-up agreements will expire in August 2015. The underwriters, however, may, in their sole discretion, waive the contractual lock-up prior to the expiration of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as of March 31, 2015, up to an additional 24,516,789 shares of common stock will be eligible for sale in the public market, of which 7,384,156 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act, and various vesting agreements. In addition, 1,997,410 shares of common stock that are subject to outstanding options as of March 31, 2015 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act. We have filed a registration statement on Form S-8 under the Securities Act covering all of the shares of common stock subject to options outstanding and reserved for issuance under our stock plans. That registration statement became effective immediately upon filing, and shares covered by that registration statement are eligible for sale in the public markets, subject to Rule 144 limitations applicable to affiliates and any lock-up agreements described above. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Insiders will exercise significant control over our company and will be able to influence corporate matters.

As of March 31, 2015, directors, executive officers, 5% or greater stockholders and their affiliates beneficially owned, in the aggregate, 67% of our outstanding capital stock. As a result, these stockholders will be able to exercise significant influence over all matters submitted to our stockholders for approval, including the election of directors and approval of significant corporate transactions, such as a merger or sale of our company or its assets. This concentration of ownership may have the effect of delaying or preventing a third party from acquiring control of our company and could adversely affect the market price of our common stock.

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

As of December 31, 2014, our total gross deferred tax assets were $29.9 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 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, 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, we may enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash 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.

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

Use of proceeds

On February 18, 2015, we completed an initial public offering, or IPO, of our common stock. In connection with the IPO, we issued and sold 7,302,500 shares of common stock at a price to the public of $16.00 per share. As a result of the IPO, we received approximately $116.8 million in gross proceeds, and $105.7 million in net proceeds after deducting underwriting discounts and commissions of $8.2 million and offering expenses of approximately $2.8 million payable by us. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of our equity securities, or to their associates, or to our affiliates. J.P. Morgan Securities LLC acted as the sole book-running manager and Cowen and Company, LLC and Leerink Partners LLC acted as co-managers for the offering.

We registered the shares under the Securities Act of 1933 on a Registration Statement on Form S-1 (Registration No. 333-201433), which was filed with the Securities and Exchange Commission, or SEC, on January 9, 2015 and declared effective on February 11, 2015, and on a Registration Statement on Form S-1 (Registration No. 333-202040), which was filed on February 11, 2015 and was immediately effective.

The IPO closed on February 18, 2015. The offering terminated after all of the shares of common stock were sold.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on February 12, 2015 pursuant to Rule 424(b).

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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.

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SIGNATURES

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

INVITAE CORPORATION

By: /s/ RANDAL W. SCOTT, PH.D.
Randal W. Scott, Ph.D.
Chief Executive Officer
Principal Executive Officer

By: /s/ LEE BENDEKGEY
Lee Bendekgey
Chief Financial Officer, General Counsel and Secretary
Principal Financial Officer

Date: May 15, 2015