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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2019

OR

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

For the transition period from _____ to _____

Commission file number: 001-37478

NATERA, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**01-0894487**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
201 Industrial Road, Suite 410 San Carlos, CA	**94070**
(Address of Principal Executive Offices)	**(Zip Code)**

(650) 249-9090
(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	NTRA	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

As of July 31, 2019, the number of outstanding shares of the registrant's common stock, par value $0.0001 per share, was 70,129,854.

Natera, Inc.

FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2019

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements. The forward-looking statements are contained principally in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” but are also contained elsewhere in this report. Forward-looking statements include information concerning our future results of operations and financial position, strategy and plans, and our expectations for future operations. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would" or the negative version of these words and similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those described in "Risk Factors" and elsewhere in this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our beliefs and assumptions only as of the date of this report. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. You should read this report completely and with the understanding that our actual future results may be materially different from what we expect.

These forward-looking statements include, but are not limited to, statements concerning the following:

- our expectation that, for the foreseeable future, a significant portion of our revenues will be derived from sales of Panorama;
- our ability to increase demand for Panorama, obtain favorable coverage and reimbursement determinations from third-party payers, and expand geographically;
- our expectation that Panorama will be adopted for broader use in average-risk pregnancies and for the screening of microdeletions and that third-party payer reimbursement will be available for these applications;
- our expectations of the reliability, accuracy, and performance of Panorama, as well as expectations of the benefits to patients, providers, and payers of Panorama;
- our ability to successfully develop additional revenue opportunities and expand our product offerings to include new tests, including our recently launched offerings;
- our efforts to successfully develop and commercialize our technology and expertise in prenatal testing into oncology and transplant rejection applications;
- the effect of improvements in our cost of goods sold;
- our estimates of the total addressable markets for our current and potential product offerings;
- our ability and expectations regarding obtaining, maintaining and expanding third-party payer coverage of, and reimbursement for, our current and future tests;
- the effect of changes in the way we account for our revenue;
- our ability to successfully commercialize our products through strategic or commercial partnerships, such as our agreements with QIAGEN and BGI Genomics Co., Ltd., and our ability to enter into additional such partnerships in the future and achieve the anticipated benefits from such partnerships;
- the scope of protection we establish and maintain for, and developments or disputes concerning, our intellectual property or other proprietary rights;
- competition in the markets we serve;
- our ability to successfully commercialize our cloud-based distribution model;
- our reliance on collaborators such as medical institutions, contract laboratories, laboratory partners, and other third parties;
- our ability to operate our laboratory facilities and meet expected demand and to successfully scale our operations;

- our reliance on a limited number of suppliers, including sole source suppliers, which may impact our ability to maintain a continued supply of laboratory instruments and materials and to run our tests or our ability to commercialize and offer our tests;
- our expectations of the rate of adoption of Panorama and of any of our other current or future tests by laboratories, clinics, clinicians, payers, and patients;
- our ability to complete clinical studies and publish clinical data in peer-reviewed medical publications regarding Panorama and any of our current or future tests;
- our SMART study and our ongoing and planned trials in oncology and transplant rejection;
- our reliance on our partners to market and offer Panorama in the United States and in international markets;
- our estimates regarding our costs and risks associated with our international operations and international expansion;
- our ability to retain and recruit key personnel;
- our reliance on our direct sales efforts;
- our expectations regarding acquisitions, other strategic transactions and strategic operations;
- our ability to fund our working capital requirements;
- our compliance with federal, state, and foreign regulatory requirements;
- the factors that may impact our financial results; and
- anticipated trends and challenges in our business and the markets in which we operate.

Any forward-looking statement made by us in this report speaks only as of the date on which it is made. Except as required by law, we disclaim any obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Natera, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 29,928	$ 46,407
Restricted cash	55	4,597
Short-term investments	208,053	107,461
Accounts receivable, net of allowance of $1,997 in 2019 and $1,788 in 2018	62,974	62,223
Inventory	15,236	13,633
Prepaid expenses and other current assets	5,721	6,197
Total current assets	321,967	240,518
Property and equipment, net	22,039	24,336
Operating lease right-of-use assets	26,229	—
Other assets	13,091	3,317
Total assets	$ 383,326	$ 268,171
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,319	$ 14,587
Accrued compensation	10,149	12,668
Other accrued liabilities	39,157	32,442
Deferred revenue, current portion	19,154	4,131
Short-term debt financing	50,146	50,153
Total current liabilities	126,925	113,981
Long-term debt financing	73,511	73,357
Deferred rent, net of current portion	—	8,613
Deferred revenue, long-term portion	60,527	40,058
Operating lease liabilities, long-term portion	29,275	—
Total liabilities	290,238	236,009
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, $0.0001 par value: 750,000 shares authorized at both June 30, 2019 and December 31, 2018, respectively; 70,035 and 62,083 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	7	7
Additional paid in capital	733,137	607,236
Accumulated deficit	(640,851)	(574,529)
Accumulated other comprehensive income (loss)	795	(552)
Total stockholders' equity	93,088	32,162
Total liabilities and stockholders' equity	$ 383,326	$ 268,171

See accompanying notes to the unaudited interim condensed consolidated financial statements.

Natera, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except per share data)

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Revenues				
Product revenues	$ 65,099	$ 60,353	$ 128,463	$ 114,622
Licensing and other revenues	9,256	2,716	12,716	10,787
Total revenues	74,355	63,069	141,179	125,409
Cost and expenses				
Cost of product revenues	41,382	39,204	82,987	78,259
Cost of licensing and other revenues	2,443	1,791	4,141	3,328
Research and development	12,124	11,852	23,559	26,192
Selling, general and administrative	47,042	37,440	90,874	75,365
Total cost and expenses	102,991	90,287	201,561	183,144
Loss from operations	(28,636)	(27,218)	(60,382)	(57,735)
Interest expense	(2,721)	(2,560)	(5,445)	(4,949)
Interest and other income (expense), net	836	(3,933)	1,289	(3,796)
Loss before income taxes	(30,521)	(33,711)	(64,538)	(66,480)
Income tax expense	(1,895)	(113)	(1,969)	(217)
Net loss	$ (32,416)	$ (33,824)	$ (66,507)	$ (66,697)
Unrealized gain (loss) on available-for-sale securities, net of tax	1,061	46	1,347	(92)
Comprehensive loss	$ (31,355)	$ (33,778)	$ (65,160)	$ (66,789)
Net loss per share (Note 13):				
Basic	$ (0.48)	$ (0.62)	$ (1.01)	$ (1.23)
Diluted	$ (0.48)	$ (0.62)	$ (1.01)	$ (1.23)
Weighted-average number of shares used in computing basic and diluted net loss per share:				
Basic	68,224	54,551	65,542	54,342
Diluted	68,224	54,551	65,542	54,342

See accompanying notes to the unaudited interim condensed consolidated financial statements.

Natera, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
(Unaudited)

	Three months ended June 30, 2018					
(in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance as of March 31, 2018	54,251	$ 6	$ 476,270	$ (904)	$ (479,248)	$ (3,876)
Issuance of common stock upon exercise of stock options	643	—	3,632	—	—	3,632
Issuance of common stock under employee stock purchase plan	206	—	1,855	—	—	1,855
Issuance of common stock upon exercise of warrants	333	—	6,762	—	—	6,762
Vesting of restricted stock	21	—	—	—	—	—
Stock-based compensation	—	—	3,368	—	—	3,368
Unrealized gain on available-for sale securities	—	—	—	46	—	46
Net loss	—	—	—	—	(33,824)	(33,824)
Balance as of June 30, 2018	55,454	$ 6	$ 491,887	$ (858)	$ (513,072)	$ (22,037)

	Six months ended June 30, 2018					
(in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance as of December 31, 2017	54,040	$ 6	$ 472,552	$ (766)	$ (446,375)	$ 25,417
Issuance of common stock upon exercise of stock options	788	—	4,196	—	—	4,196
Issuance of common stock under employee stock purchase plan	206	—	1,855	—	—	1,855
Issuance of common stock upon exercise of warrants	333	—	6,762	—	—	6,762
Vesting of restricted stock	87	—	—	—	—	—
Stock-based compensation	—	—	6,522	—	—	6,522
Unrealized loss on available-for sale securities	—	—	—	(92)	—	(92)
Net loss	—	—	—	—	(66,697)	(66,697)
Balance as of June 30, 2018	55,454	$ 6	$ 491,887	$ (858)	$ (513,072)	$ (22,037)

Natera, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
(Unaudited)

	Three months ended June 30, 2019					
(in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance as of March 31, 2019	63,340	$ 7	$ 613,680	$ (266)	$ (608,435)	$ 4,986
Issuance of common stock upon exercise of stock options	398	—	3,405	—	—	3,405
Issuance of common stock under employee stock purchase plan	132	—	2,147	—	—	2,147
Issuance of common stock for public offering, net	6,053	—	107,595	—	—	107,595
Issuance of common stock to Orbimed	25	—	506	—	—	506
Vesting of restricted stock	87	—	—	—	—	—
Stock-based compensation	—	—	5,804	—	—	5,804
Unrealized gain on available-for sale securities	—	—	—	1,061	—	1,061
Net loss	—	—	—	—	(32,416)	(32,416)
Balance as of June 30, 2019	70,035	$ 7	$ 733,137	$ 795	$ (640,851)	$ 93,088

	Six months ended June 30, 2019					
(in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance as of December 31, 2018	62,083	$ 7	$ 607,236	$ (552)	$ (574,529)	$ 32,162
Issuance of common stock upon exercise of stock options	1,468	—	5,983	—	—	5,983
Issuance of common stock under employee stock purchase plan	132	—	2,147	—	—	2,147
Issuance of common stock for public offering, net	6,053	—	107,595	—	—	107,595
Issuance of common stock to Orbimed	25	—	506	—	—	506
Vesting of restricted stock	274	—	—	—	—	—
Stock-based compensation	—	—	9,855	—	—	9,855
Unrealized gain on available-for sale securities	—	—	—	1,347	—	1,347
Cumulative-effect adjustment upon adoption of ASU 2018-07	—	—	(185)	—	185	—
Net loss	—	—	—	—	(66,507)	(66,507)
Balance as of June 30, 2019	70,035	$ 7	$ 733,137	$ 795	$ (640,851)	$ 93,088

See accompanying notes to the unaudited interim condensed consolidated financial statements.

Natera, Inc.
Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Six months ended June 30,	
	2019	**2018**
Operating activities		
Net loss	$ (66,507)	$ (66,697)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,952	3,679
Non-cash lease expense	3,849	—
Stock-based compensation	9,855	6,522
Premium amortization and discount accretion on investment securities	151	310
Amortization of debt discount	215	195
Inventory excess adjustments	212	152
Impairment of assets	—	1,544
Loss on investments	—	32
Loss from changes in fair value of warrants	—	4,119
Other non-cash charges (benefits)	203	(50)
Changes in operating assets and liabilities:		
Accounts receivable	(829)	(12,854)
Inventory	(1,815)	(3,477)
Prepaid expenses and other current assets	(4,464)	1,564
Other assets	(9,499)	415
Accounts payable	(6,378)	(784)
Accrued compensation	(2,519)	(984)
Other accrued liabilities	2,331	(3,752)
Deferred revenue	35,492	35,889
Deferred rent, net of current portion	—	(320)
Net cash used in operating activities	(35,751)	(34,497)
Investing activities		
Purchases of investments	(162,176)	(20,584)
Proceeds from sale of investments	—	27,895
Proceeds from maturity of investments	62,780	27,600
Purchases of property and equipment, net	(1,599)	(1,227)
Net cash used in (provided by) investing activities	(100,995)	33,684
Financing activities		
Proceeds from exercise of stock options	5,983	4,197
Proceeds from issuance of common stock under employee stock purchase plan	2,147	1,855
Proceeds from public offering	107,595	—
Net cash provided by financing activities	115,725	6,052
Net (decrease) increase in cash, cash equivalents and restricted cash	(21,021)	5,239
Cash, cash equivalents and restricted cash, beginning of period	51,004	13,021
Cash, cash equivalents and restricted cash, end of period	$ 29,983	$ 18,260
Supplemental non-cash investing and financing activities:		
Obtaining right-of-use assets in exchange for lease liabilities	$ 28,191	$ —
Purchases of property and equipment in accounts payable and accruals	$ 323	$

See accompanying notes to the unaudited interim condensed consolidated financial statements.

Natera, Inc.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

1. Description of Business

Natera, Inc. (the "Company") was formed in the state of California as Gene Security Network, LLC in November 2003 and incorporated in the state of Delaware in January 2007. The Company's mission is to change the management of genetic disease worldwide. The Company operates a laboratory certified under the Clinical Laboratory Improvement Amendments ("CLIA") providing a host of preconception and prenatal genetic testing services. The Company determines its operating segments based on the way it organizes its business to make operating decisions and assess performance. The Company has only one segment, which is the discovery, development and commercialization of genetic testing services, and it has a subsidiary that operates in the state of Texas.

The Company's product offerings include its Panorama Non-Invasive Prenatal Test ("NIPT") that screens for chromosomal abnormalities of a fetus typically with a blood draw from the mother; Vistara ("Vistara"), a single-gene mutations screening test performed to identify single-gene disorders; Horizon Carrier Screening ("HCS") to determine carrier status for a large number of severe genetic diseases that could be passed on to the carrier's children; Spectrum Pre-implantation Genetic Screening ("PGS") and Spectrum Pre-implantation Genetic Diagnosis ("PGD") to analyze chromosomal anomalies or inherited genetic conditions during an *in vitro* fertilization ("IVF") cycle to select embryos with the highest probability of becoming healthy children; Anora Products of Conception ("POC") test to rapidly and extensively analyze fetal chromosomes to understand the cause of miscarriage; and Non-Invasive Paternity Testing ("PAT"), to determine paternity by analyzing the fragments of fetal deoxyribonucleic acid ("DNA") in a pregnant mother's blood and a blood sample from the alleged father(s), which is marketed and sold by a licensee from whom the Company receives a royalty. All testing is available principally in the United States. The Company also offers its Panorama test to customers outside of the United States, primarily in Europe. The Company also offers Constellation ("Constellation"), a cloud-based software product that allows laboratory customers to gain access through the cloud to the Company's algorithms and bioinformatics in order to validate and launch tests based on the Company's technology. The Company also offers Evercord, which is a cord blood and cord tissue processing and storage service; and Signatera™, a circulating tumor DNA technology that analyzes and tracks mutations specific to an individual's tumor. Further, the Company has expanded its Panorama test to now screen twin pregnancies for zygosity and chromosomal abnormalities.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information. The unaudited interim condensed consolidated financial information includes only adjustments of a normal recurring nature necessary for a fair presentation of the results of operations, financial position, changes in stockholders' equity, and cash flows. The results of operations for the three and six months ended June 30, 2019, are not necessarily indicative of the results for the full year or the results for any future periods. The condensed consolidated balance sheet as of December 31, 2018 has been derived from audited financial statements at that date, these financial statements should be read in conjunction with the audited financial statements, and related notes for the year ended December 31, 2018 included in the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2019.

Effective January 1, 2019, the Company transitioned to the new accounting requirements under the Accounting Standards Update ("ASU") No. 2018-07, *Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. The Company applied the modified retrospective approach upon transition with a cumulative-effect adjustment of $0.2 million recorded to accumulated deficit as of January 1, 2019. The results in all of the prior period financial statements presented in this Form 10-Q were not retroactively adjusted. See Note 2 under *Recently Adopted Accounting Pronouncements* for further discussion.

On January 1, 2019, the Company adopted the new accounting requirements under ASU 2016-02, *Leases*, and concurrently elected ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which permitted the Company to adjust any cumulative-effect of the accounting change to the balance of accumulated deficit as of the adoption date instead of the earliest period presented by using the modified retrospective approach. None of the prior period financial results in this Form 10-Q were retroactively adjusted as a result of the adoption of ASU 2016-02. See Note 2 under *Recently Adopted Accounting Pronouncements* for more detail.

Liquidity Matters

The Company has incurred net losses since its inception and anticipates net losses and negative operating cash flows for the near future. The Company had a net loss of $66.5 million for the six months ended June 30, 2019 and recorded a cumulative-effect adjustment of $0.2 million upon the adoption of ASU 2018-07 on January 1, 2019, which increased the accumulated deficit to $640.9 million at June 30, 2019 from $574.6 million at December 31, 2018. At June 30, 2019, the Company had $30.0 million in cash and cash equivalents, $208.1 million in marketable securities, $50.1 million of outstanding balance of the Credit Line (as defined in Note 10) including accrued interest, and $73.5 million of net carrying amount of the 2017 Term Loan (as defined in Note 10). While the Company has introduced multiple products that are generating revenues, these revenues have not been sufficient to fund all operations. Accordingly, the Company has funded the portion of operating costs that exceeds revenues through a combination of equity issuances, debt issuances, and other financings.

The Company continues to develop and commercialize future products and, consequently, it will need to generate additional revenues to achieve future profitability and may need to raise additional equity or debt financing. If the Company raises additional funds by issuing equity securities, its stockholders would experience dilution. Additional debt financing, if available, may involve covenants restricting its operations or its ability to incur additional debt. Any additional debt financing or additional equity that the Company raises may contain terms that are not favorable to it or its stockholders and requires significant debt service payments, which diverts resources from other activities. Additional financing may not be available at all, or in amounts or on terms acceptable to the Company. If the Company is unable to obtain additional financing, it may be required to delay the development and commercialization of its products and significantly scale back its business and operations.

On April 23, 2019, the Company completed an underwritten equity offering to sell 5,263,158 shares of its common stock at a price to the public of $19 per share. On April 26, 2019, the Company sold an additional 789,473 shares of its common stock to the underwriters at the same price upon their exercise of the option to purchase those shares. Before offering expenses of $0.6 million, the Company received proceeds of $108.1 million net of the underwriting discount.

Based on the Company's current business plan, the Company believes that its existing cash and marketable securities will be sufficient to meet its anticipated cash requirements for at least 12 months after August 8, 2019.

Principles of Consolidation

The accompanying condensed consolidated financial statements include all the accounts of the Company and its subsidiary. The Company established a subsidiary that operates in the state of Texas to support the Company's laboratory and operational functions. All intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions about future events that affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Significant items subject to such estimates include the allowance for doubtful accounts, the operating right-of-use assets and the associated lease liabilities, deferred revenues associated with unsatisfied performance obligations, accrued liability for potential refund requests, stock-based compensation, the fair value of common stock and warrants, income tax uncertainties, and the expected consideration to be received from contracts with customers. These estimates and assumptions are based on management's best estimates and judgment. Management regularly evaluates its estimates and assumptions using historical experience and other factors,

including contractual terms and statutory limits; however, actual results could differ from these estimates and could have an adverse effect on the Company's financial statements.

Fair Value

The Company discloses the fair value of financial instruments for financial assets and liabilities for which the value is practicable to estimate. Fair value is defined as the price that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price).

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and money market deposits with financial institutions.

Restricted Cash

The Company discloses both short-term and long-term restricted cash. As of June 30, 2019, short-term restricted cash totaled $0.1 million and long-term restricted cash totaled zero in cash deposits held as collateral for the settlement of foreign currency transactions and deposit per credit card terms.

In the first quarter of 2019, the Company paid the final quarterly installment of $1.4 million in connection with the settlement agreement relating to reimbursement-related claims, and accordingly, the restriction imposed on the $4.2 million cash deposits to secure the letter of credit required under the settlement agreement was released.

Restricted cash is currently presented as a separate line item in the Company’s balance sheet. In the statements of cash flows, it is included together with cash and cash equivalents and considered as part of the total ending cash balance. The following is the reconciliation between how restricted cash is presented in the balance sheet and the statements of cash flows for all periods presented:

	June 30, 2019	December 31, 2018
	(in thousands)	
Cash and cash equivalents in balance sheet	$ 29,928	$ 46,407
Restricted cash, current portion in balance sheet	55	4,597
Total cash, cash equivalents and restricted cash in statements of cash flows	$ 29,983	$ 51,004

Investments

Investments consist primarily of debt securities such as U.S. Treasuries, U.S. agency and municipal bonds. Management determines the appropriate classification of securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company generally classifies its entire investment portfolio as available-for-sale. The Company views its available-for-sale portfolio as available for use in current operations. Accordingly, the Company classifies all investments as short-term, even though the stated maturity may be more than one year from the current balance sheet date. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported in accumulated other comprehensive income (loss), which is a separate component of stockholders’ equity.

Risk and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist of cash, accounts receivable and investments. The Company limits its exposure to credit loss by placing its cash in financial institutions with high credit ratings. The Company's cash may consist of deposits held with banks that may at times exceed federally insured limits. The Company performs evaluations of the relative credit standing of these financial institutions and limits the amount of credit exposure with any one institution.

The Company bills third-party payers for certain tests performed. The amount that is ultimately received from the payer for the Company's claim and the timing of such payments are subject to the determination of the payer based on the nature of the test performed and their view of the Company's business practices with respect to collections of plan deductibles and co-payments from patients and other activities. This determination can impact both the amount and timing of when the Company's invoices are collected. Payers may also withhold payments and request refunds of prior payments if the payer asserts that the Company has not performed in accordance with the policies of these payers.

The Company performs evaluations of financial conditions for insurance carriers, patients, clinics and laboratory partners and generally does not require collateral to support credit sales. For the three and six months ended June 30, 2019, and 2018, there were no customers exceeding 10% of total revenues on an individual basis. As of June 30, 2019 and December 31, 2018, there were no customers with an outstanding balance exceeding 10% of net accounts receivable.

Revenue Recognition

The Company adopted the new revenue recognition guidance, Accounting Standards Codification ("ASC") Topic 606, beginning January 1, 2018. ASC 606 mandates revenue recognition to be evaluated using the following five steps:

- Identification of a contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price;
- Allocation of the transaction price to the performance obligations in the contract; and
- Revenue recognition when, or as, the performance obligations are satisfied

See Note 3, *Revenue Recognition*, for detailed discussions of product revenues, licensing and other revenues, and how the five steps described above are applied.

Cost of Product Revenues

The components of cost of product revenues are material and service costs, impairment charges associated with testing equipment, personnel costs, including stock-based compensation expense, equipment and infrastructure expenses associated with testing samples, electronic medical records, order and delivery systems, shipping charges to transport samples, third-party test fees and allocated overhead including rent, information technology costs, equipment depreciation and utilities. Costs associated with the performance of diagnostic services are recorded as tests are accessioned.

Cost of Licensing and Other Revenues

The components of cost of licensing and other revenues are material costs associated with test kits, engineering costs incurred to improve and maintain the Constellation software platform, and amortization of Constellation software development costs. Costs also include collection kits consumed during the processing of cord blood samples, processing service and storage of the cord blood samples, and freight charged to transport the samples to the storage facility.

Stock-Based Compensation

Stock-based compensation is related to stock options and restricted stock units ("RSUs") granted to the Company's employees and is measured at the grant date based on the fair value of the award. The fair value is recognized as expense over the requisite service period, which is generally the vesting period of the respective awards on a straight-line basis. No compensation cost is recognized when the requisite service has not been met and the awards are therefore forfeited.

The Company also recognizes stock-based compensation from option awards and RSUs granted to non-employees. Prior to January 1, 2019, the fair value of non-employee awards was subject to remeasurement at the end of each reporting period until the vesting date of such awards, and the resulting change in fair value was recognized in the Company's statements of operations and comprehensive loss during the period that the related services were rendered.

On January 1, 2019, the Company adopted ASU 2018-07, which allows the accounting for non-employee awards to be treated the same as for employee awards. The fair value of non-employee awards is now determined based on a one-time measurement at the grant date, and it is no longer subject to periodic remeasurement. The Company continues to recognize stock-based compensation expense as services are rendered by the non-employees over the vesting period, which is accounted for on a straight-line basis. See further discussion under the *Recently Adopted Accounting Pronouncements* section within this footnote, as well as the election of certain accounting policy as a result of the adoption.

The Company uses the Black-Scholes option-pricing model and the Monte Carlo simulation model to estimate the fair value of stock options issued to employees and non-employees. The model requires the input of the Company's expected stock price volatility, the expected term of the awards, and a risk-free interest rate. Determining these assumptions requires significant judgment. See further discussion on the valuation assumptions used under Note 9.

Warrants

The Company historically accounted for warrants to purchase shares of its common stock as a liability at fair value on the balance sheet date because the Company could have been obligated to redeem these warrants at some point in the future. The warrants were subject to re-measurement at each balance sheet date, with changes in fair value of the warrants recognized as a gain or loss in interest and other income in the statements of operations and comprehensive loss. Further adjustments resulting from changes in fair value are no longer required as the warrants were fully exercised in June 2018.

Capitalized Software Held for Internal Use

The Company capitalizes salaries and related costs of employees and consultants who devote time to the development of internal-use software development projects. Capitalization begins during the application development stage, once the preliminary project stage has been completed. If a project constitutes an enhancement to previously developed software, the Company assesses whether the enhancement is significant and creates additional functionality to the software, thus qualifying the work incurred for capitalization. Once the project is available for general release, capitalization ceases and the Company estimates the useful life of the asset and begins amortization. The Company periodically assesses whether triggering events are present to review internal-use software for impairment. Changes in estimates related to internal-use software would increase or decrease operating expenses or amortization recorded during the reporting period. See *Property and Equipment, net* under Note 6 for more detail regarding an impairment charge recorded to write off certain project development costs during the first quarter of 2018.

The Company amortizes its internal-use software over the estimated useful lives of three years. The net book value of capitalized software held for internal use was $1.8 million and $1.7 million as of June 30, 2019 and December 31, 2018, respectively. Amortized expense for amounts previously capitalized for the three months ended June 30, 2019 and 2018 was $0.3 million for each period; and $0.6 million and $0.7 million for the six months ended June 30, 2019 and 2018, respectively.

Accumulated Other Comprehensive Income (Loss)

Comprehensive loss and its components encompass all changes in equity other than those with stockholders, and include net loss, unrealized gains and losses on available-for-sale marketable securities.

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Beginning balance	$ (266)	$ (904)	$ (552)	$ (766)
Net unrealized gain (losses) on available-for-sale securities, net of tax	1,061	46	1,347	(124)
Reclassifications of losses realized from sale of available-for-sale securities	—	—	—	32
Increase (decrease) in other comprehensive income (loss)	1,061	46	1,347	(92)
Ending balance	$ 795	$ (858)	$ 795	$ (858)

Net Loss per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average shares outstanding during the period, without consideration for potential dilutive shares. For purposes of the diluted net loss per share calculation, outstanding common stock options, RSUs, ESPP, and warrants are considered potential dilutive shares but are excluded from this calculation as the result becomes anti-dilutive, unless the consideration of any one of them gives a dilutive effect.

Property and Equipment

Property and equipment, including purchased and internally developed software, are stated at cost. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which are generally three to five years. Leasehold improvements are amortized using the straight-line method over the estimated useful lives of the assets or the remaining term of the lease, whichever is shorter.

Impairment of Long-lived Assets

The Company periodically evaluates the carrying value of its long-lived assets for indicators of possible impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. The Company then compares the carrying amount of the long-lived assets with the future net undiscounted cash flows expected to be generated by such asset. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the asset over the asset's fair value determined using discounted estimates of future cash flows. See Note 6 for more detail regarding assets impairment.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") under its accounting standard codifications or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed below, the Company believes that the impact of accounting standards updates recently issued that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Recently Adopted Accounting Pronouncements

Leases

On January 1, 2019, the Company adopted ASU 2016-02 and concurrently elected to adopt ASU 2018-11, which are collectively known as ASC 842, *Leases* ("ASC 842"). ASU 2018-11 provides an alternative transition method such that the initial application of the new lease accounting standards can be completed as of January 1, 2019 using the modified retrospective approach instead of the earliest period presented. The financial results in the statement of operations and comprehensive loss for the three and six months ended March 31, 2018 and the balance sheet as of December 31, 2018 were not retroactively restated. As a result of electing the transition guidance as described above, on January 1, 2019, the Company recorded operating right-of-use assets of $28.2 million, including the derecognition of deferred rent of $9.5 million and prepaid rent of $0.7 million, with the corresponding lease liabilities totaling $37.0 million. There was no material impact to the Company's statements of operations and comprehensive loss upon adoption.

Upon transition, the Company has elected the package of practical expedients available under ASC 842, which allows the Company not to reassess (i) whether any expired or existing contracts as of the transition date are or contain a lease, (ii) lease classification for any expired or existing leases as of the transition date, and (iii) initial direct costs for any existing leases as of the transition date. The Company has decided not to elect the practical expedient on applying hindsight in determining the lease term and the impairment of the right-of-use assets. See Note 7, *Leases*, for more detail information regarding the accounting for operating leases.

Non-employee stock-based compensation

Effective January 1, 2019, the Company transitioned to the new accounting requirements under ASU 2018-07 for non-employee stock-based awards using the modified retrospective approach. The new guidance aligns the accounting treatment for both the employee and non-employee stock-based awards, which simplifies the fair value measurement process by requiring a one-time valuation of the non-employee stock options as of the grant date. Upon transition, the Company performed the final fair value remeasurement for its existing unvested non-employee stock-based awards, which included stock options and restricted stock units, up until the transition date, and adjusted the amount of the cumulative stock-based compensation expense accordingly by $0.2 million. The Company recorded this amount as a cumulative-effect adjustment to the opening balance of accumulated deficit in its balance sheet.

Under the new guidance, the Company is permitted to carry-over the method it has used to recognize stock-based compensation expense from non-employee awards, which is accounted for on a straight-line basis as services are rendered over the vesting period. However, there are certain accounting options available for election in connection with estimated forfeitures and the valuation input for the expected term or remaining contractual term. The Company has elected to account for the actual forfeitures upon the cancellation of the awards, and to use of the same expected term valuation input as it uses for employee awards.

Reclassification of tax effects from accumulated other comprehensive income

The Company adopted ASU 2018-02 on January 1, 2019, which was established as a result of the Tax Cuts and Jobs Act passed in December 2017 and provided an opportunity for entities to reclassify residual income tax effects from accumulated other comprehensive income to retained earnings due to the reduction of the corporate income tax rate. Upon adoption, the Company had the option to apply this new guidance using either the full retrospective approach or to record the reclassifications as of the adoption date. As of January 1, 2019, the Company had a full valuation allowance reserved against its deferred tax assets, and as a result, there was no restatement or reclassification required.

Statements of stockholders' equity

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, *Disclosure Update and Simplification*. One of the amendments applicable to the Company was the presentation of the analysis of changes in stockholders' equity in its first interim financial statements following the effective date of the amendments in November 2018, which would be included in the Form 10-Q beginning the first

quarter of 2019, with comparative information for the same period in the prior year. As such, the Company has added the presentation of its consolidated statements of stockholders' equity for the three and six months ended June 30, 2019 and 2018 under Item 1 of this Form 10-Q.

New Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments* and also issued subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04, and ASU 2019-05. The standard requires measurement and recognition of expected credit losses for financial assets by requiring an allowance to be recorded as an offset to the amortized cost of such assets. For available-for-sale debt securities, expected credit losses should be estimated when the fair value of the debt securities is below their associated amortized costs. The standard will become effective for the Company in the first quarter of 2020, with early adoption permitted beginning the first quarter of 2019. The modified retrospective approach should be applied upon adoption of this new guidance. The Company is currently evaluating the impact of adopting the standard on its financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 proposes new disclosure requirements for unrealized gains or losses recognized in other comprehensive income that are attributable to fair value changes in assets and liabilities categorized within Level III of the fair value hierarchy, as well as quantitative information about significant unobservable inputs used to value such assets and liabilities. It eliminates the requirement to disclose the reasons for the transfers of assets and liabilities measured in fair value on a recurring basis between Level I and Level II. ASU 2018-13 is effective for the Company for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year, with early adoption permitted. The Company is currently assessing the impact of this standard on its consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, Topic 808 precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. This guidance will be effective for the Company beginning January 1, 2020. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

3. Revenue Recognition

The Company recognizes revenues when, or as, performance obligations in the contracts are satisfied, in the amount reflecting the expected consideration to be received from the goods or services transferred to the customers.

Product Revenues

Product revenues are derived from contracts with insurance carriers, laboratory partners and patients in connection with sales of prenatal genetic tests. The majority of the Company's revenues is derived from Panorama NIPT, HCS (as defined in Note 1), and to a lesser extent, other genetic tests. The Company enters into contracts with insurance carriers with primarily payment terms related to tests provided to the patients who have health insurance coverage. Insurance carriers are considered as third-party payers on behalf of the patients, and the patients are considered as the customers who receive genetic test services. Tests may be billed to insurance carriers, patients, or a combination of insurance carriers and patients. Further, the Company sells tests to a number of domestic and international laboratory partners and identifies the laboratory partners as customers provided that there is a test services agreement between the two parties.

A performance obligation represents a promise in a contract to transfer a distinct good or service to a customer, which represents a unit of accounting in accordance with ASC 606. A portion of the consideration should be allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. The

Company evaluates its contracts with insurance carriers, laboratory partners and patients and identifies a single performance obligation in those contracts, which is the delivery of the test results.

The total consideration which the Company expect to collect in exchange for our products is an estimate and may be fixed or variable. Consideration includes reimbursement from both patients and insurance carriers, adjusted for variable consideration related to disallowed cases, discounts, refunds and doubtful accounts, and is estimated using the expected value approach. For insurance carriers with similar reimbursement characteristics, we use a portfolio of relevant historical data to estimate variable consideration and total collections for our products. The Company constrains the estimated variable consideration when we assess it is probable that a significant reversal in the amount of cumulative revenue recognized may occur in future periods. The consideration expected from laboratory partners usually includes a fixed amount, but it can be variable depending on the volume of tests performed, and the Company determines the variable consideration using the expected value approach. For insurance carriers, laboratory partners and patients, the Company allocates the total consideration to a single performance obligation, which is the delivery of the test results to the customers.

When assessing the total consideration for insurance carriers and patients, a certain percentage of revenues is further constrained for estimated refunds.

The Company generally bills an insurance carrier, a laboratory partner or a patient upon delivery of test results. The Company also bills patients directly for out-of-pocket costs involving co-pays and deductibles that they are responsible for. Tests billed to insurance carriers and directly to patients usually take an average of nine to twelve months to collect the payments, and for tests billed to laboratory distribution partners, the average collection cycle takes approximately two to three months. At times, the Company may or may not get reimbursed for the full amount billed. Further, the Company may not get reimbursed at all for tests performed if such tests are not covered under the insurance carrier's reimbursement policies or the Company is not a qualified provider to the insurance carrier, or if the tests were not previously authorized.

Product revenue is recognized in an amount equal to the total consideration (as described above) at a point in time when the test results are delivered. The Company reserves certain amounts in other accrued liabilities on the balance sheet in anticipation of requests for refunds of payments previously made by insurance carriers, which are accounted for as reductions in product revenues in the statement of operations and comprehensive loss. During the three and six months ended June 30, 2019, $0.8 million and $1.3 million were released from amounts previously held in reserves in other accrued liabilities and recognized as product revenue, compared to $0.9 million and $1.8 million for the three and six months ended June 30, 2018.

Licensing and Other Revenues

The Company recognizes licensing revenues from its cloud-based distribution service offering, Constellation, by granting licenses to its licensees to use certain of the Company's proprietary intellectual properties and cloud-based software. The Company also recognizes revenues from Evercord for the collection and storage of newborn cord blood and cord tissue units.

Constellation

The laboratory partners with which the Company enters into a licensing arrangement represent the licensees and are identified as customers. The licensees do not have the right to possess the Company's software, but rather receive the software as a service. These arrangements often include: (i) the delivery of the software as a service, (ii) the necessary support and training, and (iii) the reagent kits ("IVD kits") to be consumed as tests are processed. The Company does not consider the software as a service, the support and training as being distinct in the context of such arrangements, and therefore they are combined as a single performance obligation. The software, support and training are delivered simultaneously to the licensees over the term of the arrangement.

The Company provides IVD kits that are customized for its licensees to process tests using its cloud-based software. IVD kits revenues are recognized based on their standalone selling price at a point in time upon delivery to the licensees.

The Company bills the majority of licensees, who process the tests in their laboratories, a fixed price for each test processed. Licensing revenues are recognized as the performance obligations are satisfied over time and reported in licensing and other revenues in the statements of operations and comprehensive loss.

Evercord

The Company recognizes revenues from Evercord for the collection and storage of newborn cord blood and cord tissue units. The patient enters into an enrollment agreement with the Company. According to the agreement, there are two performance obligations: (i) the provision of a collection kit and the processing of newborn cord blood and cord tissue units, which are considered delivered at the beginning of the process (the "processing services"), and (ii) the storage of the cord blood and cord tissue units (the "storage services"), for either an annual fee or a prepayment covering an extended period or the lifetime of the newborn donor.

The Company offers its processing services together with storage services, and each of them is capable of being distinct, and is distinct in the context of the contract, and therefore, represents separate performance obligations. Evercord customers may pay for both processing and storage services over a period of six, 12, or 18 months. The transaction price for the processing and storage services is calculated as the stated contract price, adjusted for discounts, refunds, and significant financing components. The Company determines that the transaction price represents the standalone selling prices that are observable in the market for both the processing and storage services. The total consideration is allocated between the processing services and storage services based on their standalone selling prices.

Upon the completion of the processing services, the Company issues a certificate of preservation indicating that the cord blood and cord tissue units are ready for storage, and processing revenues are recognized at this particular point in time. Storage revenues are recognized over time, which is the applicable storage period. The Company believes the methodology of recognizing storage revenues over time meaningfully depicts the timing of storage services delivered to customers as it exerts the necessary efforts to deliver such services equally over time. Evercord revenues are reported in licensing and other revenues in the statements of operations and comprehensive loss.

Qiagen

In March 2018, the Company entered into a License, Development and Distribution Agreement ("the Qiagen Agreement") with Qiagen under which the Company granted Qiagen a license to develop, manufacture, distribute and commercialize NGS-based genetic testing assays and sequencing systems utilizing such assays, which incorporate the Company's proprietary technology. According to the terms of the agreement, the Company is initially entitled to receive an upfront license fee and prepaid royalties totaling $40.0 million, which was fully collected in 2018. All or a portion of the prepaid royalties are refundable in limited circumstances. In addition, the Company is entitled to potential milestone payments from Qiagen upon the successful achievement of certain volume, regulatory and commercial milestones, and tiered royalties of $10.0 million, of which the Company has received $5.0 million due as of December 31, 2018. The Qiagen Agreement has a term of 10 years and expires in March 2028, and it may be terminated earlier in certain circumstances. Upon termination of the Qiagen Agreement, the license granted to Qiagen will also terminate, except in certain limited circumstances. The Company provided to Qiagen standard indemnification protections, which is part of an assurance that the license meets the contract's specifications and is not an obligation to provide goods or services.

The Company identified the following goods and services in the agreement that it concluded were distinct performance obligations:

Technology license. The Company granted the right to Qiagen to use its proprietary intellectual properties ("technology license") to develop, manufacture, distribute and commercialize genetic testing assays and sequencing systems in certain countries. The technology license was transferred to Qiagen at the inception of this agreement when the license became effective and the technology transfer was completed.

Development services. The Company is responsible for providing certain support services to assist Qiagen in its design and development of the genetic testing assays.

Market development support. The Company is required to support Qiagen's market development for the genetic testing assays.

Option to expand commercialization to another country. The Company has provided an option to Qiagen to expand the commercialization of its genetic testing assays to another country following all of the necessary regulatory approvals.

The initial transaction price was primarily comprised of the upfront non-refundable fee and a payment associated with the initial milestone under the agreement. The Company constrains the estimated variable consideration when it assesses it is probable that a significant reversal in the amount of cumulative revenue recognized may occur in future periods. The remaining milestone and prepaid royalty amounts were constrained and not included in the transaction price due to the uncertainties of research and development and the potential for prepaid royalty refund. The Company re-evaluates the transaction price, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur. The allocation of the transaction price was performed based on standalone selling prices, which are based on estimated amounts that the Company would charge for a performance obligation if it were sold separately. Future variable consideration such as milestones and royalties are considered associated with the technology license performance obligation. The amounts included in the initial transaction price were allocated to the remaining value of the technology license, as well as development services, market development support and the option to expand commercialization using the relative standalone selling price approach. The amount initially allocated to the technology license was $5.5 million.

For the three months ended June 30, 2019 and 2018, the Company recognized revenue of $0.5 million and $0.1 million, respectively, related to support services provided and the delivery of its technology license to Qiagen. For the six months ended June 30, 2019 and 2018, the Company recognized revenues of $0.7 million and $5.6 million, respectively. Costs of revenue consist primarily of labor and other costs of development activities and are included in research and development expense in the statements of operations. Such costs were $0.1 million for the three and six months ended June 30, 2019.

In accordance with ASC 340-40, any incremental costs incurred to obtain a contract with a customer are required to be capitalized and amortized over the period in which the goods and services are transferred to the customer. The Company has elected to apply a practical expedient under ASC 340-40 to recognize the incremental costs of obtaining a contract as an expense when incurred provided that the amortization period of such costs, if capitalized, is one year or less.

BGI Genomics

In February 2019, the Company entered into a License Agreement with BGI Genomics Co., Ltd. ("BGI Genomics") to develop, manufacture, and commercialize NGS-based genetic testing assays for clinical and commercial use. The agreement has a term of ten years and expires in February 2029. According to the agreement, the Company is entitled to a total of $50 million, comprised of upfront technology license fees, prepaid royalties relating to future sales of licensed products and performance of assay interpretation services, and milestone payments, as well as additional future royalties. During the three months ended June 30, 2019, the Company received $35.6 million, net of withholding taxes, of these amounts. Also, as required by the agreement with BGI Genomics, in June 2019 the Company prepaid $6.0 million to BGI Genomics for future sequencing services and $4.0 million for future sequencing equipment. These advance payments for equipment and services to be received in future periods aggregating $10 million were recorded in long-term advances.

Pursuant to the agreement, the Company licensed its intellectual property and will provide development services. Following completion of development services, the Company will provide assay interpretation services over the term of the agreement. The Company concluded that the license is not a distinct performance obligation as it does not have a stand-alone value to BGI Genomics apart from the related development services. Therefore, license and related development services, for each of NIPT and Oncology products, represents a single performance obligation.

The Company is responsible for transferring specified licensed intellectual property and performing certain development activities to customize its genetic testing assays for oncology and NIPT for use with BGI Genomics' sequencing instruments and proprietary technology platform. Revenue associated with these performance obligations is recognized over time using the input method, based on costs incurred to perform the development services, since the level of costs incurred over time best reflect the transfer of development services. The estimated period of performance and project cost is reviewed quarterly and adjusted, as needed, to reflect the Company's current assumptions regarding the timing of its deliverables. There were no material changes in estimates during the three and six months ended June 30, 2019. Revenue associated with the assay interpretation services will be recognized upon delivery of these services. Funds received in advance are recorded as deferred revenue and will be recognized as the related services are delivered.

The initial transaction price was primarily comprised of license and milestone fees. The Company constrains the estimated variable consideration when it assesses it is probable that a significant reversal in the amount of cumulative revenue recognized may occur in future periods. Certain milestone and license fees were constrained and not included in the transaction price due to the uncertainties of research and development. The Company re-evaluates the transaction price, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur. The allocation of the transaction price was performed based on standalone selling prices, which are based on estimated amounts that the Company would charge for a performance obligation if it were sold separately.

For the three and six months ended June 30, 2019, the Company recognized approximately $5.0 million of revenue from the License Agreement with BGI Genomics. This revenue is presented as Licensing and other revenue. Costs of revenue consist primarily of labor and other costs of development activities and are included in research and development expense in the statements of operations. Such costs were $0.4 million for the three and six months ended June 30, 2019.

In accordance with ASC 340-40, any incremental costs incurred to obtain a contract with a customer are required to be capitalized and amortized over the period in which the goods and services are transferred to the customer. The Company has elected to apply a practical expedient under ASC 340-40 to recognize the incremental costs of obtaining a contract as an expense when incurred provided that the amortization period of such costs, if capitalized, is one year or less. The incremental costs incurred in connection with the BGI arrangement is not material on an accumulated basis and therefore will not be capitalized on the balance sheet but will be expensed as incurred.

Disaggregation of Revenues

The primary source of the Company's revenues relates to the sale of prenatal genetic tests. The Company also recognizes licensing revenues from its cloud-based software platform, Constellation and other revenues. The following table shows disaggregation of revenues by types of products and services, with sales of genetic tests further disaggregated by test families:

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
(Amounts in thousands)				
Sales of genetic tests				
Panorama NIPT	$ 36,467	$ 35,715	$ 73,713	$ 68,982
HCS	24,286	21,421	47,035	39,683
Other genetic tests	4,346	3,217	7,715	5,957
Product revenues	65,099	60,353	128,463	114,622
Licensing and other				
Constellation	1,312	1,293	2,644	2,598
Qiagen	527	94	675	5,594
BGI	5,018	—	5,018	—
Other	2,399	1,329	4,379	2,595
Licensing and other revenues	9,256	2,716	12,716	10,787
Total revenues	$ 74,355	$ 63,069	$ 141,179	$ 125,409

The Company measures its performance results primarily based on revenues recognized from the three categories described below. The following table shows disaggregation of revenues by payer types:

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
(Amounts in thousands)				
Insurance carriers	$ 50,777	$ 48,321	$ 100,978	$ 92,463
Laboratory partners	15,132	10,132	25,155	25,020
Patients	8,446	4,616	15,046	7,926
Total revenues	$ 74,355	$ 63,069	$ 141,179	$ 125,409

The following table presents total revenues by geographic area based on the location of the Company's payers:

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
(Amounts in thousands)				
United States	$ 62,393	$ 56,631	$ 122,676	$ 106,995
Americas, excluding U.S.	767	847	1,585	1,697
Europe, Middle East, India, Africa	4,318	3,756	8,322	13,078
Other	6,877	1,835	8,596	3,639
Total revenues	$ 74,355	$ 63,069	$ 141,179	$ 125,409

The following table summarizes the Company's beginning and ending balances of accounts receivable and deferred revenues:

(Amounts in thousands)	Balance at June 30, 2019	Balance at December 31, 2018
Assets:		
Accounts receivable	$ 62,974	$ 62,223
Liabilities:		
Deferred revenue, current portion	$ 19,154	$ 4,131
Deferred revenue, long-term portion	60,527	40,058
Total deferred revenues	$ 79,681	$ 44,189

As of June 30, 2019, accounts receivable of $63.0 million included trade receivables, as well as receivables from Evercord customers who selected certain prepayment plans for storage services to be delivered over the duration of lifetime or 18 years. Evercord customers have the option to either prepay for storage services in full upfront or finance their prepayment plans over the period of six, 12, or 18 months. Generally, prepayments collected by the Company for the lifetime or 18-year storage plans are non-refundable unless the storage service agreement is terminated. However, Evercord customers who choose the financing option will be obligated to make the remainder of their payments pursuant to the terms of the financing plan, and this represents the Company's unconditional right to the consideration from its customers. Total receivables pertaining to the financing options was $4.4 million, of which $0.3 million was related to financing over the period greater than 12 months. The Company reclassified $0.3 million to other noncurrent assets in its condensed consolidated balance sheet as of June 30, 2019.

The following table shows the changes in the balance of deferred revenues during the period:

	Deferred Revenues (in thousands)
Balance at December 31, 2018	$ 44,189
Increase in deferred revenues	45,524
Revenue recognized during the period that was included in deferred revenues at the beginning of the period	(733)
Revenue recognized from performance obligations satisfied within the same period	(9,299)
Balance at June 30, 2019	$ 79,681

During the six months ended June 30, 2019, revenue recognized that was included in the deferred revenue balance at the beginning of the period totaled approximately $0.7 million, of which $0.4 million was related to genetic testing services, $0.2 million pertained to undelivered Evercord storage services over the remaining contractual life of such services, and approximately $0.1 million was related to the Qiagen Agreement.

The following table shows the balance of current and long-term portions of deferred revenues during the period:

Deferred Revenues	Current	Long-term	Total
BGI agreement	15,000	19,982	34,982
Qiagen agreement	1,963	36,568	38,531
Other deferred revenues	$ 2,191	$ 3,977	$ 6,168
Balance at June 30, 2019	$ 19,154	$ 60,527	$ 79,681

4. Fair Value Measurements

The Company's financial assets and liabilities carried at fair value are comprised of investment assets that include money market and investments.

The fair value accounting guidance requires that assets and liabilities be carried at fair value and classified in one of the following three categories:

Level I: Quoted prices in active markets for identical assets and liabilities that the Company has the ability to access.

Level II: Observable market-based inputs or unobservable inputs that are corroborated by market data, such as quoted prices, interest rates, and yield curves.

Level III: Inputs that are unobservable data points that are not corroborated by market data.

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

Assets and Liabilities That Are Measured at Fair Value on a Recurring Basis

The following table represents the fair value hierarchy for the Company's financial assets and financial liabilities measured at fair value on a recurring basis:

	June 30, 2019				December 31, 2018			
	Level I	Level II	Level III	Total	Level I	Level II	Level III	Total
	(in thousands)							
Financial Assets:								
Money market deposits	$ 630	$ —	$ —	$ 630	$ 26,539	$ —	$ —	$ 26,539
U.S. Treasury securities	159,097	—	—	159,097	75,685	—	—	75,685
U.S. agency securities	—	12,977	—	12,977	—	12,891	—	12,891
Municipal securities	—	35,979	—	35,979	—	18,885	—	18,885
Total financial assets	$ 159,727	$ 48,956	$ —	$ 208,683	$ 102,224	$ 31,776	$ —	$ 134,000

During the six months ended June 30, 2019, the Company did not make any transfers between Level I and Level II assets.

5. Financial Instruments

The Company elected to invest a portion of its cash assets in conservative, income earning, and liquid investments. Cash equivalents and investments, all of which are classified as available-for-sale securities, consisted of the following:

	June 30, 2019				December 31, 2018			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
	(in thousands)							
Money market deposits	$ 630	$ —	$ —	$ 630	$ 26,539	$ —	$ —	$ 26,539
U.S. Treasury securities	158,429	733	(65)	159,097	76,061	29	(405)	75,685
U.S. agency securities	13,004	—	(27)	12,977	13,017	—	(126)	12,891
Municipal securities	35,825	162	(8)	35,979	18,935	7	(57)	18,885
Total	$ 207,888	$ 895	$ (100)	$ 208,683	$ 134,552	$ 36	$ (588)	$ 134,000
Classified as:								
Cash equivalents				$ 630				$ 26,539
Short-term investments				208,053				107,461
Total				$ 208,683				$ 134,000

The Company invests in U.S. Treasuries, U.S. agency and high quality municipal bonds which mature at par value and are all paying their coupons on schedule. The Company has therefore concluded there is currently no other than temporary impairment of its investments and will continue to recognize unrealized gains and losses in other comprehensive income (loss). During the six months ended June 30, 2019, there were no sales of investments, and during the six months ended June 30, 2018, the amount of gross realized gains and realized losses upon sales of investments were insignificant. The Company uses the specific investment identification method to calculate realized gains and losses and amounts reclassified out of other comprehensive income to net income. As of June 30, 2019, the Company had 7 investments in an unrealized loss position in its portfolio.

The following table summarizes the Company's portfolio of available-for-sale securities by contractual maturity as of June 30, 2019:

	June 30, 2019	
	Amortized Cost	Fair Value
	(in thousands)	
Less than one year	$ 97,180	$ 97,276
Greater than one year but less than five years	110,077	110,777
Total	$ 207,257	$ 208,053

6. Balance Sheet Components

Property and Equipment, net

The Company's property and equipment consisted of the following:

	Useful Life	June 30, 2019	December 31, 2018
		(in thousands)	
Machinery and equipment	3-5 years	$ 36,614	$ 35,400
Furniture and fixtures	3 years	1,376	1,319
Computer equipment	3 years	1,949	2,117
Capitalized software held for internal use	3 years	5,545	4,868
Leasehold improvements	Lesser of useful life or lease term	12,580	10,916
Construction-in-process		2,201	4,013
		60,265	58,633
Less: Accumulated depreciation and amortization		(38,226)	(34,297)
Total Property and Equipment, net		$ 22,039	$ 24,336

During the three months ended March 31, 2018, an asset impairment charge of $1.6 million was recorded in research and development expenses in the statements of operations and comprehensive loss. This charge was recorded to write off the project development costs that were previously capitalized.

Other Assets

In April 2016, the Company entered into a four-year agreement with a health insurance carrier whereby in return for partial exclusivity and the right to pricing benefits, the Company agreed to a total consideration payment of $3.2 million. As of June 30, 2019 and December 31, 2018, $0.6 million and $1.0 million of deferred costs related to the total consideration paid were included in other long-term assets, respectively. The deferred costs are being amortized ratably over the four-year term of the agreement. During the three months ended June 30, 2019 and 2018, amortization of such costs totaling $0.2 million was recorded for each of the two periods; and for the six months ended June 30, 2019 and 2018, $0.4 million of such costs was recorded for each of the two periods as a reduction of product revenues in the statements of operations and comprehensive loss.

In August 2017, the Company entered into the 2017 Term Loan with OrbiMed (as described in Note 10) and issued 300,000 shares of its common stock in exchange for OrbiMed's initial and remaining funding commitments. In April 2019, the Company issued an additional 25,000 shares of its common stock to OrbiMed for extending the expiration date to draw the unused borrowing capacity until December 31, 2019. The Company has classified $1.2 million out of the total debt issuance costs in noncurrent assets for the unused borrowing capacity of $50.0 million. The debt discount is being amortized on a straight-line basis over the remaining term of the loan. For the three and six months ended June 30, 2019 and 2018, debt discount amortized from noncurrent assets was insignificant. As of June 30, 2019, total unamortized remaining in noncurrent assets was $1.0 million.

As of June 30, 2019, other assets also included long-term advances to BGI of $10.0 million for future sequencing equipment and services and receivables from Evercord customers who selected the financing option for their prepayment plans (as described in Note 3). Total receivables associated with the financing option over the period greater than 12 months were $0.3 million.

Accrued Compensation

The Company's accrued compensation consisted of the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Accrued paid time off	$ 1,839	$ 1,825
Accrued commissions	3,584	4,492
Accrued bonuses	2,325	3,757
Other accrued compensation	2,401	2,594
Total accrued compensation	$ 10,149	$ 12,668

Other Accrued Liabilities

The Company's other accrued liabilities consisted of the following:

(Amounts in thousands)	June 30, 2019	December 31, 2018
Settlement accrued for reimbursement related claims	$ —	$ 1,378
Reserves for refunds to third-party payers	10,897	10,012
Accrued charges for outsourced testing	5,993	5,001
Testing and laboratory materials from suppliers	2,253	2,742
Marketing and corporate affairs	2,112	1,306
Legal, audit and consulting fees	2,082	1,058
Accrued shipping charges	255	852
Sales tax payable	906	1,255
Accrued specimen service fees	1,355	1,378
Accrued rent	—	903
Clinical trials and studies	1,310	1,694
Operating lease liabilities, current portion	5,339	—
Other accrued expenses	6,655	4,863
Total other accrued liabilities	$ 39,157	$ 32,442

In December 2017, the Company accrued a total of $11.4 million for amounts due under a settlement agreement related to reimbursement related claims and was required to make periodic payments as described in Note 8 under *Legal Proceedings*. In 2018, payments totaling $10.3 million including interest were made by the Company, with the final quarterly installment of $1.4 million remaining in other accrued liabilities as of December 31, 2018. The Company paid the final quarterly installment in March 2019.

Reserves for refunds to third-party payers include overpayments from and amounts to be refunded to insurance carriers, and additional amounts that the Company estimates as reserves for potential refund requests during the period. When the Company releases these previously reserved amounts, they are recognized as product revenues in the statements of operations and comprehensive loss. As of December 31, 2018, reserves relating to payers were $10.0 million. During the six months ended June 30, 2019, the Company reserved an additional $4.8 million, while a reduction of $3.9 million occurred within the same period resulting from the release of previously reserved amounts from payers and refunds of overpayments. Remaining reserves relating to payers in other accrued liabilities were $10.9 million as of June 30, 2019.

7. Leases

In October 2016, the Company entered into a lease directly with its landlord for laboratory and office spaces at its corporate headquarters located in San Carlos, California. The Company currently occupies approximately 113,000 square feet comprised of two office spaces (the "First Space" and the "Second Space"). The First Space covers approximately 88,000 square feet, and the Second Space totals approximately 25,000 square feet. The term of this lease is approximately 84 months and expires in October 2023. This lease contains an option to renew the lease term for five years, but the fair market rent amount upon renewal is not available from the landlord.

In addition, the Company entered into a sublease agreement in June 2019 with a third party to sublease 25,879 square feet of space located on the third floor of the San Carlos, California building while maintaining its primary obligation as the intermediate lessor. The term of this lease is approximately 48 months commencing in October 2019 and expiring in September 2023. The yearly lease payment starts at $1.9 million and will escalate annually starting in October 2020.

In March 2018, the Company entered into a lease for its cord blood tissue storage facility in Tukwila, Washington that covers approximately 10,000 square feet. The lease term of this facility began in June 2018 with rent payment commencing in August 2018. The lease term is 62 months expiring in July 2023. The Company has the option to extend this lease for five years, and the fair market rent upon renewal is not determinable.

In September 2015, the Company's subsidiary entered into a long-term lease agreement for laboratory and office space totaling approximately 94,000 square feet in Austin, Texas. The lease term is 132 months beginning in December 2015 and expiring in November 2026 with monthly payments beginning in December 2016.

As a result of electing the package of practical expedients, the Company did not reassess the classification for the three existing leases described above upon the adoption of ASC 842, which carried over as operating leases. These leases are not impacted by any renewal or termination option. In addition, the Company has also entered into leases of individual workspaces at premises located in different locations on a month-to-month basis and is not committed to an established lease term. The Company has elected to not recognize them as the right-of-use assets on the balance sheet as they are all considered as short-term leases. Short-term lease expenses were insignificant in the three and six months ended June 30, 2019.

The operating lease right-of-use assets are classified as noncurrent assets in the balance sheet. The corresponding lease liabilities are separated into current and long-term portions as follows:

(Amounts in thousands)	June 30, 2019
Operating lease liabilities, current portion included in other accrued liabilities	$ 5,339
Operating lease liabilities, long-term portion	29,275
Total operating lease liabilities	$ 34,614

The initial recognition of the operating lease liabilities was measured as the present value of the future minimum lease payments using a discount rate determined as of January 1, 2019. The operating right-of-use assets was calculated as the operating lease liabilities discounted at the present value, less the amount of cumulative lease expense recognized up until the adoption date. The discount rate used was the Company's incremental borrowing rate given that the implicit rate to each lease was not readily determinable. As of the adoption date, the incremental borrowing rate was estimated as the annual percentage yield resulting from a corporate debt financing over a loan term approximating the remaining term of each lease, with the effect of certain credit risk rating. As of June 30, 2019, the weighted-average remaining lease term was 3.33 years and the weighted-average discount rate was 10.77%.

Subsequent to the adoption date, the Company continues to recognize lease expense on a straight-line basis as was required under the previous guidance, ASC 840. The lease expense includes the amortization of the right-of-assets with the associated interest component estimated by applying the effective interest method. For the three and six months ended June 30, 2019, total lease expense of $2.0 million and $3.8 million, respectively, was recognized in the statements of operations and comprehensive loss. Cash paid for amounts in the measurement of operating lease liabilities totaled $2.1 million for the three months ended June 30, 2019.

The present value of the future annual minimum lease payments under all non-cancelable operating leases as of June 30, 2019 are as follows:

	Operating Leases (in thousands)
Year ending December 31:	
2019 (remaining 6 months)	$ 4,320
2020	8,825
2021	9,067
2022	9,319
2023	7,797
2024 and thereafter	7,130
	46,458
Less: imputed interest	(11,844)
Operating lease liabilities	$ 34,614

8. Commitments and Contingencies

Legal Proceedings

From time to time, the Company is involved in disputes, litigation, and other legal actions. The Company is aggressively defending its current litigation matters, and while there can be no assurances and the outcome of these matters is currently not determinable, the Company currently believes that there are no existing claims or proceedings that are likely to have a material adverse effect on its financial position. There are many uncertainties associated with any litigation and these actions or other third-party claims against the Company may cause the Company to incur costly litigation and/or substantial settlement charges.

In addition, the resolution of any intellectual property litigation may require the Company to make royalty payments, which could adversely affect gross margins in future periods. If this were to occur, the Company's business, financial condition, results of operations, and cash flows could be adversely affected. The actual liability in any such matters may be materially different from the Company's estimates, if any, which could result in the need to record or adjust a liability and record additional expenses. During the periods presented, the Company has not recorded any accrual for loss contingencies associated with such legal proceedings, determined that an unfavorable outcome is probable or reasonably possible, or determined that the amount or range of any possible loss is reasonably estimable, except for the amount accrued in connection with the settlement agreement with the United States Department of Justice described below.

On or about March 26, 2019, CareDX, Inc., or CareDX, the Company’s primary competitor in the transplant rejection testing field, filed suit against it in the United States District Court for the District of Delaware. The suit alleges that the Company infringed two of CareDX’s patents, 9,845,497 and 8,703,652. The complaint seeks unspecified damages and injunctive relief. On May 16, 2019, the Company filed a motion to dismiss CareDX’s patent infringement complaint for failure to state a claim, after which both parties filed answering briefs in June and July 2019. In addition, on or about April 10, 2019, CareDX filed suit against the Company in the United States District Court for the District of Delaware, alleging false advertising, trademark disparagement, unfair competition, and unfair or deceptive trade practices based on statements describing studies that concern the Company’s technology and CareDX’s technology. The complaint seeks unspecified damages and injunctive relief. On May 30, 2019, the Company filed a motion to dismiss the entirety of CareDX’s second complaint for failure to state a claim, after which both parties filed answering briefs in

June 2019. The parties are currently awaiting a hearing date and/or order from the court on the motions. The Company intends to defend both of these matters vigorously, but cannot provide any assurance as to the ultimate outcome of either matter or that an adverse resolution to either matter or both matters would not have a material adverse effect on its financial condition and results of operations. The Company is unable to predict the ultimate outcome of either matter and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome of either matter.

On March 15, 2019, a purported class action lawsuit was filed against the Company in the United States District Court for the Northern District of California, alleging that the plaintiff received an unauthorized text message to her cellular telephone in violation of the Telephone Consumer Protection Act. Among other relief, the complaint seeks statutory and other damages, injunctive relief, attorneys' fees, and costs. On June 18, 2019, the Company filed a motion to dismiss, which is currently pending. The Company intends to vigorously defend the matter but cannot provide any assurance as to the ultimate outcome or that an adverse resolution would not have a material adverse effect on its financial condition and results of operations. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

On January 22, 2019, a lawsuit was filed against the Company in the Superior Court of the State of California for the County of San Mateo, by a patient family alleging claims relating to a discordant test result. The complaint seeks unspecified damages. On April 23, 2019, Natera filed a demurrer, a motion to strike portions of the complaint, and a motion to dismiss, or in the alternative stay, the action for *forum nonconveniens.* On July 8, 2019, the court issued a minute order granting the *forum nonconveniens* motion and staying the action until October 3, 2019, and the minor plaintiff dismissed her claim without prejudice. The Company intends to continue to defend the matter vigorously, but cannot provide any assurance as to the ultimate outcome or that an adverse resolution would not have a material adverse effect on its financial condition and results of operations. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

On March 16, 2018, a lawsuit (the '831 lawsuit) against the Company was filed in the United States District Court for the Northern District of California by Illumina, Inc., or Illumina, alleging that the Company's Panorama test infringes certain claims of U.S. Patent No. 9,493,831 (the '831 patent). Among other relief, the complaint seeks damages or other monetary relief including costs and pre- and post-judgment interest, treble damages, injunctive relief, attorneys' fees and costs. On June 29, 2018, the Company filed a petition for *inter partes* review to challenge the validity of the '831 patent with the Patent Trial and Appeal Board of the United States Patent Office, or PTAB, which petition was not instituted. On August 16, 2018, the Company filed a patent infringement action in the United States District Court for the Northern District of California against Illumina, alleging that certain of Illumina's tests infringe on the Company's U.S. Patent No. 8,682,592 (the '592 patent). Among other relief, Natera seeks damages or other monetary relief including costs and pre- and post-judgment interest, treble damages, injunctive relief, attorneys' fees and costs. On January 16, 2019, the United States District Court for the Northern District of California held a claim construction hearing, and on January 30, 2019, issued an order construing certain claims. On June 13, 2019, Illumina field a petition for *inter partes* review of the '592 patent. The Company intends to vigorously defend against the claims in the '831 lawsuit and assert its own claims with respect to the '592 patent, but cannot provide any assurance as to the ultimate outcome of either matter or that an adverse resolution of either lawsuit would not have a material adverse effect on its financial condition and results of operations. The Company is unable to predict the outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

On each of February 17, 2016, March 10, 2016, March 28, 2016 and April 4, 2016, purported class action lawsuits were filed in the Superior Court of the State of California for the County of San Mateo (the "San Mateo Superior Court"), against Natera, its directors, certain of its officers and 5% stockholders and their affiliates, and each of the underwriters of the Company's July 1, 2015 initial public offering (the "IPO"). The complaints assert claims under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended. The complaints allege, among other things, that the Registration Statement and Prospectus for the Company's IPO contained materially false or misleading statements, and/or omitted material information that was required to be disclosed, about the Company's business and prospects. Among other relief, the complaints seek class certification, unspecified compensatory damages, rescission, attorneys' fees, and costs. The Company removed these actions to the United States District Court for the Northern District of

California, and the actions were subsequently remanded back to the San Mateo Superior Court. The Company has appealed the remand and discovery has been stayed pending the appeal. The Company also filed a demurrer, or a request for dismissal as a matter of law, in the San Mateo Superior Court, which was granted on October 23, 2017. The San Mateo Superior Court demurred the claims under Sections 12(a)(2) and 15 of the Securities Act of 1933, as amended, without leave to re-file, and granted the demurrer as to Section 11 of the Act with leave to re-file. Plaintiffs refiled an amended complaint on November 22, 2017. The Company filed a motion for judgment on the pleadings under the amended complaint on January 25, 2018, which the plaintiffs opposed. Hearings on the motion were held in May and July of 2018. On August 7, 2018 the judge granted the Company's motion for judgment on the pleadings, without leave to amend, and ordered that judgment be entered in favor of the defendants. Plaintiffs filed a notice of appeal on or about October 18, 2018 and their brief on or about March 29, 2019. Natera filed its brief in response on June 27, 2019. The Company intends to continue to defend the matter vigorously, but cannot provide any assurance as to the ultimate outcome or that an adverse resolution would not have a material adverse effect on its financial condition and results of operations. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome

On December 12, 2015, the Company received a civil investigative demand from the United States Department of Justice in connection with a qui tam action related to past reimbursement submissions for some of its testing. The qui tam action was originally filed under seal by the relators on January 26, 2015 in the United States District Court for the Western District of Kentucky. The qui tam complaint alleged that Natera submitted false claims to government health care programs for its testing services performed during the period from January 1, 2013 to December 31, 2016, and sought damages and penalties. The complaint was unsealed on February 8, 2018. On March 7, 2018, the Company reached agreement with the United States Department of Justice to resolve all claims made against it in the action. Under the settlement agreement, the Company will pay a total of approximately $11.4 million to the federal government and the participating state Medicaids, of which approximately $5.3 million plus applicable interest will be paid in four equal quarterly installments, subject to the Company's option to prepay without penalty. In exchange for the payment of the settlement amounts, the United States and the relators agreed to release the Company from certain claims, including civil or administrative monetary relief sought under the complaint. The settlement agreement does not contain or represent an admission of liability or wrongdoing by the Company, and there will be no corporate integrity agreement. For the year ended December 31, 2017, the Company recorded a charge of $11.4 million associated with this settlement in its statements of operations and comprehensive loss. During the year ended December 31, 2018, the Company paid $5.3 million and the required quarterly installments, and the final quarterly installment of $1.4 million was paid in March 2019. See Note 6 under *Other Accrued Liabilities* for more detail on payments made.

Director and Officer Indemnifications

As permitted under Delaware law, and as set forth in the Company's Certificate of Incorporation and its Bylaws, the Company indemnifies its directors, executive officers, other officers, employees and other agents for certain events or occurrences that may arise while in such capacity. The maximum potential amount of future payments the Company could be required to make under this indemnification is unlimited; however, the Company has insurance policies that may limit its exposure and may enable it to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits and other policy provisions, the Company believes any obligations under this indemnification would not be material, other than an initial $1.5 million for securities related claims and $0.3 million for commercial general liability claims. However, no assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case the Company may incur substantial liabilities as a result of these indemnification obligations.

Third-Party Payer Reimbursement Audits

From time to time, the Company receives recoupment requests from third-party payers for alleged overpayments. The Company disagrees with the contentions of pending requests and/or has recorded an estimated reserve for the alleged overpayments.

Contractual Commitments

As of June 30, 2019, the Company has non-cancelable contractual commitments with a supplier for approximately $5.8 million and other material supplier commitments for approximately $4.4 million for inventory material used in the laboratory testing process.

As of June 30, 2019, the Company has a non-cancelable application service agreement with a vendor, in which a license was granted to the Company to utilize the proprietary technology for gene sequencing data analysis. The minimum committed fees remaining under the agreement is $1.3 million, which covers services through March 2020.

As of June 30, 2019, the Company has non-cancelable contractual commitments with a vendor for biological sample processing and storage totaling approximately $0.3 million for the next 9 months.

As of June 30, 2019, the Company has non-cancelable minimum purchase commitments with a supplier of diagnostic reagents totaling approximately $0.4 million through February 2020.

As of June 30, 2019, the Company has remaining non-cancelable commitments to have a minimum number of genetic tests processed by a vendor totaling approximately $2.6 million through December 2019. The term of this vendor agreement expires in December 2020.

As of June 30, 2019, the Company has a remaining non-cancellable minimum purchase commitment with a supplier of gene sequencing reagents and kits, which requires a minimum annual purchase commitments totaling approximately $1.4 million through April 2021.

9. Stock-Based Compensation

2015 Equity Incentive Plan

In June 2015, the Board adopted, and the Company's stockholders approved, the Company's 2015 Equity Incentive Plan (the "2015 Plan"), which, by its terms, took effect as of the Company's IPO on July 2, 2015. The 2015 Plan replaced the Company's 2007 Stock Plan (the "2007 Plan"). No further awards have been granted under the 2007 Plan after July 1, 2015. However, any remaining awards that were outstanding under the 2007 Plan will continue to be governed by the terms of that plan. The Company initially reserved 3,451,495 shares of its common stock for issuance under the 2015 Plan; in addition, the Company authorized the reservation of up to 9,890,310 shares of common stock to cover shares reserved but unissued under the 2007 Plan and shares subject to outstanding awards under the 2007 Plan that expire or lapse unexercised or shares issued under the 2007 Plan that are subsequently reacquired by the Company.

Performance-based Awards

In June 2017, the Board approved a stock option grant of 425,000 shares to the Company's executive chairman, of which 200,000 shares are performance-based options. The vesting of these performance-based options is contingent upon the completion of requisite service for the next three years and the achievement of certain milestones within such time period. The milestones are (i) to successfully secure a specified strategic arrangement, at which point 50,000 shares will begin vesting over one year in equal quarterly installments, (ii) to successfully secure a specified licensing arrangement, at which point 75,000 shares will begin vesting over one year in equal quarterly installments, and (iii) to successfully secure specified licensing arrangements related to oncology, at which point 75,000 shares will begin vesting over one year in equal quarterly installments. Each milestone is independent of the other.

Milestones (i) and (ii) described above have been achieved during the first quarter of 2019 and 2018, respectively. During the three and six months ended June 30, 2019, total stock-based compensation expense recorded for the performance-based options was $0.2 million and $0.2 million, respectively; and during the three and six months ended June 30, 2018, the Company recognized stock-based compensation expense of $0.1 million and $0.3 million, respectively.

In December 2018, the Board approved a performance-based option grant of 600,000 shares to the Company's executive chairman. The vesting of these performance-based options is contingent upon the achievement of a certain milestone, and provided that the completion of requisite service is through the date of such vesting, at which point the performance-based options will become fully vested and exercisable. The revenue milestone was not achieved or was not probable of being achieved during the six months ended June 30, 2019, and the Company did not recognize any stock-based compensation expense associated with it.

In January 2019, the Board approved a stock option grant of 200,000 shares and 100,000 restricted stock units to the Company's chief executive officer, which are performance-based awards with market conditions. Such awards will vest based on the achievement of certain values of the Company's common stock at two separate thresholds within certain periods and are contingent upon the completion of requisite service through the date of such vesting. The Company utilized a Monte Carlo Simulation to determine the grant date fair value of such awards and the period when such award will become probable. The Company recorded approximately $0.2 million of stock-based compensation related to such awards during the three and six months ended June 30, 2019.

Additionally, the Board approved 100,000 restricted stock units each to the Company's chief financial officer and chief operating officer in March 2019. These two awards also have performance and market conditions, which are based on the same stock value performance target as that of the chief executive officer's before such awards vest and are contingent upon the completion of requisite service through the date of such vesting. The Company utilized a Monte Carlo Simulation to determine the grant date fair value of such awards and the period when such award will become probable. The Company recorded approximately $0.4 million of stock-based compensation related to such awards during the three and six months ended June 30, 2019.

Employee Stock Purchase Plan

In the second quarter of 2015, the Company's stockholders approved the 2015 Natera, Inc. Employee Stock Purchase Plan (the "ESPP"), which became effective upon the Company's IPO on July 2, 2015. Under the ESPP, employees may purchase the Company's common stock through payroll deductions at a price equal to 85% of the lower of the fair market values of the stock as of the beginning or the end of six-month offering periods. An employee's payroll deductions under the ESPP are limited to 15% of the employee's compensation and employees may not purchase more than 5,000 shares of stock during any offering period. A participant shall not be granted an option under the ESPP if such option would permit the participant's rights to purchase stock to accrue at a rate that exceeds $25,000 fair market value of stock for each calendar year in which such option is outstanding at any time. The Company has made 893,548 shares available for issuance under the Plan, a number that is automatically increased by the least of (i) 1% of the total number of shares of common stock actually issued and outstanding on the last business day of the prior fiscal year, (ii) 880,000 shares of common stock (subject to certain adjustments pursuant to Subsection (c) below), or (iii) a number of shares of common stock determined by the Board.

The first offering period of 2019 started on November 1, 2018 and ended on April 30, 2019, and 132,177 shares were purchased at the end of the first offering period for total proceeds of $2.1 million. The second offering period of 2019 started on May 1, 2019 and will end on October 31, 2019. As of June 30, 2019, no shares had been purchased in the second offering period.

Stock Options

The following table summarizes option activity for the six months ended June 30, 2019:

(in thousands, except for contractual life and exercise price)	Shares Available for Grant	Outstanding Options: Number of Shares	Outstanding Options: Weighted-Average Exercise Price	Outstanding Options: Weighted-Average Remaining Contractual Life (In years)	Outstanding Options: Aggregate Intrinsic Value
Balance at December 31, 2018	5,431	9,463	$ 7.69	6.91	$ 61,718
Additional shares authorized	2,483	—			
Options granted	(1,697)	1,697	$ 17.94		
Options exercised	—	(1,468)	$ 4.08		
Options forfeited/cancelled	286	(286)	$ 14.10		
Balance at June 30, 2019	6,503	9,406	$ 9.90	7.24	$ 166,273
Exercisable at June 30, 2019		5,028	$ 6.51	5.79	$ 105,948
Vested and expected to vest at June 30, 2019		9,219	$ 9.80	7.19	$ 163,939

Restricted Stock Units

The following table summarizes RSU activity for the six months ended June 30, 2019:

(in thousands, except for grant date fair value)	Shares	Weighted-Average Grant Date Fair Value
Balance at December 31, 2018	1,084	$ 11.72
Granted	1,625	$ 17.70
Vested	(273)	$ 10.24
Canceled/forfeited	(105)	$ 15.86
Balance at June 30, 2019	2,331	$

Stock-Based Compensation Expense

Employee stock-based compensation expense was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods, if actual forfeitures differ from those estimates. Non-employee stock-based compensation expense was not adjusted for estimated forfeitures up until the occurrence of the actual forfeiture of the associated awards.

The following tables present the effect of employee and non-employee stock-based compensation expense on selected statements of operations line items for the three and six months ended June 30, 2019 and 2018.

	Three months ended June 30,					
	2019			2018		
	Employee	Non-Employee	Total	Employee	Non-Employee	Total
	(in thousands)					
Cost of revenues	$ 215	$ 10	$ 225	$ 152	$ 1	$ 153
Research and development	1,264	—	1,264	1,013	—	1,013
Selling, general and administrative	4,226	89	4,315	2,206	(4)	2,202
Total	$ 5,705	$ 99	$ 5,804	$ 3,371	$ (3)	$ 3,368

	Six months ended June 30,					
	2019			2018		
	Employee	Non-Employee	Total	Employee	Non-Employee	Total
	(in thousands)					
Cost of revenues	$ 383	$ 10	$ 393	$ 290	$ 5	$ 295
Research and development	2,157	—	2,157	1,916	—	1,916
Selling, general and administrative	6,873	432	7,305	4,314	(3)	4,311
Total	$ 9,413	$ 442	$ 9,855	$ 6,520	$ 2	$ 6,522

As of June 30, 2019, approximately $43.7 million of unrecognized compensation expense, adjusted for estimated forfeitures, related to unvested option awards and RSUs will be recognized over a weighted-average period of approximately 2.92 years.

Valuation of Stock Option Grants to Employees and Non-employees

Upon the adoption of ASU 2018-07 on January 1, 2019, the fair value of stock options granted to both employees and non-employees is estimated on the grant date using the Black-Scholes option-pricing model except for the performance-based options with a market condition. Prior to January 1, 2019, the Company only estimated the fair value of the stock options granted to its employees on the grant date, while the fair value of its unvested non-employee stock options was remeasured at the end of each reporting period up until their vesting date. The fair value of the stock options is amortized on a straight-line basis over the requisite service period of the awards, which is generally the vesting period.

The Company utilizes Black-Scholes option pricing model when estimating the fair value of stock options. For the three and six months ended June 30, 2019, the following valuation assumptions were applied on both the employee and non-employee options. In the same period of the prior year, the valuation assumptions as follows were only used for stock options granted to employees.

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Expected term (years)	5.30 — 10.00	5.61 — 5.62	5.30 — 10.00	5.24 — 5.62
Expected volatility	42.71 % — 43.49 %	40.77 % — 40.98 %	42.53 % — 43.49 %	40.28 % — 40.98 %
Expected dividend rate	0.00 %	0.00 %	0.00 %	0.00 %
Risk-free interest rate	1.78 % — 2.51 %	2.70 % — 2.86 %	1.78 % — 2.60 %	2.37 % — 2.86 %

For the three and six months ended June 30, 2018, the Company used a different set of Black-Scholes valuation assumptions when estimating the fair value of stock options granted to its non-employees. The fair value was remeasured at the end of each reporting period up until December 31, 2018. The following table summarizes the valuation assumptions used:

	Three months ended June 30, 2018		Six months ended June 30, 2018		
Expected term (years)	2.75		2.72 —	2.75	
Expected volatility	42.03	%	41.48 % —	42.03	%
Expected dividend rate	0.00	%		0.00	%
Risk-free interest rate	2.58	%	2.36 % —	2.58	%

Expected Term: The expected term of options represents the period of time that options are expected to be outstanding. The Company determines its expected term for the employee and non-employee stock options by calculating the average of (1) historical stock options exercise behavior, and (2) the weighted-average of the time-to-vesting and the total contractual life of the options. For stock options granted to non-employees prior to January 1, 2019, the Company estimated the expected term by assessing their historical exercise behavior and length of service and calculated the average of these two components.

Expected Volatility: The Company derived the expected volatility from the average historical volatilities of comparable publicly traded companies in the DNA sequencing, diagnostics, or personalized medicine industries over a period approximately equal to the expected term. When selecting these companies, certain comparable characteristics such as enterprise value and financial leverage were considered. The selected companies also had sufficient historical stock price volatility commensurate with the expected term of the Company's stock options.

Expected Dividend Rate: The Company has not paid and does not anticipate paying any dividends in the near future.

Risk-Free Interest Rate: The risk-free interest rate assumption is based on U.S. Treasury yield in effect at the time of grant for zero coupon U. S. Treasury notes with maturities approximately equal to the expected term.

As of June 30, 2019, total options outstanding include 105,584 shares of option awards that were granted to non-employees, of which 24,721 shares are unvested. Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock option is earned and the services are rendered. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services rendered.

10. Debt

Credit Line Agreement

In September 2015, the Company entered into a credit line with UBS (the "Credit Line") providing for a $50.0 million revolving line of credit that can be drawn down in increments at any time. The Credit Line bears interest at 30-day LIBOR plus 1.10%. The Credit Line is secured by a first priority lien and security interest in the Company's money market and marketable securities held in its managed investment account with UBS. UBS has the right to demand full or partial payment of the Credit Line Obligations and terminate the Credit Line, in its discretion and without cause, at any time.

For the three months ended June 30, 2019 and 2018, the Company recorded interest expense on the Credit Line of $0.5 million and $0.4 million, respectively; and for the six months ended June 30, 2019 and 2018, interest expense on the Credit Line of $0.9 million and $0.7 million was recorded, respectively. Interest payments on the Credit Line were made within the same periods. As of June 30, 2019, remaining accrued interest was $1.1 million, and the total principal amount outstanding with accrued interest was $50.1 million.

2017 Term Loan

In August 2017, the Company entered into the 2017 Term Loan with OrbiMed, which has a maximum borrowing capacity of $100.0 million. On the closing date of August 8, 2017, the Company borrowed $75.0 million, with the remaining $25.0 million available to borrow at the Company's option at any time through December 31, 2018, subject to standard conditions. The amounts borrowed under 2017 Term Loan have and will continue to primarily be used for general corporate purposes and to fund and support the Company's business and operations. Interest is accrued on the outstanding balance of the loan at a rate equal to the sum of (i) 8.75% plus (ii) the higher of 1.00% or LIBOR. The 2017 Term Loan has an eighty-four month term and will mature in August 2024. The Company is required to make interest payments on a quarterly basis, with repayment of the full outstanding balance on the maturity date. The Company's obligations under the 2017 Term Loan are secured by substantially all of its assets, including its intellectual property, subject to certain customary exceptions.

On December 31, 2018, the Company amended certain terms in the 2017 Term Loan with OrbiMed. The amendment increased the existing unused borrowing capacity from $25.0 million to $50.0 million and extended the expiration date for the option to draw the unused capacity to March 31, 2019. If such option were exercised by the Company, the interest rate described above would instead decrease to the sum of (i) 8.50% plus (ii) the higher of 1.00% or LIBOR.

In April 2019, the Company entered into a second amendment on the 2017 Term Loan with OrbiMed to further extend the expiration date until December 31, 2019 to draw the unused borrowing capacity of $50.0 million. The second amendment reduces the interest rate to the sum of (i) 8.25% plus (ii) the higher of 1.00% or LIBOR from previously the sum of (i) 8.50% plus (ii) the higher of 1.00% of LIBOR, provided that a minimum capacity of $25.0 million were drawn. As a fee in consideration of extending the commitment to provide this option to draw until December 31, 2019, the Company issued an additional 25,000 shares of its common stock to OrbiMed as of April 29, 2019. As of June 30, 2019, the Company had not exercised such option.

The 2017 Term Loan contains customary affirmative and negative covenants including financial information maintenance covenants, indebtedness limitation covenants, minimum net revenues covenants, and investment covenants. It also includes standard events of default such as payment defaults and nonperformance of obligations and covenants described above. Upon an event of default, an additional interest of 3.00% may be applied to the outstanding debt balance until such default is cured, and OrbiMed may declare all outstanding obligations immediately due and payable. As of June 30, 2019, the Company was in compliance with all of its covenants under the 2017 Term Loan.

The Company is allowed to voluntarily make prepayments on its outstanding debt balance either partially or in full. When prepayments are made, an additional prepayment premium will be applied to the outstanding principal amount at the time. The prepayment premium will gradually reduce from 12.5% to 2.5% over the term of the loan.

Initially, the Company paid OrbiMed a fee in consideration of providing the 2017 Term Loan by issuing 300,000 shares of its common stock at a fair value of $2.7 million. Following the second amendment on the term loan as described above, an additional 25,000 shares were issued to OrbiMed on April 29, 2019 at a fair value of $0.5 million. The fair value for total fees paid to date was $3.2 million, which is accounted for as a debt discount to be amortized on a straight-line basis over the remaining term of the loan. The Company has classified the cumulative debt discount of $2.0 million as a direct reduction from the outstanding debt balance of $75.0 million, while the remaining $1.2 million is classified as noncurrent assets (as described in Note 6).

For the three months ended June 30, 2019 and 2018, the Company recorded interest expense for the 2017 Term Loan totaling $2.2 million and $2.0 million, respectively, and $4.5 million and $4.0 million for the six months ended June 30, 2019 and 2018, respectively, which also included the amortization of debt discount. Debt discount amortized as interest expense in the statements of operations and comprehensive loss for the three months ended June 30, 2019 and 2018 was $0.1 million in each of the two periods, and $0.2 million in each of the six month period ended June 30, 2019 and 2018. In addition, the Company made interest payments totaling $4.3 million and $4.0 million during the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, the amount of the unamortized debt discount was $1.5 million, and the net carrying amount of the debt was $73.5 million.

11. Warrants

In April 2014, the Company granted approximately 376,691 warrants to purchase common stock with an exercise price of $2.3229 per common share. The warrants were granted to ROS Acquisition Offshore LP ("ROS") in connection with a senior secured term loan that has since been repaid. It was determined that the warrants granted are detachable and therefore are a standalone component of the senior secured term loan to be fair valued using Level III inputs as a separate derivative.

On June 26, 2018, the warrants were fully exercised by ROS using the option of net share settlement. Instead of remitting cash exercise proceeds to purchase the shares, ROS elected to receive a net amount of 332,896 shares. The Company remeasured the fair value of its warrant liability to $6.8 million during this period until June 26, 2018 and reclassified this amount to stockholders' equity.

12. Income Taxes

During the three and six months ended June 30, 2019, the Company recorded total income tax expense of $1.9 million and $2.0 million, respectively. The Company provides testing to clinics and licenses cloud-based software and intellectual property, that are based in a foreign country, which contributed to a foreign income tax expense of approximately $1.9 million and $2.0 million for the three and six months ended June 30, 2019, respectively. In addition, the Company recorded $20,000 in state income tax expense for the three and six months ended June 30, 2019. During the three and six months ended June 30, 2018, the Company recorded total income tax benefit of $0.1 million and $0.2 million, respectively. Total income tax expense included a foreign income tax expense of $65,000 and $0.1 million for the three and six months ended June 30, 2018, respectively. State income tax expense of $48,000 and $92,000 was also recorded during the three and six months ended June 30, 2018, respectively.

Due to the Company's history of cumulative operating losses, the Company concluded that, after considering all the available objective evidence, it is not more likely than not that all of the Company's net deferred tax assets will be realized. Accordingly, all of the Company's deferred tax assets, which includes net operating loss or NOL carryforwards and tax credits related primarily to research and development, continue to be subjected to a valuation allowance as of June 30, 2019. The Company will continue to maintain a full valuation allowance until there is sufficient evidence to support recoverability of its deferred tax assets.

In December 2017, the U.S. Congress passed the Tax Cuts and Jobs Act of 2017 ("Tax Act"). As a result, corporate tax rate was reduced to 21%, effective January 1, 2018. ASC 740, *Income Taxes*, requires entities to recognize the effect of the tax law changes in the period of enactment. Shortly after the enactment of the Tax Act, the Securities and Exchange Commission ("SEC") staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when an entity does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. The Company made provisional adjustments to reduce its deferred tax assets and liabilities as of December 31, 2017, based on the reduction of the U.S. federal corporate tax rate from 34% to 21% and assessed the realizability of its deferred tax assets based on its current understanding of the provisions of the new law. As of December 31, 2018, the Company completed its assessment of the tax rate change and determined no additional adjustments were required.

The Company had $8.1 million and $7.4 million in unrecognized tax benefits at June 30, 2019 and December 31, 2018, respectively. The reversal of the uncertain tax benefits would not affect the effective tax rate to the extent that the Company continues to maintain a full valuation allowance against its deferred tax assets. Unrecognized tax benefits may change during the next twelve months for items that arise in the ordinary course of business.

Interest and/or penalties related to income tax matters are recognized as a component of income tax expense. As of June 30, 2019, there were no accrued interest and penalties related to uncertain tax positions.

13. Net Loss per Share

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, excluding shares subject to repurchase and without consideration of potentially dilutive securities. Diluted net loss per share is computed by giving effect to all potentially dilutive common shares outstanding for the period. For purposes of this computation, outstanding common stock options, restricted stock units and warrants are considered to be common share equivalents. Common share equivalents are excluded from the computation in periods in which they have an anti-dilutive effect, unless the consideration of any one of them gives a dilutive effect.

The following table provides the basic and diluted net loss per share computations for the three and six months ended June 30, 2019 and 2018.

	Three months ended June 30,		Six months ended June 30,	
(in thousands, except per share data)	2019	2018	2019	2018
Numerator:				
Net loss, basic and diluted	$ (32,416)	$ (33,824)	$ (66,507)	$ (66,697)
Denominator:				
Weighted-average number of shares used in computing net loss per share, basic and diluted	68,224	54,551	65,542	54,342
Net loss per share, basic	$ (0.48)	$ (0.62)	$ (1.01)	$ (1.23)
Net loss per share, diluted	$ (0.48)	$ (0.62)	$ (1.01)	$ (1.23)

The following table shows total outstanding potentially dilutive shares excluded from the computation of diluted loss per share as their effect would be anti-dilutive, as of June 30, 2019 and 2018:

	June 30,	
	2019	2018
	(in thousands)	
Options to purchase common stock	9,406	10,255
Restricted stock units	2,331	1,025
Employee stock purchase plan	54	70
	11,791	11,350

14. Subsequent Events

None.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this report.

Overview

We are a growing diagnostics company with proprietary molecular and bioinformatics technology that we are deploying to change the management of genetic disease worldwide. Our goal is to develop and commercialize non- or minimally-invasive tests to evaluate risk for a wide range of genetic conditions, such as Down syndrome, the results of which can enable early detection, diagnosis and treatment. Our technology has been proven clinically and commercially in the prenatal testing space. We have begun translating this success into the liquid biopsy space, where we are leveraging our core expertise to develop products for oncology diagnostic applications, and are also working to develop a transplant rejection test. We seek to enable even wider adoption of our technology through our global cloud-based distribution model. In addition to our direct sales force in the United States, we have a global network of over 100 laboratory distribution partners, including many of the largest international laboratories.

Since 2009, we have launched a comprehensive suite of ten products in women's health and prenatal testing—nine molecular diagnostic tests and a newborn stem cell banking offering to complement our prenatal testing portfolio—and our personalized liquid biopsy technology for oncology diagnostic applications, for research use only by oncology researchers and biopharmaceutical companies. We generate a majority of our revenues from the sale of Panorama, our non-invasive prenatal test, or NIPT, which we commercially launched in March 2013. We launched our microdeletions panel for Panorama in 2014 and our twins, egg donor, and surrogate screening capabilities in 2017. We also generate a significant portion of our revenues from the sale of our Horizon Carrier Screening (HCS) test, which we launched in 2012. We launched our Constellation software platform, which forms the core of our cloud-based distribution model, in May 2015. Our revenues were $74.4 million and $141.2 million for the three and six months ended June 30, 2019, respectively, compared to $63.1 million and $125.4 million for the three and six months ended June 30, 2018, respectively.

We were formed in 2003 under our former name, Gene Security Network. From 2006 through 2013, the National Institutes of Health awarded us cumulative grants of $5.7 million to conduct various research projects including non-invasive aneuploidy screening on circulating fetal cells for prenatal diagnosis. An initial period of research and development was followed by the commercialization of Spectrum Preimplantation Genetic Screening (PGS) in 2009 and Spectrum Preimplantation Genetic Diagnosis (PGD) in 2010; Anora Products of Conception (POC) in 2010; our non-invasive prenatal paternity test in 2011; Horizon Carrier Screen in 2012; Panorama NIPT in 2013; our microdeletions panel for Panorama in 2014; Constellation in 2015; and Evercord™, Vistara, Signatera™ (RUO) and our Panorama twins capability in 2017.

In the six months ended June 30, 2019, we processed most of our tests in our laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, in San Carlos, California. A portion of our HCS and Vistara testing is performed by third-party laboratories. Our customers include independent laboratories, national and regional reference laboratories, medical centers and physician practices for our screening tests; individual patients and families for our Evercord cord blood and tissue service; and research laboratories and pharmaceutical companies for our Signatera (RUO) liquid biopsy technology. We market and sell our prenatal screening tests both through our sales force and those of our laboratory distribution partners. We bill clinics, laboratory distribution partners, patients and insurance payers for the tests we perform. In cases where we bill laboratory distribution partners, our partners in turn bill clinics, patients and insurers. The majority of our revenues comes from insurers. Insurers with which we have in-network contracts reimburse for NIPT procedures based on positive coverage determinations, which means that the insurer has determined that NIPT in general is medically necessary for this category of patient. In the United States, the majority of insurance providers provide positive NIPT coverage. As of June 30, 2019, we have in-network contracts with insurance providers that account for over 209 million commercial covered lives in the United States. A "covered life" means a subscriber, or a dependent of a subscriber, who is insured under an insurance policy with the insurance carrier identified. The number of covered lives represented by insurers that have positive coverage determinations or with which we or our laboratory distribution partners have a contract provides a measure of our access to the healthcare market. Although our target market for NIPT

is a much smaller subset of the total number of covered lives because it excludes subscribers for whom our NIPT would not be performed, such as men, children and post-menopausal women, we believe the number of U.S. covered lives for whom we have access under contract represents an important indicator of our access to the total available market for our products. Insurers may also reimburse for our products through out-of-network claims submission processes in situations where we do not have a contract with that insurer.

The principal focus of our commercial operations currently is to distribute molecular diagnostic tests through both our direct sales force and laboratory distribution partners, and our Constellation licensees under our cloud-based distribution model. The number of tests that we accession is a key indicator that we use to assess our business. A test is accessioned when we receive the test at our laboratory, the relevant information about the test is entered into our computer system and the test sample is routed into the appropriate sample flow. This number is a subset of the number of tests that we process, which includes tests distributed through our Constellation licensees and cord blood and/or cord tissue samples banked. The number of tests that we process is a key metric as it tracks overall volume growth, particularly as our laboratory partners may transition from sending samples to our laboratory to our cloud-based distribution model. During the six months ended June 30, 2019, we processed 394,655 tests, comprised of approximately 368,300 tests accessioned in our laboratory and 23,800 processed through our Constellation software platform, or Constellation units, compared to approximately 327,162 tests processed during the six months ended June 30, 2018, comprised of approximately 306,400 tests accessioned and 19,300 Constellation units. This increase in volume primarily represents continuous commercial growth of Panorama, both as tests performed in our laboratory as well as through our Constellation software platform, and HCS. We accessioned approximately 249,500 Panorama tests during the six months ended June 30, 2019, which represents an increase of approximately 18% over the same period in the prior year. We accessioned approximately 107,400 HCS tests during the six months ended June 30, 2019, which represents an increase of approximately 29% over the same period in the prior year.

Prior to 2016, we experienced rapid growth in our U.S.-based internal sales force as part of our effort to increase the number of tests distributed through our direct sales force, because we generate a higher gross margin when we sell testing services directly. The percent of our revenues attributable to our U.S. direct sales force for the six months ended June 30, 2019 was 82%, up from 80% for the six months ended June 30, 2018. The percent of our revenues attributable to U.S. laboratory distribution partners for the six months ended June 30, 2019 was 5%, flat from 5% in the same period in the prior year. Our ability to increase our revenues and gross profit will depend on our ability to further penetrate the U.S. market with our direct sales force. The percent of our revenues attributable to international laboratory distribution partners and other international sales for the six months ended June 30, 2019 was 13%, down from 15% for the six months ended June 30, 2018, due primarily to the increase in US direct sales as a percentage of revenue.

In addition to distributing molecular diagnostic tests to be performed at our laboratory, either directly or through our laboratory distribution partners, we seek to establish licensing arrangements with laboratories under our cloud-based distribution model, whereby our laboratory licensees run the molecular workflows themselves and then access our bioinformatics algorithms through our cloud-based Constellation software. This cloud-based distribution model results in lower revenues and gross profit per test than in cases where we process a test ourselves; however, because we don't incur the costs of processing the tests, our costs per test under this model are also lower. We began entering into these licensing arrangements starting in the fourth quarter of 2015. We are also a party to a licensing and service arrangement with DNA Diagnostics Center, Inc., or DDC, to enable the development of a non-invasive prenatal paternity test based on our proprietary technology. DDC commercializes this test, and we receive royalty revenues from DDC. We have recognized $1.4 million in revenues from the DDC arrangement in the six months ended June 30, 2019 and 2018. Regarding revenues recognized from our Constellation licensing arrangements, we have recognized $1.3 million and $1.2 million in the six months ended June 30, 2019 and 2018, respectively.

In April 2017, we launched Evercord, a private cord blood and cord tissue processing and storage service. Our U.S. direct sales force sells Evercord to the same OB/GYNs who prescribe and order Panorama and HCS tests, and our own inside sales force offers this product to our existing and past patients who have used our Panorama or HCS tests. Upon the launch of Evercord, we also entered into an agreement with a cord blood bank to perform processing and testing of cord blood and cord tissue units and store those units at its facility. Our Evercord service includes the provision of a collection kit and the collection, processing and storage of newborn cord blood and cord tissue units. Evercord customers pay a one-time fee for the processing of the units. Customers have the option to store their units under an annual plan, or

to pre-pay for 18 years or the duration of their lifetime (for which we assume a useful life of 78 years); they also have the option to pay for storage in full at the time of collection of the unit, or over a period of six, 12, or 18 months.

In May 2017, we launched Vistara, an NIPT that screens for single-gene disorders and offered as a complement to Panorama. Upon the launch of Vistara, we entered into an agreement with a laboratory partner to collaborate in improving test performance and to launch Vistara commercially.

In August 2017, we launched Signatera (RUO), which is a circulating tumor DNA technology that analyzes and tracks mutations specific to an individual's tumor, for research use only by oncology researchers and biopharmaceutical companies.

In October 2017, we expanded our Panorama test to now screen twin pregnancies for zygosity and chromosomal abnormalities.

For the six months ended June 30, 2019, our revenues increased to $141.2 million from $125.4 million in the six months ended June 30, 2018. Panorama revenues accounted for $73.7 million, or 52%, of our revenues for the six months ended June 30, 2019 and $69.0 million, or 55%, of our revenues for the six months ended June 30, 2018. HCS revenues accounted for $47.0 million, or 33%, of our revenues for the six months ended June 30, 2019 and $39.7 million, or 32%, of our revenues for the six months ended June 30, 2018. A significant proportion of our revenues were derived from in-network payer contracts. For the six months ended June 30, 2019 and 2018, there were no customers exceeding 10% of total revenue on an individual basis. Revenues from customers outside of the United States were $18.5 million and $18.4 million for the six months ended June 30, 2019 and 2018, respectively. Most of our revenues have been denominated in U.S. dollars, but we began to generate revenue in foreign currency in 2015, primarily denominated in Euros and Singapore Dollars.

Our net losses for the six months ended June 30, 2019 and 2018, were $66.5 million and $66.7 million, respectively. This included non-cash stock compensation expense of $9.9 million and $6.5 million for the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, we had an accumulated deficit of $640.9 million.

Components of the Results of Operations

Revenues

We generate revenues from the sale of our genetic tests, primarily from the sale of our Panorama and HCS tests. Our two primary distribution channels are our direct sales force and our laboratory partners. In cases where we promote our tests through our direct sales force, we generally bill directly to a patient, clinic or insurance carrier, or a combination of the insurance carrier and patient for the fees.

In cases where we sell our tests through our laboratory partners, the majority of our laboratory partners bill the patient, clinic or insurance carrier for the performance of our tests and we are entitled to either a fixed price per test or a percentage of their collections.

Starting in the fourth quarter of 2015, we began recognizing licensing revenues through the licensing and the provisioning of services to support the use of our proprietary technology by licensees under our cloud-based distribution model. Starting in the second quarter of 2017, we began recognizing revenues from our Evercord offering.

Sales of Panorama, HCS and Vistara tests are recorded as product revenues. Revenues recognized from tests processed through our Constellation software platform, Evercord and Signatera revenues, and revenue recognized from the Qiagen Agreement are reported in licensing and other revenues. As of June 30, 2019, we have commercially launched 15 licensing and service arrangements with laboratories under our cloud-based distribution model from which we recognized revenue from in the three months ended March 31, 2019.

Prior to 2018, we recognized the majority of our revenues from contracts with insurance carriers upon receipt of cash due to limited historical experience and uncertainty in determining the amount of revenue and timing of collections.

Effective January 1, 2018, we adopted the new revenue guidance, Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*, using the full retrospective approach. In accordance with ASC 606, the total consideration we expect to collect from insurance carriers and patients in exchange for the goods and services provided is accrued in the period in which our tests are reported to customers. Due to potential future changes in insurance coverage policies, contractual rates, and other trends in the reimbursement of our tests, our collections may fluctuate significantly over time.

Our ability to increase our revenues will depend on our ability to further penetrate the domestic and international markets and, in particular, generate sales through our direct sales force, develop and commercialize additional tests, obtain reimbursement from additional third-party payers and increase our reimbursement rate for tests performed. In particular, our financial performance depends on reimbursement for Panorama in the average risk population and for microdeletions. The use of Panorama in the average risk population is not yet broadly reimbursed, although many third-party payers have begun to reimburse for this. Many third-party payers do not currently reimburse for microdeletions screening, as further discussed in the risk factor entitled "*Reimbursement and Regulatory Risks Related to Our Business— If we are unable to expand or maintain third-party payer coverage and reimbursement for Panorama and our other tests, or if we are required to refund any reimbursements already received, our revenues and results of operations would be adversely affected*," in part because there is currently limited published data on the performance of microdeletions screening tests. A new current procedure terminology, or CPT, code for microdeletions went into effect beginning January 1, 2017. We have experienced low average reimbursement rates thus far for microdeletions testing under this new code, and we expect that this new code will cause, at least in the near term, our microdeletions reimbursement to remain low, due to third-party payers declining to reimburse and through reduced reimbursement under the new code. This has had, and we expect it will continue to have, an adverse impact on our revenues. In addition, a new CPT code for expanded carrier screening went into effect beginning January 1, 2019, and has had, and may continue to have, an adverse effect on our reimbursement rates for our broader Horizon carrier screening panel for which we previously primarily received reimbursement on a per-condition basis, as those tests may be reimbursed as a combined single panel instead of as multiple individual tests. Because our revenues from Horizon continue to represent an increasing proportion of our overall revenues, a decline in our reimbursement rates for, and therefore our average selling price of, Horizon, could result in a decline in our overall revenue.

Our financial performance is also impacted by our having increased our in-network coverage with third-party payers, which we believe is crucial to our growth and long-term success. However, because the negotiated fees under our contracts with third-party payers are typically lower than the list price of our tests, as we enter into additional in-network contracts with insurance providers, our average reimbursement per test decreases. While we expect the reduction in average reimbursement per test from in-network pricing to reduce our revenues and gross margins in the near term, in-network pricing is more predictable than out-of-network pricing, and we intend to continue to mitigate the impact by driving more business from our most profitable accounts. In addition, our strategy to offer our tests to laboratory licensees via our Constellation cloud-based software platform may also cause our revenues to decrease because we do not process the tests and perform the molecular biology analysis in our own laboratory under this model, and therefore are not able to charge as high an amount, and as a result realize lower revenues, per test than when we perform the entire test ourselves. However, cost of licensing and other revenues for the Constellation software platform are relatively low, and therefore, its associated gross margin is higher.

Cost of Product Revenues

The components of our cost of product revenues are material and service costs, impairment charges associated with testing equipment, personnel costs, including stock-based compensation expense, equipment and infrastructure expenses associated with testing samples, electronic medical records, order and delivery systems, shipping charges to transport samples, costs incurred from outsourcing our tests to third parties, and allocated overhead such as rent, information technology costs, equipment depreciation and utilities. Costs associated with performing tests are recorded when the test is accessioned. We expect cost of product revenues in absolute dollars to increase as the number of tests we perform increases.

However, having rapidly achieved scale, we have increased our focus on more efficient use of labor, automation, and DNA sequencing. For example, we updated the molecular and bioinformatics process for Panorama to further reduce the sequencing reagents, test steps and associated labor costs required to obtain a test result, while increasing the accuracy

of the test to allow it to run with lower fetal fraction input. These improvements also reduced the frequency of the need to require blood redraws from the patient.

Cost of Licensing and Other Revenues

The components of our cost of licensing and other revenues are material costs associated with test kits, engineering costs incurred by our research and development team to improve and maintain our Constellation software platform, and amortization of Constellation software development costs. Cost of licensing and other revenues also include costs associated with Evercord. Such costs are related to collection kits consumed during the processing of cord blood samples, fees paid to our partner for the processing service and storage of the cord blood samples, and freight charged to transport the samples to the storage facility.

We currently have 15 revenue generating licensing and service agreements with laboratories and continue to have active discussions with many other potential licensees under our Constellation distribution model. We consider our cost of licensing and other revenues for the Constellation software platform to be relatively low, and therefore we expect its associated gross margin is higher. While costs associated with licensing arrangements have become steady over time, we expect additional costs associated with Evercord and Signatera to cause cost of licensing and other revenues to increase.

Research and Development

Research and development expenses include costs incurred to develop our technology, collect clinical samples and conduct clinical studies to develop and support our products. These costs consist of personnel costs, including stock-based compensation expense, prototype materials, laboratory supplies, consulting costs, regulatory costs, electronic medical records set up costs, costs associated with setting up and conducting clinical studies at domestic and international sites and allocated overhead, including rent, information technology, equipment depreciation and utilities. We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses to increase in absolute dollars as we continue to invest in research and development activities related to developing enhanced and new products.

Selling, General and Administrative

Selling, general and administrative expenses include executive, selling and marketing, legal, finance and accounting, human resources, billing and client services. These expenses consist of personnel costs, including stock-based compensation expense, direct marketing expenses, audit and legal expenses, consulting costs, training and medical education activities, payer outreach programs and allocated overhead, including rent, information technology, equipment depreciation, and utilities. In 2019, we expect general and administrative expenses to increase due to the planning and implementation of policies and procedures required to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, as well as the associated accounting and audit fees, while expenses incurred from compliance with the rules and regulations of the Securities and Exchange Commission and the Nasdaq Global Select Market, insurance expenses, and investor relations activities remain steady. We expect our selling and marketing related expenses to remain relatively flat.

Interest Expense

Interest expense is attributable to borrowing under our Credit Line and 2017 Term Loan, as well as the amortization of debt discount associated with the 2017 Term Loan.

Interest and Other Income

Interest and other income is from interest earned on our cash, realized gains and losses on investments, foreign currency remeasurement gains and losses, changes in the fair value of our warrants, and finance charges related to the unused borrowing capacity of our 2017 Term Loan.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, 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.

We consider our critical accounting policies and estimates to be revenue recognition, leases, fair value measurements, and stock-based compensation.

On January 1, 2019, we adopted the new accounting requirements under ASC 842 using the modified retrospective approach, which now requires most leases to be recognized as right-of-use assets and corresponding lease liabilities in the balance sheet. Upon adoption, we had three existing leases that were classified as operating leases, and the present value of their minimum future lease payments was determined by discounting the cash flows using the incremental borrowing rate with a term approximating the remaining term of each lease. We elected the optional transitional guidance under ASC 842 that allowed the initial recognition of the operating right-of-use assets and the corresponding lease liabilities as of January 1, 2019 instead of the earliest period presented.

Effective January 1, 2019, we also transitioned to the new accounting requirements under Accounting Standards Update ("ASU") ASU 2018-07 for non-employee stock-based awards using the modified retrospective approach. The new guidance changes the fair value measurement requirements for our non-employee stock-based awards from remeasuring them at the end of each reporting period to a one-time measurement as of the grant date using the Black-Scholes option pricing model, while the method of recognizing the stock-based compensation remains unchanged. Starting January 1, 2019, we have elected to use expected term rather than remaining contractual term when determining the fair value of the non-employee awards, as well as the option to recognize actual forfeitures as they occur. Upon adoption, we recorded a $0.2 million cumulative-effect adjustment to the balance of accumulated deficit in the balance sheet.

Revenue Recognition

Effective January 1, 2018, we adopted the new revenue recognition standard, ASC 606, using the full retrospective approach, which required us to record a cumulative-effect adjustment to accumulated deficit as of the earliest period presented in the financial statements.

We recognize revenues when, or as, performance obligations in the contracts are satisfied, in the amount reflecting the expected consideration to be received from the goods or services transferred to the customers.

Product Revenues

Product revenues are derived from contracts with insurance carriers, laboratory partners and patients in connection with sales of prenatal genetic tests. The majority of our revenues are derived from Panorama NIPT, HCS, and to a lesser extent, other genetic tests. We enter into contracts with insurance carriers with primarily payment terms related to tests provided to the patients who have health insurance coverage. Insurance carriers are considered as third-party payers on behalf of the patients, and the patients are considered as the customers who receive genetic test services. Tests may be billed to insurance carriers, patients, or a combination of insurance carriers and patients. Further, we sell tests to a number of domestic and international laboratory partners and identify the laboratory partners as customers provided that there is a test services agreement between us and them.

A performance obligation represents a promise in a contract to transfer a distinct good or service to a customer, which represents a unit of accounting in accordance with ASC 606. A portion of the consideration should be allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. We

evaluate our contracts with insurance carriers, laboratory partners and patients and identify a single performance obligation in those contracts, which is the delivery of the test results.

The total consideration which we expect to collect in exchange for our products is an estimate and may be fixed or variable. Consideration includes reimbursement from both patients and insurance carriers, adjusted for variable consideration related to disallowed cases, discounts, refunds and doubtful accounts, and is estimated using the expected value approach. For insurance carriers with similar reimbursement characteristics, we use the portfolio of relevant historical data to estimate variable consideration and total collections for our products. We constrain the estimated variable consideration when we assess it is probable that a significant reversal in the amount of cumulative revenue recognized may occur in future periods. The consideration expected from laboratory partners usually includes a fixed amount, but it can be variable depending on the volume of tests performed, and we determine the variable consideration using the expected value approach. For insurance carriers, laboratory partners and patients, we allocate the total consideration to a single performance obligation, which is the delivery of the test results to the customers.

When assessing the total consideration for insurance carriers and patients, a certain percentage of revenues is further constrained for estimated refunds.

We generally bill an insurance carrier, a laboratory partner or a patient upon delivery of test results. We also bill patients directly for out-of-pocket costs involving co-pays and deductibles that they are responsible for. Tests billed to insurance carriers and directly to patients usually take an average of nine to twelve months to collect the payments, and for tests billed to laboratory distribution partners, the average collection cycle takes approximately two to three months. At times, the Company may or may not get reimbursed for the full amount billed. Further, we may not get reimbursed at all for tests performed if such tests are not covered under the insurance carrier's reimbursement policies or we are not a qualified provider to the insurance carrier, or if the tests were not previously authorized.

Product revenue is recognized in an amount that equals the total consideration (as described above) at a point in time when the test results are delivered. We reserve certain amounts in other accrued liabilities on the balance sheet in anticipation of requests for refunds of payments previously made by insurance carriers, which are accounted for as reductions in product revenues in the statement of operations and comprehensive loss. During the three and six months ended June 30, 2019, $0.8 million and $1.3 million were released from amounts previously held in reserves in other accrued liabilities, and $0.9 million and $1.8 million of such reserves were released during the three and six months ended June 30, 2018, respectively. The release of amounts reserved were recognized as product revenue within that period.

Licensing and Other Revenues

We recognize licensing revenues from our Constellation cloud-based distribution model, pursuant to which we grant licenses to laboratories to access our proprietary bioinformatics algorithms through our cloud-based software to analyze the results of molecular workflows that such licensees perform in their laboratories.

We also recognize revenues from our Evercord offering for the processing and storage of newborn cord blood and cord tissue units, Signatera (RUO), and our Qiagen and BGI Agreements.

Results of operations

Comparison of the three months ended June 30, 2019 and 2018

(In thousands except percentage)	Three months ended June 30, 2019	2018	Change Amount	Percent
Revenues				
Product revenues	$ 65,099	$ 60,353	$ 4,746	7.9 %
Licensing and other revenues	9,256	2,716	6,540	240.8
Total revenues	74,355	63,069	11,286	17.9
Cost and expenses				
Cost of product revenues	41,382	39,204	2,178	5.6
Cost of licensing and other revenues	2,443	1,791	652	36.4
Research and development	12,124	11,852	272	2.3
Selling, general and administrative	47,042	37,440	9,602	25.6
Total cost and expenses	102,991	90,287	12,704	14.1
Loss from operations	(28,636)	(27,218)	(1,418)	5.2
Interest expense	(2,721)	(2,560)	(161)	6.3
Interest and other (expense) income, net	836	(3,933)	4,769	(121.3)
Loss before income taxes	(30,521)	(33,711)	3,190	(9.5)
Income tax expense	(1,895)	(113)	(1,782)	1,577.0
Net loss	$ (32,416)	$ (33,824)	$ 1,408	(4.2)%

Revenues

Total revenues are comprised of product revenues, which are primarily driven by sales of our Panorama and HCS tests, and licensing and other revenues, which include primarily licensing of our Constellation software to our licensees and revenues from our Evercord business. Total revenues increased by $11.3 million, or 17.9%, when compared to the three months ended June 30, 2018. Effective January 1, 2018, revenues were reported under the new revenue recognition guidance, ASC 606.

Product Revenues

During the three months ended June 30, 2019, product revenues increased by $4.7 million, or 7.9%, as a result of continued revenue growth in Panorama and HCS tests. Panorama and HCS revenues had a net increase of $0.8 million and $2.9 million, respectively. A portion of the net increase in Panorama and HCS revenues pertained to cumulative catch-up revenue adjustments totaling $0.6 million and $0.4 million recognized in the current period, respectively, due to collections from appeals on claims in the prior periods. Revenues from other tests increased by $1.1 million. The number of Panorama and HCS tests accessioned continued to grow during the three months ended June 30, 2019 when compared to the same period in the prior year, and the resulting growth in revenues was partially offset by an erosion in collection trends driven by factors such as prior authorization requirements by insurance carriers.

Licensing and Other Revenues

Licensing and other revenues increased by $6.5 million, or 241%, during the three months ended June 30, 2019 when compared to the three months ended June 30, 2018. Revenue recognized from the agreement we entered into with BGI was $5.0 million, revenue recognized from our agreement with Qiagen increased by $0.4 million due primarily to recognition of revenue based on completion of performance obligations in the current period compared the same period of the prior year, while revenues from our Evercord business increased by approximately $1.0 million, while revenues associated with our Constellation software licensing arrangements with our licensees and the associated IVD kits were approximately flat.

During the three months ended June 30, 2019, we processed 195,168 tests, comprised of approximately 181,800 tests accessioned and 12,000 Constellation units. Approximately 123,100 Panorama tests and 53,100 HCS tests were accessioned during the three months ended June 30, 2019. During the three months ended June 30, 2018, we processed approximately 162,807 tests, comprised of approximately 152,500 tests accessioned and 9,500 Constellation units. Approximately 105,300 Panorama tests and 41,800 HCS tests were accessioned during the three months ended June 30, 2018.

We derive our revenues from tests based on units reported to customers. All reported units are either accessioned in our laboratory or processed through our Constellation software platform. During the three months ended June 30, 2019, total reported units were approximately 187,600, comprising of approximately 174,800 reported units that were accessioned and 11,500 Constellation units. Within this period, we recognized revenues on approximately 118,500 Panorama tests accessioned and 9,800 Panorama Constellation units, and approximately 51,700 HCS tests accessioned. During the three months ended June 30, 2018, total reported units were approximately 155,100, comprising of approximately 145,900 reported units that were accessioned and 9,200 Constellation units. Within this period, we recognized revenues on approximately 103,200 Panorama tests accessioned and 7,600 Panorama Constellation units, and approximately 38,700 HCS tests accessioned.

Revenues from customers outside of the United States were $12.0 million and $6.3 million for the three months ended June 30, 2019 and 2018, respectively.

Cost of Product Revenues

During the three months ended June 30, 2019, cost of product revenues increased by $2.2 million, or 5.6%, when compared to the three months ended June 30, 2018 primarily due to higher labor and overhead of approximately $3.2 million were allocated to product costs for support activities on both Panorama and HCS automation workflows. Furthermore, we recorded higher costs related to inventory consumption of $0.8 million primarily driven by increase in billable cases, offset by a net decrease of $1.8 million of cost savings as we performed work that had previously been performed by third party vendors.

Cost of Licensing and Other Revenues

Cost of licensing and other revenues for the three months ended June 30, 2019, when compared to the three months ended June 30, 2018, increased by $0.7 million, or 36.4%. During the three months ended June 30, 2019, the increase in licensing costs was due primarily to increased volumes of materials and processing costs for our Evercord cord blood services and Signatera.

Research and Development

Research and development expenses during the three months ended June 30, 2019 increased by $0.3 million, or 2.3%, when compared to the three months ended June 30, 2018. The increases were primarily driven by increases in salary and consulting related expenditures.

Selling, General and Administrative

Selling, general and administrative expenses increased by $9.6 million, or 25.6%, in the three months ended June 30, 2019 compared to the three months ended June 30, 2018. The increase in selling, general and administrative expenses was primarily attributable to higher salaries and related expenses of $4.5 million resulting from the combined effect of headcount growth, bonuses and commissions, merit salary increases and stock-based compensation for additional stock awards to employees; higher outside service costs of $2.9 million in connection with legal fees paid to outside litigation counsel, higher travel related expenses of $0.3 million incurred from sales and marketing events, and higher corporate related expenses of $2.0 million associated with increased collection efforts by our third-party vendors and fees charged to customers paying for our tests on credit, offset partially by a net decrease in other marketing related activities and office related expenses of $0.1 million.

Interest Expense

Interest expense increased by $0.2 million in the three months ended June 30, 2019 compared to the same period in the prior year. The increase was primarily the result of the change in Libor rate in connection with our 2017 Term Loan.

Interest and Other Income

Interest and other income was $0.8 million for the three months ended June 30, 2019, compared to interest and other expense of $3.9 million in the same period of the prior year, an increase of $4.7 million. This increase in interest and other income was the result of the higher balance maintained in our investment portfolio in the second quarter of 2019 due to proceeds from the Company's equity offering which closed in April 2019, and a $4.0 million charge in the second quarter of 2018 from the revaluation of the warrants to ROS upon exercise.

Comparison of the six months ended June 30, 2019 and 2018

	Six Months Ended June 30,		Change	
	2019	2018	Amount	Percent
(In thousands except percentage)				
Revenues:				
Product revenues	$ 128,463	$ 114,622	$ 13,841	12.1 %
Licensing and other revenues	12,716	10,787	1,929	17.9
Total revenues	141,179	125,409	15,770	12.6
Cost and expenses:				
Cost of product revenues	82,987	78,259	4,728	6.0
Cost of licensing and other revenues	4,141	3,328	813	24.4
Research and development	23,559	26,192	(2,633)	(10.1)
Selling, general and administrative	90,874	75,365	15,509	20.6
Total cost and expenses	201,561	183,144	18,417	10.1
Loss from operations	(60,382)	(57,735)	(2,647)	4.6
Interest expense	(5,445)	(4,949)	(496)	10.0
Interest and other (expense) income, net	1,289	(3,796)	5,085	(134.0)
Loss before income taxes	(64,538)	(66,480)	1,942	(2.9)
Income tax expense	(1,969)	(217)	(1,752)	807.4
Net loss	$ (66,507)	$ (66,697)	$ 190	(0.3)%

Revenues

Total revenues are comprised of product revenues, which are primarily driven by sales of our Panorama and HCS tests, and licensing and other revenues, which include primarily licensing of our Constellation software to our licensees and revenues from our Evercord business. Total revenues increased by 15.8 million, or 12.6%, when compared to the six months ended June 30, 2018. Effective January 1, 2018, revenues were reported under the new revenue recognition guidance, ASC 606.

Product Revenues

During the six months ended June 30, 2019, product revenues increased by $13.8 million, or 12%, when compared to the six months ended June 30, 2018, as a result of continued revenue growth in Panorama and HCS tests. Panorama and HCS revenues had a net increase of $4.7 million and $7.3 million, respectively. A portion of the net increase in Panorama and HCS revenues pertained to cumulative catch-up revenue adjustments totaling $1.1 million and $0.8 million recognized in the current period, respectively, due to collections from appeals on claims in the prior periods. Revenues from other tests increased by $1.8 million. The number of Panorama and HCS tests accessioned continued to grow during the six months ended June 30, 2019 when compared to the same period in the prior year, and the resulting growth in revenues

was partially offset by an erosion in collection trends driven by factors such as prior authorization requirements by insurance carriers.

Licensing and Other Revenues

Licensing and other revenues increased by $1.9 million, or 18%, during the six months ended June 30, 2019 when compared to the six months ended June 30, 2018. Revenue recognized from the collaboration agreement we entered into with BGI was $5.0 million and revenues from our Evercord business increased $1.6 million, along with nominal revenue increases in our Signatera tests, and Constellation software licensing arrangements and the associated IVD kits; while revenues from the Qiagen agreement decreased by $4.9 million due to a one-time revenue recognition from the transfer of our technology license in the same period of the prior year.

During the six months ended June 30, 2019, we processed 394,655 tests, comprised of approximately 368,300 tests accessioned and 23,800 Constellation units. Approximately 249,500 Panorama tests and 107,400 HCS tests were accessioned during the six months ended June 30, 2019. During the six months ended June 30, 2018, we processed approximately 327,162 tests, comprised of approximately 306,400 tests accessioned and 19,300 Constellation units. Approximately 212,100 Panorama tests and 83,300 HCS tests were accessioned during the three months ended June 30, 2018.

We derive our revenues from tests based on units reported to customers. All reported units are either accessioned in our laboratory or processed through our Constellation software platform. During the six months ended June 30, 2019, total reported units were approximately 373,400, comprising of approximately 348,200 reported units that were accessioned and 22,800 Constellation units. Within this period, we recognized revenues on approximately 238,000 Panorama tests accessioned and 19,300 Panorama Constellation units, and approximately 101,500 HCS tests accessioned. During the six months ended June 30, 2018, total reported units were approximately 302,300, comprising of approximately 283,800 reported units that were accessioned and 18,500 Constellation units. Within this period, we recognized revenues on approximately 200,200 Panorama tests accessioned and 15,100 Panorama Constellation units, and approximately 75,900 HCS tests accessioned.

Revenues from customers outside of the United States were $18.5 million and $18.3 million for the six months ended June 30, 2019 and 2018, respectively.

Cost of Product Revenues

During the six months ended June 30, 2019, cost of product revenues increased by $4.7 million, or 6.0%, when compared to the six months ended June 30, 2018 primarily due to higher overhead of approximately $1.9 million allocated to product costs for support activities on both Panorama and HCS automation workflows. In addition, we experienced an increase in volume of tests processed, which resulted in an increase in direct material costs of $1.6 million, with the majority of materials consumed by our in-house HCS automation workflow, and higher labor and consulting services increased by $1.2 million primarily driven by the increase of billable units.

Cost of Licensing and Other Revenues

Cost of licensing and other revenues, when compared to the six months ended June 30, 2018, increased by $0.8 million, or 24.4%. During the six months ended June 30, 2019, the increase in licensing costs was due primarily to increased volumes of materials and processing costs for our Evercord cord blood services and Signatera.

Research and Development

Research and development expenses during the six months ended June 30, 2019 decreased by $2.6 million, or 10.1%, when compared to the six months ended June 30, 2018. The decrease was primarily driven by performance of work that had previously been performed by third party vendors, shifting $1.5 million of expenses to cost of product and license revenues. In addition, an impairment charge of $1.6 million was recorded in the six months ended June 30, 2018 for certain

project development costs that were subsequently written off, and no such costs were recorded in the six months ended June 30, 2019. This was offset by increased expenses in clinical trials of $0.5 million and other expenses.

Selling, General and Administrative

Selling, general and administrative expenses increased by $15.5 million, or 20.6%, in the six months ended June 30, 2019 compared to the six months ended June 30, 2018. The increase in selling, general and administrative expenses was primarily attributable to higher salaries and related expenses of $8.0 million resulting from the combined effect of headcount growth in sales and marketing offset partially by a reduction in general and administration resulting from moving certain billing functions to a third party vendor, bonuses and commissions, merit salary increases and stock-based compensation for additional stock awards to employees; higher outside service costs of $3.7 million primarily in connection with legal fees paid to outside litigation counsel, higher travel related expenses of $0.5 million incurred from sales and marketing events, expenses associated with increased third party billing and collection efforts by our third-party vendors and fees charged to customers paying for our tests on credit of $2.4 million, and higher corporate related and office expenses of $1.4 million, offset partially by a decrease in marketing and communication related activities of $0.5 million.

Interest Expense

Interest expense increased by $0.5 million in the six months ended June 30, 2019 compared to the same period in the prior year. The increase was the combined result of $0.3 million of interest incurred in connection with our 2017 Term Loan, and $0.2 million of interest charged at the variable interest rate on the Credit Line, primarily related to a change in LIBOR rate.

Interest and Other Income

Interest and other income was $1.3 million for the six months ended June 30, 2019, compared to interest and other expenses of $3.8 million in the same period of the prior year, an increase of $5.9 million. This increase in interest income was the result of the higher balance maintained in our investment portfolio in the second quarter of 2019, and a $4.0 million charge in the second quarter of 2018 from the revaluation of the warrants to ROS upon exercise.

Liquidity and Capital Resources

We have incurred net losses each year since our inception. For the six months ended June 30, 2019, we had a net loss of $66.5 million, and we expect to continue to incur losses in future periods as we continue to devote a substantial portion of our resources to our research and development and commercialization efforts for our existing and new products. As of June 30, 2019, we had an accumulated deficit of $640.9 million. We had $30.0 million in cash and cash equivalents, $208.1 million in marketable securities, $50.1 million of outstanding balance of the Credit Line including accrued interest, and $73.5 million of net carrying amount of the 2017 Term Loan.

While we have introduced multiple products that are generating revenues, these revenues have not been sufficient to fund all operations. Accordingly, we have funded the portion of operating costs that exceeds revenues through a combination of equity issuances and debt and other financings. We expect to develop and commercialize future products and, consequently, we will need to generate additional revenues to achieve future profitability and may need to raise additional equity or incur additional debt. If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders and requires significant debt service payments, which diverts resources from other activities. Additional financing may not be available at all, or in amounts or on terms acceptable to us. If we are unable to obtain additional financing, we may be required to delay the development and commercialization of our products and significantly scale back our business and operations.

On April 23, 2019, we completed an underwritten equity offering to sell 5,263,158 shares of our common stock at a price to the public of $19 per share. On April 26, we sold an additional 789,473 shares of our common stock to the underwriters at the same price upon their exercise of the option to purchase those shares. Before offering expenses of $0.5 million, we received proceeds of $108.1 million net of underwriting discount.

Based on our current business plan, we believe that our existing cash and marketable securities will be sufficient to meet our anticipated cash requirements for at least 12 months after August 8, 2019.

Credit Line Agreement

In September 2015, we entered into the Credit Line with UBS providing for a $50.0 million revolving line of credit that can be drawn down in increments at any time. The Credit Line currently bears interest at 30-day LIBOR plus 1.10%. The Credit Line is secured by a first priority lien and security interest in our money market and marketable securities accounts held in our managed investment account with UBS. UBS has the right to demand full or partial payment of the Credit Line obligations and terminate the Credit Line, in its discretion and without cause, at any time.

For the three months ended June 30, 2019 and 2018, we recorded interest expense of $0.5 million and $0.4 million, respectively; and $0.9 million and $0.7 million for the six months ended June 30, 2019 and June 30, 2018, respectively. Interest payments on the Credit Line were made within the same periods. As of June 30, 2019, remaining accrued interest was $1.1 million, and the total principal amount outstanding with accrued interest was $50.1 million.

2017 Term Loan

In August 2017, we entered into the 2017 Term Loan with OrbiMed, which has a maximum borrowing capacity of $100.0 million. On the closing date of August 8, 2017, we borrowed $75.0 million, with the remaining $25.0 million available for borrowing at our option at any time through December 31, 2018, subject to standard conditions. The amounts borrowed under the 2017 Term Loan are primarily being used for general corporate purposes and to fund and support our business and operations. Interest is accrued on the outstanding balance of the loan at a rate equal to the sum of (i) 8.75% plus (ii) the higher of 1.00% or LIBOR. The 2017 Term Loan has an 84 month term and will mature in August 2024. We are required to make interest payments over the term of the loan, with repayment of the full outstanding balance on the maturity date. Our obligations under the 2017 Term Loan are secured by substantially all of our assets, including our intellectual property, subject to certain customary exceptions.

On December 31, 2018, we amended certain terms in the 2017 Term Loan with OrbiMed. The amendment increased the existing unused borrowing capacity from $25.0 million to $50.0 million and extended the expiration date for the option to draw the unused capacity to March 31, 2019. If such option were exercised by us, the interest rate described above would instead decrease to the sum of (i) 8.50% plus (ii) the higher of 1.00% or LIBOR.

In April 2019, we entered into a second amendment of the 2017 Term Loan with OrbiMed to further extend the expiration date until December 31, 2019 to draw the unused borrowing capacity of $50.0 million. The second amendment reduced the interest rate to the sum of (i) 8.25% plus (ii) the higher of 1.00% or LIBOR from the prior sum of (i) 8.50% plus (ii) the higher of 1.00% of LIBOR, provided we draw the minimum capacity of $25.0 million. As a fee in consideration of extending the commitment to provide this option to draw until December 31, 2019, we issued an additional 25,000 shares of its common stock to OrbiMed as of April 29, 2019. As of June 30, 2019, the we did not exercise such option.

For the three months ended June 30, 2019 and 2018, we recorded interest expense totaling $2.2 million and $2.0 million, respectively, and $4.5 million and $4.0 million for the six months ended June 30, 2019 and 2018, respectively, which also included the amortization of debt discount. In addition, we made interest payments totaling $4.3 million and $4.0 million during the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, the amount of unamortized debt discount was $1.5 million, and the net carrying amount of the debt was $73.5 million.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Six Months Ended June 30,	
	2019	2018
(Amounts in thousands)		(As Revised)
Cash (used in) provided by operating activities	$ (35,751)	$ (34,497)
Cash provided by investing activities	(100,995)	33,684
Cash provided by financing activities	115,725	6,052
Net (decrease) increase in cash, cash equivalents and restricted cash	(21,021)	5,239
Cash, cash equivalents and restricted cash, beginning of period	51,004	13,021
Cash, cash equivalents and restricted cash, end of period	$ 29,983	$ 18,260

Cash Used in Operating Activities

Cash used in operating activities during the six months ended June 30, 2019 was $35.8 million. The net loss of $66.5 million includes $18.4 million in non-cash charges resulting from $4.0 million of depreciation and amortization, $3.8 million of amortization of the operating right-of-use assets on a straight-line basis subsequent to the adoption of ASC 842, $9.9 million of stock-based compensation expense; amortization of debt discount, premium amortization and discount accretion on investment securities totaling $0.4 million, $0.2 million of inventory excess adjustments, and $0.1 million in other non-cash charges. Operating assets had $16.6 million cash outflow resulting from $0.8 million increases in accounts receivable, $1.8 million increases in inventory, $4.5 million increases in prepaid and other current assets, $9.5 million increases in other assets. Operating liabilities generated cash inflows of $28.9 million due to an increase of deferred revenues of $35.5 million primarily driven by prepaid license, royalties and one milestone payment from BGI, and an increase in other accrued liabilities by $2.3 million, offset by a decrease in accounts payable of $6.4 million and a decrease in accrued compensation of $2.5 million.

Cash used in operating activities during the six months ended June 30, 2018 was $34.5 million. The net loss of $66.7 million includes $16.5 million in non-cash benefits resulting from $6.5 million of stock-based compensation expense, $4.1 million of remeasurement loss on the change in the fair value of our warrant liability, $3.7 million of depreciation and amortization, an impairment charge of $1.5 million recorded to write off the project development costs previously capitalized following our decision to terminate a cell-free DNA extraction automation project, $0.3 million of premium amortization and discount accretion on investment securities, $0.2 million of amortization of debt discount in connection

with our 2017 Term Loan, and $0.2 million of inventory excess adjustments. Operating assets generated cash outflows of $14.3 million primarily due to a $12.8 million increase in accounts receivable and a $3.5 million increase in inventory, offset by a $1.6 million reduction in prepaid expenses and other current assets and a $0.4 million decrease in other assets. Operating liabilities generated cash inflows of $30.0 million due to an increase in deferred revenue of $35.9 million primarily driven by prepaid sales-based royalties and performance obligations not yet delivered to Qiagen, offset by decreases in deferred rent of $0.3 million, other accrued liabilities of $3.8 million, accrued compensation of $1.0 million and accounts payable of $0.8 million.

Cash Used in Investing Activities

Cash used in investing activities for the six months ended June 30, 2019 totaled $101.0 million, which was comprised of purchasing new investments of $162.2 million, acquisitions of property, plant and equipment of $1.6 million, offset by $62.8 million in proceeds resulting from maturities of investments.

Cash provided by investing activities for the six months ended June 30, 2018 totaled $33.7 million, which was comprised of $55.5 million in proceeds resulting from sales and maturities of investments, offset by purchases of investments of $20.6 million and acquisitions of property and equipment of $1.2 million.

Cash Provided by Financing Activities

Cash provided by financing activities for the six months ended June 30, 2019 and 2018 totaled $115.7 million and $6.1 million, respectively. The cash proceeds were primarily comprised $107.6 million net of underwriting discount and issuance costs from the equity offering completed in the second quarter of 2019. The remainder were comprised of proceeds from exercise of stock options and shares purchased from the employee stock purchase plan.

Contractual Obligations and Other Commitments

Except as follows, there were no material changes outside of the ordinary course of business in our contractual obligations from those as of December 31, 2018.

In April 2019, we entered into a two year contractual agreement with a supplier of gene sequencing reagents and kits, which requires a minimum annual purchase commitment through April 2021 totaling approximately $1.4 million.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

JOBS Act Accounting Election

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. Our Credit Line has an interest rate of one-month LIBOR plus 1.10%. The LIBOR rate is variable. Our 2017 Term Loan has an interest rate of three-month variable LIBOR plus 8.75%. An incremental change in the borrowing rate of 100

basis points would increase our annual interest expense by $1.3 million based on our $125.2 million gross debt outstanding, including principal and accrued interest as of June 30, 2019. Our investment portfolio is exposed to market risk from changes in interest rates. This risk is mitigated as we have maintained a relatively short average maturity for our investment portfolio. An incremental change in the borrowing rate of 100 basis points would increase our annual interest income by approximately $2.1 million annually in relation to amounts we would expect to earn, based on our short-term investments as of June 30, 2019.

Foreign Currency Exchange Rate Fluctuations

Our operations are currently conducted primarily in the United States. As we expand internationally, our results of operations and cash flows may become subject to fluctuations due to changes in foreign currency exchange rates. In periods when the U.S. dollar declines in value as compared to the foreign currencies in which we incur expenses, our foreign-currency based expenses will increase when translated into U.S. dollars. In addition, future fluctuations in the value of the U.S. dollar may affect the price at which we sell our tests outside of the United States. To date, our foreign currency risk has been minimal, and we have not historically hedged our foreign currency risk; however, we may consider doing so in the future.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2019. The term "disclosure controls and procedures," as defined in Rule 13a-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Based on the evaluation of our disclosure controls and procedures as of June 30, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the six months ended June 30, 2019, we implemented certain internal controls in connection with our adoption of ASC 842. There were no other changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The

design of any system of controls is also 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; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are involved in legal proceedings. The results of such legal proceedings and claims cannot be predicted with certainty, and regardless of the outcome, legal proceedings could have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors.

For information regarding certain current legal proceedings, see "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Unaudited Interim Condensed Consolidated Financial Statements, which is incorporated herein by reference.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information contained in this report, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our condensed consolidated financial statements and related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any unfavorable events or circumstances actually occurs, our business may suffer, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to Our Business and Industry

We derive most of our revenues from Panorama, and if our efforts to further increase the use and adoption of Panorama or to develop new products and services in the future do not succeed, our business will be harmed.

For the three months ended June 30, 2019 and the year ended December 31, 2018, 49% and 55%, respectively, of our revenues were derived from sales of our Panorama NIPT. Although we are growing our revenues from other products, in particular our Horizon carrier screen, we expect to continue to derive a significant portion of our revenues from the sales of Panorama. Continued and additional market demand for Panorama, and reimbursement for the average risk population and for microdeletions, are key elements to our future success. The market demand for NIPTs has grown in recent periods and is evolving, but this market trend may not continue or, even if it does continue, physicians may not recommend and order Panorama, and our laboratory distribution partners and licensees may not actively or effectively market Panorama.

Our ability to increase sales and establish significant levels of adoption and reimbursement for Panorama is uncertain, and it may be challenging for us to achieve profitability for many reasons, including, among others:

- the NIPT market may not grow as we expect, and NIPTs may not gain acceptance for use in the average-risk pregnancy population or as a screen for microdeletions, which would limit the market for Panorama, and we may fail to compete successfully in this market, whatever size;
- if we are unable to demonstrate that Panorama is superior to competing NIPTs, laboratories, clinics, clinicians, physicians, payers and patients may not adopt use of Panorama on a broad basis, and may not be willing to pay the price premium over other NIPTs that we have, to date, been able to achieve;
- third-party payers, such as commercial insurance companies and government insurance programs, may decide not to reimburse for Panorama, may not reimburse for uses of Panorama for the average-risk pregnancy population or for the screening of microdeletions, or may set the amounts of such reimbursements at prices that do not allow us to cover our expenses; in fact, many third-party payers currently have negative coverage determinations or otherwise do not reimburse for average-risk patient populations or for microdeletions screening and we expect low reimbursement rates for microdeletions screening to continue, at least in the near term; also, most state Medicaid programs currently either reimburse at low rates or do not reimburse for our tests;
- third-party payers have increasingly required that prior authorization be obtained prior to conducting genetic testing as a condition to reimbursing for it, which has reduced and/or delayed the reimbursement amounts we receive for Panorama or our other tests, which has impacted our results of operations since the fourth quarter of 2017, when these requirements began to take effect;
- the results of our clinical trials and any additional clinical and economic utility data that we may develop, present and publish or that comes from the commercial use of Panorama may be inconsistent with prior data, may raise questions about the performance of Panorama, or may fail to convince laboratories, clinics, clinicians, physicians, payers or patients of the value of Panorama; furthermore, we may be unable to

achieve stable reimbursement for microdeletions unless and until sufficient validation data on the sensitivity and specificity of our test for these conditions becomes available, which may take longer than we anticipate;

- we may experience supply constraints, including those due to the failure of our key suppliers to provide required sequencers and reagents in sufficient amounts or of adequate quality or disputes with our key suppliers, including those with respect to the required sequencers and reagents from our supplier, Illumina, Inc., or Illumina, who is also one of our main NIPT competitors through its subsidiary, Verinata Health Inc., or Verinata, and with whom we are currently involved in patent litigation as further described in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Consolidated Financial Statements;
- we may experience increased cost of product revenues, and cost of licensing and other revenues, as a percentage of total revenues, as has been the case in previous fiscal years;
- the U.S. Food and Drug Administration, or the FDA, or other U.S. or foreign regulatory or legislative bodies may adopt new regulations or policies, or take other actions that impose significant restrictions on our ability to market and sell Panorama or our other tests, including requiring FDA clearance or approval for the sale of Panorama or of the sequencers, reagents, kits and other consumable products that we purchase from third parties in order to perform our testing;
- our laboratory partners may choose to develop their own tests that are competitive with ours or offer tests provided by our competitors due to pricing or other reasons as has happened in the past, or otherwise fail to effectively market Panorama; and competitors may develop and commercialize more effective and/or less expensive tests that deliver comparable results as our tests;
- we may fail to adequately protect or enforce our intellectual property relating to Panorama, leading to increased competition; or other parties may claim that the practice of our technology by us or our licensees and collaborators infringes such other party's intellectual property rights, as Illumina has done in a lawsuit that it has filed against us, as discussed further in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Consolidated Financial Statements; if we are required to pay license fees in order to license third-party intellectual property rights due to actual or alleged infringement based on our running Panorama, we may experience increased costs in running Panorama, and we may be unable to pass such costs on to our customers;
- we may be unable to dedicate adequate resources to the maintenance and further technological advancement of Panorama that are necessary for Panorama to be competitive in the marketplace because of the demands placed on our research and development and product teams with respect to our other products and programs, including our Horizon carrier screen product, our Signatera cancer screening offering, our Evercord cord blood banking service, and our Prospera transplant rejection test;
- in the event that it is in our commercial or financial interest or we are forced to transition sequencing platforms for Panorama, we may be unable to do so in a commercially sustainable way and that could survive claims of infringement of intellectual property rights of Illumina and other competitors, in a timely manner or at all; and
- we may not be successful in commercializing our cloud-based distribution model.

If the market for Panorama or our market share fail to grow or grow more slowly than expected, our business, operating results and financial condition will be harmed.

We have incurred losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future, which could harm our future business prospects.

We have incurred net losses each year since our inception in 2003. To date, we have financed our operations primarily through private placements of preferred stock, convertible debt and other debt instruments, our initial public offering, and our recent public equity offering. Our net loss for the three months ended June 30, 2019 and 2018 was, respectively, $32.4 million and $33.8 million. As of June 30, 2019 and December 31, 2018, we had an accumulated

deficit of $640.9 million and $574.6 million, respectively. Such losses may continue to increase in the future as we continue to devote a substantial portion of our resources to efforts to increase adoption of, and reimbursement for, Panorama and our other products, improve these products, and research and develop and commercialize new products, an increasing proportion of which are in industries that are new to us, including oncology and transplant rejection.

In addition, the rate of growth in our revenues has generally been negative, low or flat in recent periods, and this trend may continue in future periods, including if the rate of growth of our test volumes slows. In particular, a significant element of our business strategy is to maintain increased in-network coverage with third-party payers; however, the negotiated fees under our contracts with third-party payers are typically lower than the list price of our tests, and in some cases the third-party payers that we contract with have negative coverage determinations for some of our offerings, in particular Panorama for the average-risk pregnancy population and for microdeletions screening. Therefore, being in-network with third-party payers has had, and may continue to have, an adverse impact on our revenues especially if we are unable to increase adoption of, and obtain favorable coverage determinations for reimbursement for, our products. Furthermore, a CPT code for microdeletions went into effect beginning January 1, 2017. We have experienced low average reimbursement rates for microdeletions testing under this code, and we expect that this code will continue to cause our microdeletions reimbursement to remain low, at least in the near term, either due to reduced reimbursement, or third-party payers declining to reimburse, under the microdeletions code, which has had and will likely continue to have an adverse effect on our revenues. In addition, a new CPT code for expanded carrier screening went into effect beginning January 1, 2019, and has had, and may continue to have, an adverse effect on our reimbursement rates for our broader Horizon carrier screening panel, for which we previously primarily received reimbursement on a per-condition basis, as those tests may be reimbursed as a combined single panel instead of as multiple individual tests.

As further discussed in the risk factor entitled "—*We may not be successful in commercializing our cloud-based distribution model*," our results of operations may be adversely affected if we do not sell a sufficient volume of tests under our cloud-based distribution model to offset the lower revenues per test performed under that model. As a result of our limited operating history, our ability to forecast our future operating results, including revenues, cash flows and profitability, is limited and subject to a number of uncertainties. We have also encountered and will continue to encounter risks and uncertainties frequently experienced by growing companies in the life sciences and technology industry, such as those described in this report. If our assumptions regarding these risks and uncertainties are incorrect or these risks and uncertainties change due to changes in our markets, or if we do not address these risks successfully, our operating and financial results may differ materially from our expectations, and our business may suffer.

Uncertainty in the development and commercialization of our enhanced or new tests or services could materially adversely affect our business, financial condition and results of operations.

Our success will depend in part on our ability to effectively introduce enhanced or new offerings. We continue to focus our research and development efforts on prenatal products, and have recently expanded our platform and are applying our expertise in processing and analyzing cell-free DNA in the fields of cancer diagnostics and transplant rejection. In recent years we have launched several new products or enhanced versions of existing products, including our first offering in oncology, and we expect to continue our efforts in all of these areas. The development and launch of enhanced or new tests requires the completion of certain clinical development and commercialization activities that are complex, costly, time-intensive and uncertain, and requires us to accurately anticipate patients', clinicians' and payers' attitudes and needs and emerging technology and industry trends. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals.

We have limited experience developing and commercializing cell-free DNA tests outside of the prenatal testing space, and we may not be successful in our current or future efforts to do so. We also have limited experience forecasting our future financial performance from our new products, including non-NIPT types of cell-free DNA tests, and our actual results may fall below our financial guidance or other projections, or the expectations of analysts or investors, which could cause the price of our common stock to decline. We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new tests and result in increased costs and the diversion of management's attention and resources from other business matters, such as from our Panorama and Horizon product offerings, which currently represent the significant majority of our revenues.

For example, any tests that we may enhance or develop may not prove to be clinically effective in clinical trials or commercially, or may not meet our desired target product profile, be offered at acceptable cost and with the sensitivity, specificity and other test performance metrics necessary to address the relevant clinical need or commercial opportunity; our test performance in commercial experience may be inconsistent with our validation or other clinical data; we may not be successful in achieving market awareness and demand, whether through our own sales and marketing operations or entering into collaborative arrangements; the collaborative arrangements we enter into may not be successful; healthcare providers may not order or use, or third-party payers may not reimburse for, any tests that we may enhance or develop; or we may otherwise have to abandon a test or service in which we have invested substantial resources. In particular, we are subject to the risk that the biological characteristics of the genetic mutations we seek to target, and upon which our technologies rely, are uncertain and difficult to predict. For example, in our efforts to detect and analyze circulating tumor DNA in plasma for cancer screening, our success depends on tumors shedding mutant DNA into the bloodstream in sufficient quantities such that our technology can detect such mutations. As further discussed in the risk factor entitled "*If our products do not perform as expected, our operating results, reputation and business will suffer*," we may also experience unforeseen difficulties when implementing updates to our processes, as we have occasionally experienced with Panorama and with Horizon, for which we launched a new workflow in 2018.

We cannot assure you that we can successfully complete the clinical development of any new or enhanced product, or that we can establish or maintain the collaborative relationships that may be essential to our clinical development and commercialization efforts. Clinical development requires large numbers of patient specimens and, for certain products, may require large, prospective, and controlled clinical trials. We may not be able to enroll patients or collect a sufficient number of appropriate specimens in a timely manner; or we may experience delays during clinical development due to slower than anticipated enrollment, which we experienced in the past with our SNP-based Microdeletions and Aneuploidy RegisTry (SMART) study, or due to changes in study design or other unforeseen circumstances, such as our decision to expand our SMART study to include a larger number of patients; or we may be unable to afford or manage the large-sized clinical trials that some of our planned future products may require. The data collected from any studies we complete may not be favorable or consistent with our existing data or may not be statistically significant or compelling to the medical community or to third-party payers seeking such data for purposes of determining coverage for our tests. This is particularly true with respect to testing in the average-risk pregnancy population and for microdeletions screening using our Panorama test. For example, in January 2017 we published data from our DNAFirst study showing that NIPT can be effectively and appropriately offered as a primary screen for all pregnant women regardless of risk due to maternal age or other factors; however, it remains uncertain whether or to what extent it will impact coverage or adoption of Panorama in the average-risk population.

The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for tests such as ours, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any test that is the subject of a study. Peer-reviewed publications regarding our tests may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from, clinical studies, as well as delays in the review, acceptance and publication process. If our tests or the technology underlying our current tests or future tests do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption of our tests and positive reimbursement coverage determinations for our tests could be negatively affected.

In addition, as further described in the risk factor entitled "*—If the FDA were to begin actively regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval and incur costs associated with complying with post-market controls,*" development of the data necessary to obtain regulatory clearance and approval of a test is time-consuming and carries with it the risk of not yielding the desired results. The performance achieved in published studies may not be repeated in later studies that may be required to obtain FDA premarket clearance or approval or regulatory approvals in foreign jurisdictions. Limited results from earlier-stage verification studies may not predict results from studies in larger numbers of subjects drawn from more diverse populations over longer periods of time. Unfavorable results from ongoing preclinical and clinical studies could result in delays, modifications or abandonment of ongoing analytical or future clinical studies, or abandonment of a product development program, or may delay, limit or prevent regulatory approvals or clearances or commercialization of our product candidates, which could have a material adverse effect on our business, operating results or financial condition.

These and other factors beyond our control could result in delays or other difficulties in the research and development, approval, production, launch, marketing or distribution of enhanced or new tests and could adversely affect our competitive position and results of operations.

Our quarterly results may fluctuate significantly, which could adversely impact the value of our common stock.

Our quarterly results of operations, including our revenues, gross margin, net loss and cash flows, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, our quarterly results should not be relied upon as an indication of future performance. Our quarterly results may fluctuate as a result of a variety of factors, many of which are outside of our control. Factors that may cause fluctuations in our quarterly results include, without limitation, those listed elsewhere in this "Risk Factors" section. In addition, our quarterly results have historically fluctuated because we generally recognize costs as they are incurred, but, prior to 2018, recorded most revenue only upon receipt of payment, and as a result typically experienced a delay in the related revenue recognition. However, beginning in 2018, we transitioned to accrual accounting in accordance with ASC 606 issued by the Financial Accounting Standards Board, as further described in "Note 2—Summary of Significant Accounting Policies—Recent Accounting Pronouncements—New Accounting Pronouncements Not Yet Adopted" in the Notes to Consolidated Financial Statements. In addition, to the extent that we continue to spend considerably on our internal sales and marketing and research and development efforts, we expect to incur costs in advance of achieving the anticipated benefits of such efforts. Fluctuations in quarterly results and key metrics may cause those results to fall below our financial guidance or other projections, or the expectations of analysts or investors, which could cause the price of our common stock to decline. We also face competitive pricing and reimbursement pressures, and we may not be able to maintain our premium pricing in the future, which would adversely affect our operating results.

If we are unable to compete successfully with respect to our current or future products or services, we may be unable to increase or sustain our revenues or achieve profitability.

We compete primarily in the molecular testing field, which is characterized by rapid technological changes, frequent new product introductions, reimbursement challenges, emerging competition, evolving industry standards, intellectual property disputes, price competition, aggressive marketing practices and changing customer preferences. Our principal competition in prenatal testing comes from existing testing methods, technologies and products that are used by OB/GYNs, MFM specialists or IVF centers. These include other NIPTs and carrier screening tests offered by our competitors, as well as established, traditional first-line prenatal screening methods, such as serum protein measurement, where doctors measure certain hormones in the blood, and invasive prenatal diagnostic tests like amniocentesis, which have been used for many years and are therefore difficult to displace or supplement. In addition, new testing methods may be developed which may displace or be preferred over NIPTs, such as whole genome sequencing or single cell analysis. We are new to the fields of cord blood and tissue banking, cancer diagnostics and transplant rejection, and face competition in all of these business areas from other companies, many of which are larger, more established and have more experience and more resources than we do. Some of our competitors in the liquid biopsy field, in which clinical cancer diagnostic tests examine blood samples rather than solid tumor samples, are expanding their research and development efforts to include screening for other biomarkers instead of, or in addition to, ctDNA, on the basis that analyzing multiple biomarkers may result in improved sensitivity, lower costs and earlier detection than ctDNA-based tests such as ours. We cannot assure you that research, discoveries or other advancements by other companies will not render our existing or potential products and services uneconomical or result in products and services that are superior or otherwise preferable to our current or future products and services.

We compete with numerous companies in the genetic diagnostics space. Our primary competitors in NIPT include Sequenom, which was recently acquired by LabCorp; Illumina, through its subsidiary Verinata; Ariosa, a subsidiary of Roche; Myriad Genetics, Inc., which has acquired Counsyl, Inc.; Bio-Reference, a business unit of OKPO Health, Inc.; Quest; Premaitha Health PLC; BGI; and Progenity. All of our main NIPT competitors in the United States are owned or controlled by companies much larger than ours and with much greater resources for sales, marketing and research and development efforts. Our primary competitors in carrier screening include LabCorp; Myriad Genetics, Inc.; Good Start Genetics, Inc., which has been acquired by Invitae Corp.; Progenity; Quest; Recombine Inc.; and GenPath Diagnostics, a business unit of Bio-Reference. In cord blood and tissue banking, we compete with companies such as

Cord Blood Registry; ViaCord, a division of PerkinElmer, Inc.; Cryo-Cell International, Inc.; LifeBankUSA; Americord Registry LLC; and StemCyte USA. In the field of cancer diagnostics through liquid biopsy tests, which are the same type of cancer diagnostic tests as Signatera, we face competition from various companies that offer or seek to offer competing solutions, such as Roche Molecular Systems Inc. and Foundation Medicine, Inc., both subsidiaries of Roche; Guardant Health, Inc., Adaptive Biotechnologies, Personal Genome Diagnostics, Inc.; Genomic Health Inc.; and ArcherDX, Inc. In the field of transplant rejection, we face competition from various companies that offer or seek to offer competing solutions, such as CareDx, Inc. We expect that the number of competitors in these spaces will continue to increase.

Some of our competitors' products and services are sold at a lower price than ours, which could cause sales of our tests and services to decline or force us to reduce our prices. Our current and future competitors could have greater technological, financial, reputational and market access advantages than us, and we may not be able to compete effectively against them. Increased competition is likely to result in pricing pressures, which could harm our revenues, operating income or market share. We are increasingly subject to litigation from our competitors; for example, as disclosed elsewhere in this report, we are in active litigation with both Illumina and CareDx. If we are unable to compete successfully, we may be unable to increase or sustain our revenues or achieve profitability.

We may not be successful in commercializing our cloud-based distribution model.

We utilize a cloud-based distribution model to deploy our bioinformatics technology for use by other laboratories. Under this model, clinical laboratories around the world, including in the U.S., license our technology to develop and run their own NIPT or other molecular testing assays in their own facilities, and then access our proprietary algorithms through our cloud-based Constellation software to analyze the assay results. In the diagnostics industry, the market for cloud-based solutions and services is not as mature as the market for on-premise enterprise software, and it remains uncertain whether and to what extent our cloud-based distribution model will achieve and sustain high levels of customer demand and market acceptance. As of May 1, 2019, only 14 licensees are using Constellation commercially to market NIPT products, and one licensee is using Constellation commercially to market its non-invasive prenatal paternity test in the United States and internationally. The rate of adoption of our cloud-based distribution model continues to be slower than we anticipated, and depends on a number of factors, including the cost, performance and perceived value associated with our solution, as well as our ability to address security, privacy and regulatory requirements or concerns. In particular, all of our licensees under our cloud-based distribution model are required to use Illumina sequencers and reagents to run their tests that they develop based on our technology. As further described in the risk factor entitled "*—We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers*," we are aware that Illumina has required our licensees to pay an additional license fee in certain jurisdictions in order to secure a supply agreement for the sequencers and reagents necessary to run NIPT under our cloud-based distribution model. Furthermore, Illumina competes with us through its subsidiary Verinata, and may not charge a similar license fee for Verinata's licensed-based offering to other laboratories. As a result, our potential or current licensees may be unable to commercially launch their tests under our cloud-based distribution model in a financially viable manner, which has dissuaded and could continue to dissuade potential or current licensees from licensing from us or launching a test based on our technology.

We also do not know whether, over the long term, this model will result in benefits or cost savings at the levels that we anticipate or at all. For example, to the extent that any of our laboratory customers for whom we currently perform our tests entirely in our laboratory transition to our cloud-based distribution model, our revenues from such customers will decrease because we are not able to charge as high an amount per test as when we perform the entire test ourselves. If the lower revenues per test performed is not offset by a sufficient increase in volume of tests sold, our overall revenues will be lower, and our results of operations may be adversely affected.

Among the risks to our business and results of operations from our Constellation model are the following:

- our and our licensees' ability to obtain required regulatory authorizations from the FDA and international regulatory agencies as further described in the risk factor entitled "*Reimbursement and Regulatory Risks Related to Our Business—Failure to obtain necessary regulatory approvals may adversely affect our*

ability to expand our operations internationally, including our ability to continue commercializing our cloud-based distribution model";

- supply constraints, including with respect to the blood collection tubes that are used for our Panorama test and that are supplied by Streck, Inc., as further described in the risk factor entitled "*—We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers*";
- allegations or potential third-party claims that the tests, based on our technology, developed by our licensees violate such third parties' intellectual property rights in the territories in which our licensees commercialize their tests;
- licensing portions of our proprietary technology to third parties that may not take the same security precautions as we do to protect this information; and
- an inability to achieve anticipated benefits and costs savings.

If we or other cloud-based solution providers experience security incidents, loss of customer data or disruptions in delivery or other problems, the market for cloud-based solutions in the diagnostics industry, including our solutions, may be adversely affected. Such events could also result in potential lawsuits and liability claims, which could have a material adverse effect on our business. If there is a reduction in demand for cloud-based solutions caused by technological challenges, weakening economic conditions, security or privacy concerns, competing technologies and products or other challenges, we may not be successful in executing our Constellation business model, and our results of operations may be adversely affected.

We may be subject to increased compliance risks as a result of our rapid growth, including our dependence on our sales, marketing and billing efforts.

Approximately 79.2% and 83% of our revenues for the three months ended June 30, 2019 and the year ended December 31, 2018, respectively, were attributable to our U.S. direct sales. We have had to expand our training and compliance efforts in line with our increasing reliance on personnel in our sales, marketing and billing functions; we continue to monitor our personnel, but we have in the past experienced, and may in the future experience, situations in which employees fail to strictly adhere to our policies. In addition, sales and marketing activities in the healthcare space are subject to various rules and regulations, as described in the risk factor entitled "*—Reimbursement and Regulatory Risks Related to Our Business—If we or our laboratory distribution partners, consultants or commercial partners act in a manner that violates healthcare fraud and abuse laws or otherwise engage in misconduct, we may be subject to civil or criminal penalties*"; moreover, our billing and marketing messaging can be complex and nuanced, and there may be errors or misunderstandings in our employees' communication of such messaging. Furthermore, we utilize text messaging, email, phone calls and other similar methods to communicate with patients who are existing or potential users of our products for various business purposes. These activities subject us to laws and regulations relating to communications with consumers, such as the CAN-SPAM Act and the Telephone Consumer Protection Act, violations of which could subject us to claims by consumers, who may seek actual or statutory damages, which could be material in the aggregate. As described further in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Consolidated Financial Statements, a purported class action lawsuit was recently filed against us, alleging that we sent an unauthorized text message to a plaintiff's cellular telephone. As we continue to scale up our sales and marketing efforts in line with the growth in our business, in particular our increased pace of product launches as well as further geographical expansion—for example our agreement with a transplant diagnostics company to co-market our Prospera kidney transplant rejection test in conjunction with our direct sales force—we face an increased need to continuously monitor and improve our policies, processes and procedures to maintain compliance with a growing number and variety of laws and regulations, including with respect to consumer marketing. To the extent that there is any violation, whether actual, perceived or alleged, of our policies or applicable laws and regulations, we may incur additional training and compliance costs, may receive inquiries from third-party payers or other third parties, or be held liable or otherwise responsible for such acts of non-compliance. Any of the foregoing could adversely affect our cash flow and financial condition.

We rely on internal and third-party data centers and platforms to host our laboratory and cloud-based software, and any interruptions of service or failures may impair our laboratory operations or the delivery of our cloud-based services and harm our business.

We currently maintain a data center at our laboratory facilities in San Carlos, California. In addition, our proprietary bioinformatics algorithms are a crucial component of our test processing, and combine information derived from our mmPCR assay workflows with publicly available data from the broader scientific community to analyze and return test results. We host the significant majority of these algorithms on a cloud-based software platform pursuant to an agreement with DNAnexus, Inc., or DNAnexus, and both we and our Constellation licensees access our algorithms through the DNAnexus platform. The DNAnexus platform is hosted on third-party data center hosting facilities operated by Amazon Web Services, or AWS, located in the United States and in the European Union. These algorithms cannot currently be run other than through the DNAnexus platform; they are currently used to run our Panorama NIPT and NIPT analysis for our Constellation licensees, as well as Horizon, Signatera, and certain of our research and development activities, and we plan to utilize the platform for additional applications in the future, including our Prospera transplant rejection test. In the event of any technical problems that may arise in connection with our on-site data center, the DNAnexus platform, or the AWS servers on which the DNAnexus platform is hosted, or difficulties in or termination of our relationship with DNAnexus, we could experience interruptions in our laboratory operations or our cloud-based services, and we and our Constellation licensees may be unable to access our proprietary algorithms and therefore be unable to process tests or conduct any other activities that require access to such algorithms. We do not have any backup platform, server or other means to host our algorithms, and may be unable to find and implement an alternative platform that is satisfactory for our needs on commercially reasonable terms, in a timely manner, or at all. These types of problems may be caused by a variety of factors, including infrastructure changes, human or software errors, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. Interruptions in our operations or service may reduce our revenue, cause us to issue refunds, result in the loss of customers, cause laboratory licensees to terminate their contracts with us, adversely affect our ability to attract new laboratory licensees, or harm our reputation. We could also be exposed to potential lawsuits and liability claims.

If our products do not perform as expected, our operating results, reputation and business will suffer.

Our success depends on the market's confidence that we can provide reliable, high-quality testing results, in the prenatal space as well as in cancer diagnostics and transplant rejection. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our test volumes increase and our product portfolio expands. We believe that our customers are particularly sensitive to test limitations and errors, including inaccurate test results and the need on occasion to perform second blood draws, or redraws, on patients, for which Panorama experiences a higher rate than advertised for other NIPTs. As a result, if our tests do not perform as expected or favorably in comparison to competitive tests, our operating results, reputation, and business will suffer. We may be subject to legal claims arising from such limitations, errors, or inaccuracies.

Panorama, Horizon and our other products use a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. An operational, technological or other failure in one of these complex processes or fluctuations in external variables may result in sensitivity or specificity rates that are lower than we anticipate or that vary between test runs, a higher than anticipated number of tests that require redraws or fail to produce results, or longer than expected turnaround times, which we have experienced and will likely continue to experience on occasion as a result of issues with laboratory equipment, components or materials or otherwise. In addition, we regularly evaluate and refine our testing process, as we recently did in implementing significant updates to our Horizon workflow. Any refinements we make to our testing processes may not improve our tests as we expect and may result in unanticipated issues that may adversely affect our test performance as described above. For example, we experienced longer than expected turnaround times following the implementation of our updated Horizon workflow in 2018. Such operational, technical and other difficulties adversely affect test performance, may impact the commercial attractiveness of our products, and may increase our costs or divert our resources, including management's time and attention, from other projects and priorities. Furthermore, any changes to our testing process may require us to use new or different suppliers or materials with whom or which we are unfamiliar, and which may not perform as we anticipate.

In addition, as further discussed in the risk factor entitled "*If we are unable to successfully grow revenues for our current or future products or services in addition to Panorama, our business and results of operations may be adversely affected*," we only recently launched our Evercord service, which is in a market in which we previously had no experience; we also recently launched our Vistara NIPT and our Signatera liquid biopsy test. Any failure to meet consumer expectations could harm our reputation.

We rely on third-party laboratories to perform portions of our service offerings.

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

We may not have sufficient alternative backup if one or more of the third-party laboratories that we contract with are unable to satisfy their obligations to us with sufficient performance, quality and timeliness. In particular, we do not have a backup laboratory for our Panorama, Vistara, Signatera or Evercord offerings. Any natural or other disaster, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at one or more of our third-party laboratories' facilities that causes a loss of capacity would heighten the risks that we face. Changes to or termination of our agreements or inability to renew our agreements with these third-party laboratories or enter into new agreements with other laboratories that are able to perform such portions of our service offerings could impair, delay or suspend our efforts to market and sell these tests and services. In addition, certain third-party payers, including some state Medicaid payers, that we are under contract with may take the position that sending out testing to third-party laboratories and billing for such tests is contrary to the terms of our provider agreement and may refuse to pay us for the testing. If any of these events occur, our business, financial condition and results of operations could suffer. Further, some state laws impose anti-markup restrictions that prevent an entity from realizing a profit margin on outsourced testing. If we or our subsidiaries are unable to markup outsourced testing, our revenues and operating margins may suffer.

If we are unable to successfully grow revenues for our products or services in addition to Panorama, our business and results of operations may be adversely affected.

Our ability to successfully grow revenues for products or services in addition to Panorama, such as Horizon, Spectrum, Anora, Vistara, Evercord, Signatera or Prospera, is uncertain and is subject to many of the risks we face with respect to Panorama. For example, the adoption and demand for such products or services may not grow as we expect; we may not be able to demonstrate that such products or services are equivalent to or superior to competing products or services; third-party payers may not reimburse for our tests, or may set the amounts of such reimbursements at prices that do not allow us to cover our expenses; we may fail to compete successfully in the relevant product markets, or our laboratory distribution partners may choose to more actively or exclusively market tests by competitors; we may experience supply constraints; and we may fail to adequately protect our intellectual property relating to our products or others may claim we infringe their intellectual property rights, which has occurred, as disclosed elsewhere in these Risk factors, with respect to active litigation with Illumina regarding Panorama and with CareDx regarding Prospera. In

particular, because our revenues from Horizon continue to represent an increasing proportion of our overall revenues, any adverse impact we experience with respect to Horizon could result in an impact to our overall revenues, or a component of such overall revenues; for example, a decline in our reimbursement rates for, and therefore our average selling price of, Horizon, could result in a decline in our overall blended average selling price. If we are not able to increase adoption of and grow revenues for these products or services, our business and results of operations may be adversely affected.

We launched our Evercord cord blood and cord tissue banking service in April 2017; our Vistara single-gene mutations screening test in May 2017; our Signatera (RUO) recurrence monitoring liquid biopsy offering for research use in August 2017; our twin pregnancies screening capability for Panorama in October 2017; our Signatera CLIA test in 2019; and we began to focus research, development and commercialization efforts on our planned Prospera transplant rejection test in 2018. Our success with these offerings is subject to many of the risks affecting our business generally, as well as the inherent difficulty associated with launching a new offering, including risks inherent in launching multiple new offerings simultaneously. Moreover, our Evercord offering is in an industry that is new to us and that includes competitors who have been operating for many years. We may face unforeseen difficulties in a number of areas, including with Bloodworks Northwest, or Bloodworks, which is our partner providing the processing and storage services, and storage facility, for this offering; our other suppliers and service providers; our and Bloodworks' ability to maintain required regulatory registrations from the FDA or accreditations from AABB; or disruption of our business and distraction of our employees and management, as described in the risk factor entitled "*If we are unable to successfully scale our operations, our business could suffer*." Our Signatera offering and our planned Prospera test, while based upon molecular diagnostic technology, are in fields that are new to us; and Vistara is subject to the risks inherent in commercializing a product with a laboratory partner. We have had to review and, in some cases, revise our processes, procedures and agreements with our business partners to address unforeseen operational issues and other contingencies, and will likely continue to do so as these areas of our business grow. We cannot assure you that our Evercord, Vistara, Signatera or Prospera offerings will be successful.

If our sole CLIA-certified laboratory facility becomes inoperable, we will be unable to perform our tests and our business will be harmed.

We do not currently have redundant commercial laboratory facilities, other than third-party laboratories that we employ to perform a significant portion of our Horizon carrier screen testing, our Vistara single-gene mutations testing, and the processing and storage of cord blood and cord tissue for our Evercord offering. While we are in the process of scaling up our laboratory facility in Austin, Texas to support continued growth in our Panorama and Horizon tests, we currently have no backup or redundant facility to perform our main product and source of revenue, Panorama, which we perform at our San Carlos, California laboratory facility. In addition, our Signatera test is currently performed at this facility, and we also plan to perform our Prospera test, once commercially launched, at this facility; we expect that our efforts in oncology and transplant rejection will represent significant areas of focus for us, both operationally and financially, in the near term. This laboratory facility is situated near active earthquake fault lines. Our facility may be harmed or rendered inoperable, or samples could be damaged or destroyed, by natural or manmade disasters, including earthquakes, flooding, power outages and contamination, 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 of tests that could develop if our facility is inoperable for even a short period of time may result in the loss of customers or harm our reputation.

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

We have sourced and will continue to source components of our technology, including sequencers, reagents, tubes and other laboratory materials, from third parties. In particular, our sequencers, many of our reagents, including for Panorama and Signatera as described below, as well as those that are required to run our recently updated Horizon workflow, and our blood collection tubes, are sole sourced.

For example, our molecular diagnostics tests are currently only validated to perform on Illumina's sequencing platform; in addition, Illumina is currently the sole supplier of our sequencers and related reagents for Panorama and Signatera and for our development activities relating to oncology diagnostics, along with certain hardware and software,

pursuant to a supply agreement that expires in June 2026. Without sequencers and the related reagents, we would be unable to run our tests and commercialize our products. In addition, all of the licensees under our cloud-based distribution model do not have alternatives other than to use Illumina sequencers and reagents to run the tests that they develop based on our technology. In addition, Illumina and Sequenom, which has been acquired by LabCorp, have entered into a patent pooling agreement pursuant to which both parties have pooled their intellectual property directed to NIPT. We understand from public filings that under the patent pooling agreement, Illumina has the exclusive worldwide rights to, among other things, license third-party laboratories to develop and sell NIPTs utilizing the pooled intellectual property and to enforce the pooled intellectual property against suspected infringers. Under our supply agreement with Illumina, we do not have an express license to the pooled intellectual property for running our own tests or to grant rights under the pooled intellectual property to the licensees under our cloud-based distribution model. We are aware that Illumina has required our licensees, in order to secure a supply agreement for the sequencers and reagents necessary to run NIPT under our cloud-based distribution model, to pay an additional fee for a license under the pooled intellectual property in jurisdictions in which Illumina believes certain of the pooled intellectual property is enforceable. This additional fee has dissuaded and could continue to dissuade potential or current licensees from licensing from us or launching a test based on our technology. In addition, Illumina has filed a patent infringement lawsuit against us, as further described in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Consolidated Financial Statements, alleging that our performance of part of our Panorama test infringes one of the patents in the patent pool. While we believe that our commercialization of Panorama in the United States does not infringe any valid patents included in the pooled intellectual property, we cannot be certain as to the outcome of this lawsuit, including based on further claims that could be brought during the course of the litigation, and the costs and distraction to management of defending against this lawsuit could be significant. In addition, Illumina directly competes with us in the NIPT market through its subsidiary, Verinata. We understand Illumina supplies the same or similar sequencers and consumables to Verinata. Because of Illumina's ownership of Verinata, we face increased risk and uncertainty regarding continuity of a successful working relationship with Illumina under our supply agreement, as well as in our ability to compete with Verinata in the marketplace in view of economic advantages enjoyed by Verinata with respect to the cost of sequencers and related consumables. Our failure to maintain a continued supply of the sequencers and reagents, along with the right to use certain hardware and software, would adversely impact our business, financial condition, and results of operations. In particular, while we are seeking to validate our tests on additional sequencing platforms, such as under our license, distribution and development agreement with Qiagen LLC, or Qiagen, and under our license agreement with BGI Genomics Co., Ltd., or BGI Genomics, we have not, to date, validated any alternative sequencing platform on which our testing could be run in a commercially viable manner. These efforts will require significant resources, expenditures and time and attention of management, and there is no guarantee that we will be successful in implementing any such sequencing platforms in a commercially sustainable way. We also cannot guarantee that we will appropriately prioritize or select alternative sequencing platforms on which to focus our efforts, in particular given our limited product and research and development resources and various business initiatives, which could result in increased costs and delayed timelines or otherwise impact our business and results of operations.

In addition, our Panorama test is currently only validated to be performed using Streck, Inc., or Streck's, blood collection tubes, and Streck is the sole supplier of the blood collection tubes included in our Panorama test under a supply arrangement with Streck under which we are required to exclusively use Streck tubes. Similarly, all of the licensees under our cloud-based distribution model also have no current alternative but to use these blood collection tubes to run the tests that they develop based on our technology. Furthermore, the blood collection tubes supplied by Streck are intended for research use only and are labeled as RUO. Our sequencers, sourced from Illumina, as well as certain other reagents we use for Panorama and our other tests, are also labeled as RUO. As discussed further in the risk factor entitled *"Reimbursement and Regulatory Risks Related to Our Business—Changes in the way the FDA regulates the reagents, other consumables, and testing equipment we use when developing, validating, and performing our tests could result in delay or additional expense in bringing our tests to market or performing such tests for our customers,*" the FDA may determine that a product labeled RUO is, nonetheless, intended to be used diagnostically, and could take enforcement action against the supplier of the product. If this were to occur with respect to Streck, Illumina or any of our other suppliers of RUO products, we could be required to obtain one or more alternative sources of these products, and we may not be able to do so on commercially reasonable terms or at all. In addition, Streck's blood collection tubes have not been registered as a medical device in all countries in which we market our Panorama test. As discussed in the risk factor entitled "*Reimbursement and Regulatory Risks Related to Our Business— Failure to obtain necessary regulatory approvals may adversely affect our ability to expand our operations internationally, including our ability to continue*

commercializing our cloud-based distribution model," the regulatory authorities in some of these countries may determine that such registration is required, which could impact our ability to offer Panorama in such countries. Furthermore, because our licensees under our cloud-based distribution model also exclusively use such sole-sourced components to run the tests they develop based on our technology, and our laboratory distribution partners must use certain of such sole-sourced components in order to utilize our tests, any enforcement action against the supplier by the FDA or any other regulatory authority in the jurisdictions in which our licensees and laboratory distribution partners are located could have an adverse impact on our business.

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

In the event of any adverse developments with our sole suppliers, or if any of our sole suppliers modifies any of the components they supply to us, our ability to supply our products may be interrupted, and obtaining substitute components could be difficult or require us to re-design or re-validate our products. In addition, if we obtain FDA clearance, approval or authorization for any of our tests as an in vitro diagnostic, or IVD, such issues with suppliers or the components that we source from suppliers could affect our commercialization efforts for such an IVD, as further described in the risk factor entitled "*Reimbursement and Regulatory Risks Related to Our Business—If the FDA were to begin actively regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval and incur costs associated with complying with post-market controls.*" Our failure to maintain a continued supply of components, or a supply that meets our quality control requirements, or changes to or termination of our agreements or inability to renew our agreements with these parties or enter into new agreements with other suppliers, particularly in the case of sole suppliers such as Streck and Illumina, could result in the loss of access to important components of our tests and impact our test performance or affect our ability to perform our tests in a timely manner or at all, which could impair, delay or suspend our commercialization activities. In the event that we transition to a new supplier from any of our sole suppliers, doing so could be time-consuming and expensive, may result in interruptions in our ability to supply our products to the market, could affect the performance of our tests or could require that we re-validate Panorama and our other tests using replacement equipment and supplies, which could delay the performance of our tests and result in increased costs. Any of these occurrences could have a material adverse effect on our business, financial condition and results of operations.

We rely on commercial courier delivery services to transport samples to our facilities in a timely and cost-efficient manner and if these delivery services are disrupted, our business will be harmed.

Our core business depends on our ability to quickly and reliably deliver test results to our customers. We typically receive blood samples for analysis at our San Carlos, California facility within days of collection from the patient. Likewise, we rely on courier services to transport cord blood and tissue samples to Bloodworks' facility in which the samples are processed and stored. Disruptions in delivery service, whether due to error by the courier service, labor disruptions, bad weather, natural disaster, terrorist acts or threats or for other reasons, could adversely affect specimen integrity, our ability to process or store samples in a timely manner and to service our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services on commercially reasonable terms, our operating results may be adversely affected.

Security breaches, loss of data and other disruptions, including with respect to cybersecurity, 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 reputation.

In the ordinary course of our business, we collect and store sensitive data, including legally-protected personal information, such as test results and other patient health information, credit card and other financial information, insurance information, and personally identifiable information. We also store sensitive intellectual property and other proprietary business information, including that of our customers, payers and collaboration partners. 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. 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 are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit, and store this critical information. We also communicate sensitive data, including patient data, telephonically, through our website, through facsimile, through integrations with third party electronic medical records systems, and through relationships with third party vendors and their subcontractors, both in the United States and internationally. The laws of some foreign countries do not protect data privacy to the same extent as the laws of the United States.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy. Although we take measures to protect sensitive information from unauthorized access, use or disclosure, our information technology and infrastructure, and that of our technology and other third party service providers and their subcontractors, may nevertheless be vulnerable to cyber-attacks by hackers or viruses or breaches due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our data security, and the information we store could be inaccessible by us or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure, modification, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, European data privacy regulations, such as the General Data Protection Regulation, or GDPR, and regulatory penalties. We may be required to comply with state breach notification laws, become subject to mandatory corrective action, or be required to verify the correctness of database contents. Several states in which we operate, including the State of California, have proposed laws or regulations that will further regulate our collection and storage of data. Failure to comply with these new laws or regulations could result in legal claims or proceedings. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, develop and commercialize tests, collect, process and prepare company financial information, provide information about our tests, and manage the administrative aspects of our business, any of which could damage our reputation and adversely affect our business. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may compound these adverse consequences. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

For example, in May 2019, we were notified of a data security incident that compromised the computer systems of Retrieval-Masters Creditors Bureau, Inc. d/b/a American Medical Collection Agency, or AMCA, one of our third party vendors, and affected a limited number of our patients whose data was stored in AMCA's systems. While the accessed data did not include Social Security numbers, the credit card information of a small number of the patients was compromised. We have notified the affected individuals as required by HIPAA.

Our cloud-based distribution model adds additional data privacy risk, as certain personal health and other information may be sent to and stored in the cloud by our laboratory licensees, many of which are located outside of the United States. We contractually prohibit our licensees from sending personally identifiable information to our cloud servers, and the vendor that hosts our software in the cloud is contractually required to comply with data privacy laws, such as HIPAA and GDPR. However, we cannot be certain that these third parties will comply with the terms of our agreements, nor that they will not experience security breaches or other disruptions.

Damage to or loss of our Evercord customers' cord blood and cord tissue samples held in our custody could potentially result in significant legal liability and harm our reputation.

Our reputation among clients and the medical and birthing services community is extremely important to the commercial success of our Evercord service offering. This is due in significant part to the nature of the service we provide—as we are assuming custodial care of a child's umbilical cord blood stem cells entrusted to us by the parents for potential future use as a therapeutic for the child or a close relative. We believe that our reputation, and Bloodworks' reputation, enables us to market Evercord as a competitive cord blood and tissue preservation service in a crowded marketplace. However, we have occasionally and will likely continue to experience unforeseen issues, such as loss of or damage to a sample during transit, during the preservation process or while in storage. For example, if Bloodworks' facility, or our new storage facility upon our commencement of operations there, or the equipment in either facility, are significantly damaged or destroyed by natural or manmade disasters, including earthquakes, flooding or power outages, we could suffer a loss of some or all of the stored cord blood and tissue units. In addition, if we encounter problems during transportation, including while our customers' samples are in the possession of third-party commercial carriers that we contract with to transport the samples, some or all of the transported units could be damaged. Any such problems, particularly if publicized, could negatively impact our reputation, which could adversely affect our business and business prospects. If our Evercord offering does not meet customer or other public expectations, any resulting harm to our reputation could extend beyond Evercord to our core women's health and genetic testing business, which comprises the substantial portion of our revenue, because Evercord is promoted to the same OB/GYNs who prescribe and order many of our other products.

In addition to reputational damage, we face the risk of legal liability for loss of or damage to cord blood units. We do not own the cord blood units banked by our cord blood banking customers; instead, we act as custodian on behalf of the child-donor's parent or guardian. Loss of or damage to the units would be loss of or damage to the customer's property. We have included provisions in our enrollment agreement for this service, limiting our liability. However, we cannot be sure to what extent we could nevertheless be found liable for damages suffered as a result of harm to or loss of a cord blood unit, and if we are found liable, whether our insurance coverage will be sufficient to cover such damages.

We offer a quality service guarantee that provides that, subject to certain conditions, if an Evercord customer's cord blood and tissue sample is used for a transplant and fails to engraft, or begin to grow and develop, we will refund all service fees paid to us by the customer plus an additional $100,000. Failure to engraft can occur for a variety of reasons, and may occur more frequently than we anticipate. Frequent failures to engraft could result in many customers making claims under our quality service guarantee, which could adversely impact the profitability of this service offering.

The marketing, sale, and use of Panorama and our other products could result in substantial damages arising from product liability or professional liability claims that exceed our resources.

The marketing, sale and use of Panorama and our other products could lead to product liability claims against us if someone were to allege that our test failed to perform as it was designed or as claimed in our promotional materials, was performed pursuant to incorrect or inadequate laboratory procedures, if we delivered incorrect or incomplete test results, or if someone were to misinterpret test results. In addition, we may be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide, or for failure to provide such information, in connection with our marketing and promotional activities or as part of the results generated by Panorama and our other products. For example, Panorama could provide a low-risk result which a patient or physician may rely upon to make a conclusion about the health of the fetus, which may, in fact, have the condition for which we delivered a low-risk result because the Panorama result was a so-called false negative. Even though Panorama and our other tests are highly accurate, they are not 100% accurate and we may report false negative results. If the resulting baby with the condition is born, the family may file a lawsuit against us claiming product or professional liability. We are currently involved in a product liability lawsuit by a patient who allegedly received a false negative Panorama result. See "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Consolidated Financial Statements. 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 product and professional liability insurance, our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or professional liability claim brought against us,

with or without merit, could increase our insurance rates, cause our insurance coverage to be terminated or prevent us from securing insurance coverage in the future. Additionally, any product liability or professional liability lawsuit could harm our reputation, result in a cessation of our services or cause our partners to terminate our agreements with them, any of which could adversely impact our results of operations.

If we are unable to successfully scale our operations, our business could suffer.

Our overall test volumes grew from approximately 447,600 to 515,200 and further to 668,600 tests processed during the years ended December 31, 2016, 2017 and 2018, respectively, and since 2009 we have launched 11 product offerings, four of them in 2017 alone, and an additional two offerings in 2019. We processed approximately 195,168 tests in the three months ended June 30, 2019. In addition, we regularly evaluate and refine our testing process, often significantly updating our workflows, as with Panorama in 2017 and Horizon in 2018. As our test volumes and product offerings continue to grow, we will need to continue to ramp up our testing capacity and, with respect to our Evercord offering, storage capacity, and implement increases in scale. We will need additional or new equipment, laboratory space and qualified laboratory personnel, and will need to increase office space, expand our customer service capabilities, implement billing and systems process improvements, enhance our controls and procedures and expand our internal quality assurance program and technology platform. The value of Panorama, Horizon and our other products depends on our ability to perform the tests on a timely basis and at an exceptionally high standard of quality, and on maintaining our reputation for such timeliness and quality. Failure to implement necessary procedures, transition to new facilities, equipment or processes or to hire the necessary personnel in a timely and effective manner could result in higher processing costs or an inability to meet market demand, or could otherwise affect our operating results, as has happened in the past when we experienced a delay in our claims submissions and processing as a result of transitioning most of our insurance billing operations from our headquarters in San Carlos, California to our facility in Austin, Texas. We have recently transitioned a component of our insurance billing operations to a third party service provider, and may face similar challenges in connection with this transition. In addition, our efforts to scale our operations may be unable to keep pace with an increase in the frequency of our launches of new or enhanced products and services. We launched four new products in 2017 alone, two of which are in markets or industries that are new to us, with two additional offerings in 2019, one of which is in a third market, transplant rejection, that is also new to us. As we continue to launch additional offerings and product enhancements, we will need to manage our resources among various initiatives, and such competing priorities could lead to delays in one or more of our business initiatives. Conversely, to the extent that we scale our operations, infrastructure and other resources but do not ultimately meet our anticipated timelines in our product development efforts, we will experience higher costs and expenses than necessary until our project timelines and operational resources become aligned. We may also, intentionally or unintentionally, allocate resources to new products or initiatives in a manner disproportionate to the amount of revenue that such initiatives generate compared to our existing or core offerings. We cannot assure you that our efforts to scale our commercial operations will not negatively affect the quality of our test process or results, or that we will be successful in managing the growing complexity of our business operations.

To execute our growth plan, we must attract and retain highly qualified personnel. Competition for these personnel is intense, especially for sales, scientific, medical, laboratory, research and development and other technical personnel, and especially in the San Francisco Bay Area where our headquarters and laboratory facilities are located, and the turnover rate of such personnel can be high. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for highly qualified personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached their legal obligations to their former employers, which occurs from time to time. In addition, job candidates and existing employees in the San Francisco Bay Area often consider the value of the equity awards they receive in connection with their employment. To the extent that our current or potential employees perceive the value of our equity awards to be low, our ability to recruit, retain and motivate highly skilled employees may be adversely affected, which could then have an adverse effect on our business and future growth prospects. Furthermore, to the extent that we are unable to retain our employees and they leave our company to join one of our competitors, we cannot assure you that any invention, non-disclosure or non-compete agreements we have in place will provide meaningful protection against a departing employee's unauthorized use or disclosure of our confidential information, as further discussed in "*—Risks Relating to our Intellectual Property—If we are not able to adequately protect our trade secrets and other proprietary information, the value of our technology and products could be significantly diminished*."

In addition, our growth may place a significant strain on our operating and financial systems and our management, sales, marketing and administrative resources. As a result of our growth, our operating costs may escalate faster than we anticipate, we may face difficulties in obtaining additional office or laboratory space, and some of our internal systems may need to be enhanced or replaced. If we cannot effectively manage our expanding operations and our costs, we may not be able to grow successfully or we may grow at a slower pace, and our business could be adversely affected.

If our sales and distribution partnerships are not successful and we are not able to offset the resulting impact through our direct sales efforts or through agreements with new partners, our commercialization activities may be impaired and our financial results could be adversely affected.

While we have increased the focus of our commercial efforts on our U.S. direct sales force, we continue to rely on relationships with laboratory and other partners to sell Panorama and our other products, both in the United States and internationally. For example, we have entered into a license, distribution and development agreement with Qiagen pursuant to which, among others, we will rely on Qiagen for the distribution of an NIPT based on our Panorama test, on a new sequencing platform that has not yet been fully validated for our test to be run in a commercially viable manner; we have also recently entered into an agreement with a transplant diagnostics company to co-market our Prospera test in conjunction with our direct sales force. Distributing Panorama and our other products through partners reduces our control over our revenues, our market penetration and our gross margin on sales by the partner if we could have otherwise made that sale through our direct sales force. The financial condition of these laboratories could weaken, these laboratory partners could stop selling our products, reduce their marketing efforts in respect of our products, develop and commercialize or otherwise sell competing products, or otherwise breach their agreements with us. Furthermore, our laboratory partners may misappropriate our trade secrets or use our proprietary information in such a way as to expose us to litigation and potential liability; and our compliance risk may increase to the extent that we are responsible for our partners' sales and marketing activities. Disagreements or disputes with our laboratory partners, including disagreements over customers, proprietary rights or our or their compliance with contractual obligations, might cause delays or impair the commercialization of Panorama or our other tests, lead to additional responsibilities for us with respect to new tests, or result in litigation or arbitration, any of which would divert management attention and resources and be time-consuming and expensive. As is typical for companies in our industry, we are continually evaluating and pursuing various strategic or commercial partnerships, relationships, or collaborations, some of which may involve the sale and issuance of our common stock, which could result in additional dilution of the percentage ownership of our stockholders and could cause the price of our common stock to decline.

In addition, we face the risk of our laboratory partners terminating their relationship with us and completely suspending the sale of our products, which has happened in the past. Laboratory partners that are not bound by obligations of exclusivity or non-competition to us or our products could decide to develop their own product that competes with ours or sell a competing product, in addition to or in lieu of our tests. For example, we terminated our licensing and distribution agreement with Bio-Reference in 2017, and Bio-Reference began selling a competing NIPT. Moreover, our partners could merge with or be acquired by a competitor of ours or a company that chooses to de-prioritize the efforts to sell our products.

If our partnerships are not successful, our ability to increase sales of Panorama and our other products and to successfully execute our strategy could be compromised.

Our financial condition and results of operations may be adversely affected by international regulatory and business risks.

As we expand our operations, including by offering our tests in other countries, we are increasingly subject to varied and complex foreign and international laws and regulations due to operating, offering our products, or contracting with employees, contractors and other service providers in various other countries. Compliance with these laws and regulations often involves significant costs and may require changes in our business practices that may result in reduced revenues and adversely affect our operating results.

We are subject to the Foreign Corrupt Practices Act of 1977, as amended, or 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 laboratories to sell Panorama and other products 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 field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with foreign government officials. 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. 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 we could be subject to severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures, any of which could result in a material adverse effect on our business, prospects, financial condition, or results of operations.

In addition, our international activities are subject to U.S. economic and trade sanctions, which restrict or otherwise limit our ability to do business in certain designated countries. Other limitations, such as restrictions on the import into the United States or the export to other countries of tissue or genetic data necessary for us to perform our tests, or restrictions on importation and circulation of blood collection tubes or other equipment or supplies by countries outside of the United States, may limit our ability to offer our tests internationally. We may also face competition from companies located in the countries in which we or our partners or licensees offer our tests, and in which we may be at a competitive disadvantage because the country may favor a local provider or for other reasons.

By operating internationally, we may experience longer accounts receivable payment cycles and difficulties in collecting accounts receivable; realize lower margins due to lower pricing in many countries; incur potentially adverse tax consequences, including the complexities of foreign value added tax systems, tax inefficiencies related to our corporate structure and restrictions on the repatriation of earnings; experience financial accounting and reporting burdens and complexities; experience difficulties in staffing and managing foreign operations, including under labor and employment laws and regulations that are new or unfamiliar to us; be subject to trade barriers such as tariffs, quotas, preferential bidding or import or export licensing requirements; be exposed to political, social and economic instability abroad, including terrorist attacks and security concerns; be exposed to fluctuations in currency exchange rates; and experience reduced or varied protection for intellectual property rights and practical difficulties in enforcing intellectual property and other rights, including with respect to assignment of inventions to us by our consultants in foreign jurisdictions.

Outside of the United States we enlist local and regional laboratories, contract employees and other contracted service providers to assist with various aspects of our business operations, including blood draws, engineering, sales, marketing, billing and customer support. Subject to regulatory clearance where required, we also contract with international licensees to run the molecular portion of our tests in their own labs and then access our algorithm for analysis of the resulting data through our cloud-based Constellation platform. Locating, qualifying and engaging additional distribution partners and local laboratories with local industry experience and knowledge is necessary to effectively market and sell our tests outside of the United States. We may not be successful in finding, attracting and retaining such distribution partners or laboratories, or we may not be able to enter into such arrangements on favorable terms. Sales practices and other activities utilized by our distribution partners, contract employees and other service providers, some of which may be locally acceptable, may not comply with relevant standards required under United States laws that apply to our operations overseas, including through third parties, which could create additional compliance risk. Our training and compliance program and our other internal control policies and procedures, and our contractual terms with these third parties, may not always protect us from acts committed by our employees, contractors, partners or agents abroad. Non-compliance by us or our employees, contractors, partners or agents, whether maliciously or in error, of any applicable laws or regulations could result in fines or penalties, or adversely affect our ability to operate and grow our business. Even if we are able to effectively manage our international operations, if our distribution partners and local and regional laboratory licensees are unable to effectively manage their businesses, our business and results of operations could be adversely affected. Furthermore, the legal landscape governing advertising, promotional and other marketing activities can vary widely from jurisdiction to jurisdiction, and is often more complex, less clear or

less developed than in the United States. If our marketing activities are found to be in violation of local laws, regulations or practices, we may be subject to fines and other penalties, and may be required to cease marketing or commercialization activities in such jurisdiction. If our sales and marketing efforts are not successful outside of the United States, we may not achieve market acceptance for our tests outside of the United States, which would harm our business.

Operating internationally requires significant management attention and financial resources. We cannot be certain that the investment and additional resources required to increase international revenues or expand our international presence will produce desired levels of revenues or profitability.

If we lose the services of our founder and Executive Chairman or other members of our senior management team, we may not be able to execute our business strategy.

Our success depends in large part upon the continued service of our senior management team. In particular, our founder and Executive Chairman, Matthew Rabinowitz, as well as Steve Chapman, our Chief Executive Officer, are critical to our vision, strategic direction, culture, products and technology. Although Dr. Rabinowitz spends significant time with us and is active in our management, he is no longer our Chief Executive Officer. In addition, we do not maintain key-man insurance for Dr. Rabinowitz, Mr. Chapman or any other member of our senior management team. The loss of our founder and Executive Chairman, our Chief Executive Officer or one or more other members of our senior management team could have an adverse effect on our business.

We may engage in acquisitions, dispositions or other strategic transactions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

From time to time, we may enter into transactions to acquire or dispose of businesses, products or technologies or to engage in other strategic transactions. Because we have not made any such acquisitions or dispositions to date, our ability to do so successfully is unproven. Even if we identify suitable transactions, we may not be able to complete such transactions on favorable terms or at all. Any acquisitions or other strategic transactions we consummate may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue shares of our common stock or other equity securities to the stockholders of the acquired company, which would cause dilution to our existing stockholders. We could incur losses resulting from such strategic transactions, including undiscovered liabilities of an acquired business that are not covered by any indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate any acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Any dispositions may also cause us to lose revenue and may not strengthen our financial position. Strategic transactions may also divert management attention from day-to-day responsibilities, increase our expenses, result in accounting charges, and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future strategic transactions or the effect that any such transactions might have on our operating results.

We may need to raise additional capital, and if we cannot do so when needed or on commercially acceptable terms, we may have to curtail or cease operations.

We may need to raise additional funds through public or private equity or debt financings, corporate collaborations or licensing arrangements to continue to fund or expand our operations.

Our actual liquidity and capital funding requirements will depend on numerous factors, including:

- our ability to achieve broader commercial success with Panorama, Horizon and our other products;
- the costs and success of our research, development, and commercialization efforts for potential new products;
- our ability to obtain more extensive coverage and reimbursement for our tests, including in the average-risk patient population and for microdeletions screening;
- our ability to generate sufficient revenues from our cloud-based distribution model;

- our ability to collect on our accounts receivable;
- our need to finance capital expenditures and further expand our clinical laboratory operations;
- our ability to manage our operating costs; and
- the timing and results of any regulatory authorizations that we are required to obtain for our tests.

Additional capital, if needed, may not be available on satisfactory terms or at all. Furthermore, any additional capital raised through the sale of equity or equity-linked securities, or grant of equity or equity-linked securities in connection with any debt financing, will dilute stockholders' ownership interests in us and may have an adverse effect on the price of our common stock. In addition, the terms of any financing may adversely affect stockholders' holdings or rights. Debt financing, if available, may include restrictive covenants, and may impose other constraints on us and our operations, as is the case under our 2017 Term Loan, as further described in the risk factor entitled "*—Our outstanding debt may impair our financial and operating flexibility*." To the extent that we raise capital through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or grant licenses on terms that may not be favorable to us.

If we are not able to obtain adequate funding when needed, we may have to delay development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our tests or market development programs, which could lower the economic value of those programs to our company.

Our outstanding debt may impair our financial and operating flexibility.

As of June 30, 2019 and December 31, 2018, we had approximately $123.6 million and $127.3 million, respectively, of debt outstanding with accrued interest. In August 2017, we completed our 2017 Term Loan under which we borrowed $75.0 million. In addition, we have $50.1 million outstanding under our Credit Line with UBS, including unpaid interest. Except for operating leases, we do not have any off-balance sheet financing arrangements in place or available. Our 2017 Term Loan contains various restrictive covenants and is secured by substantially all of our assets, including our intellectual property. These restrictions could limit our ability to use operating cash flow in other areas of our business because we must use a portion of these funds to make principal and interest payments on our debt; conversely, our ability to make principal and interest payments on our indebtedness will depend on our ability to generate cash. If we default under the 2017 Term Loan or the Credit Line and if the default is not cured or waived, the lenders could terminate their commitments to lend to us and cause any amounts outstanding to be payable immediately. Under certain circumstances, they could also exercise their rights under the security agreements entered into in connection with the loans. Such a default could also result in cross defaults under other debt instruments. Moreover, any such default would limit our ability to obtain additional financing, which may have an adverse effect on our cash flow and liquidity. Any refinancing of our existing indebtedness or the incurrence of additional indebtedness could have similar or more restrictive terms.

We may incur additional indebtedness in the future. If we incur additional debt, a greater portion of our cash flows may be needed to satisfy our debt service obligations, and if we do not generate sufficient cash to meet our debt service requirements, we may need to seek additional financing. In that case, it may be more difficult, or we may be unable, to obtain financing on terms that are acceptable to us. As a result, we would be more vulnerable to general adverse economic, industry and capital markets conditions in addition to the risks associated with indebtedness described above.

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

DNA testing, like that conducted using Panorama, Horizon, Signatera, and our other products, 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 genomic information or genomic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Patients may also refuse to use genetic tests even if permissible, for similar reasons; they may also refuse genetic testing due to concerns regarding eligibility for life or other insurance. Ethical and social concerns may also influence U.S. and foreign

patent offices and courts with regard to patent protection for technology relevant to our business. These and other ethical, legal and social concerns may limit market acceptance of our tests or reduce the potential markets for services and products enabled by our technology platform, either of which could harm our business.

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

We have a significant amount of net operating loss, or NOL, carryforwards that can be used to offset potential future taxable income and related income taxes. As of December 31, 2018, we had federal and state NOL carryforwards of approximately $394.0 million and $201.4 million, respectively, which, if not utilized, begin to expire in 2027 and 2028, respectively. We also had federal research and development credit carryforwards of approximately $14.1 million, which begin to expire in 2027, and state research and development credit carryforwards of approximately $10.5 million, which can be carried forward indefinitely. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change, by value, in equity ownership over any three-year period), the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may have experienced an "ownership change" upon our initial public offering; we may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may not be within our control. Our ability to use these carryforwards could be limited if we experience an "ownership change."

Our estimates of total addressable market opportunity and forecasts of market growth may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates.

Total addressable market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. Our publicly announced estimates and forecasts relating to the size and expected growth of our market may prove to be inaccurate. Even if the market in which we compete meets our size estimates and forecasted growth, our business could fail to grow at similar rates.

Reimbursement and Regulatory Risks Related to Our Business

If we are unable to expand, maintain or obtain third-party payer coverage and reimbursement for Panorama and our other tests, or if we are required to refund any reimbursements already received, our revenues and results of operations would be adversely affected.

Our business depends on our ability to obtain or maintain adequate reimbursement coverage from third-party payers and patients. Third-party reimbursement for our testing represents a significant portion of our revenues, and we expect third-party payers such as insurance companies and government healthcare programs to continue to be our most significant source of payments. In particular, we believe that the following will be necessary for us to continue to achieve commercial success: expanding insurance coverage from the high-risk to the average-risk pregnancy population, which represents roughly 80% of the United States pregnancy market, and for microdeletions screening, and obtaining positive coverage determinations and favorable reimbursement rates from commercial third-party payers, the Centers for Medicare & Medicaid, or CMS, and state reimbursement programs for our tests. We do not expect to receive reimbursement for a significant number of Panorama tests for average-risk patients and for microdeletions that we performed in the quarter ended June 30, 2019. In addition, we have recently commercially launched our Signatera oncology test as a laboratory developed test, or LDT, and it remains unclear whether and to what extent liquid biopsy or other oncology sequencing tests will be reimbursed. We are also working to commercially launch our Prospera transplant rejection test, and while we are basing our reimbursement estimates on the rate at which a similar test currently on the market is reimbursed, we cannot guarantee that our test, once developed, will be reimbursed at the same or a similar rate, nor that the current rate will be in effect when we launch our test. If we are unable to obtain or maintain adequate reimbursement coverage from, or achieve in-network status with, third-party payers for our existing or future tests, our ability to generate revenues will be limited. For example, physicians may be reluctant to order our tests due to the potential of a substantial cost to the patient if reimbursement coverage is unavailable or insufficient.

In making coverage determinations, third-party payers often rely on practice guidelines issued by professional societies. The American College of Medical Genetics, or ACMG, has issued updated guidelines recommending informing pregnant women that NIPT is the most sensitive screening option for Patau, Edwards and Down syndromes,

as well as of the availability of the expanded use of NIPT to screen for clinically relevant copy number variants, or CNVs, in the context of counseling that includes the risks/benefits and limitations of screening for CNVs. A CNV is a genetic mutation in which a segment of the genome has been deleted or duplicated, including microdeletions in which a small segment of a chromosome is deleted. The International Society for Prenatal Diagnosis, or ISPD, has issued guidelines that are supportive of performing NIPT in average-risk pregnancies, as well as high-risk pregnancies. However, the Society for Maternal Fetal Medicine, or SMFM, has issued guidelines for NIPT stating that, while all pregnant women should be informed of the option to receive NIPT, conventional screening methods, such as traditional serum screening, rather than NIPT, remain the most appropriate choice for first-line screening for average-risk pregnancies. While we expect the ACMG and SMFM guidelines to result in an increase in the number of average-risk women who are informed of NIPT and that may request it as a result, not all third-party payers reimburse for NIPT for these average-risk patients. Currently, Aetna Inc., UnitedHealthcare Insurance Company and a number of other third-party payers have negative coverage determinations for NIPT in average-risk patient populations, meaning that their policy is not to reimburse for NIPT for patients in the average-risk population. The SMFM guidelines also echoed a previous statement from SMFM that routine screening for microdeletions should not be performed. Many third-party payers do not reimburse for microdeletions screening. While we have published data on the performance of Panorama for the 22q11.2 deletion syndrome, we have and may continue to experience a negative impact on third-party payers' reimbursement for Panorama for microdeletions, at least until additional validation data on the sensitivity and specificity of our tests becomes available. If we are unable to present satisfactory additional data on the performance of Panorama for 22q11.2 deletion syndrome, including from our SMART study, we may be unable to obtain positive coverage determinations for our test. If third-party payers do not reimburse for NIPT for average-risk pregnancies or microdeletions in the future, our future revenues and results of operations would be adversely affected, particularly to the extent that we continue to perform large volumes of tests for which third-party payors do not reimburse.

In addition, a CPT code for microdeletions took effect in January 2017. We have experienced low average reimbursement rates for microdeletions under this code, and we expect that this code will continue to cause our microdeletions reimbursement to remain low, at least in the near term, due to third-party payers declining to reimburse and as a result of reduced reimbursement, under the code, which has had, and we expect to continue to have, an adverse effect on our revenues. In addition, a new CPT code for expanded carrier screening tests took effect in January 2019. The new code has caused and may continue to cause reimbursement rates for our broader Horizon carrier screening panel to decrease because those tests may be reimbursed as a combined single panel instead of as multiple individual tests.

The reimbursement environment, particularly for molecular diagnostics, is continually changing and our efforts to broaden reimbursement for our tests with third-party payers may not be successful. Third-party payers from whom we have received reimbursement may withdraw coverage or decrease the amount of reimbursement coverage for our tests at any time and for any reason. In some cases, our tests or their uses within certain populations, such as for microdeletions, are considered experimental by third-party payers and, as a result, some payers have decided not to reimburse for such tests. In addition, some third-party payers bundle payment for multiple tests or tests that screen for multiple conditions, such as our Horizon test or our Panorama test and the separate Panorama screen for microdeletions, into a single payment rate, thereby limiting our reimbursement in those situations. Payers may also dispute our billing or coding. Based on any of the foregoing, third-party payers may also decide to deny payment or recoup payment for testing that they contend to have been not medically necessary, against their coverage determinations, or for which they have otherwise overpaid, and we may be required to refund reimbursements already received. We deal with requests for recoupment from third-party payers from time to time in the ordinary course of our business, and it is likely that we will continue to do so in the future. See "Note 8—Commitments and Contingencies—Third-Party Payer Reimbursement Audits" in the Notes to Consolidated Financial Statements. If a third-party payer denies payment for testing, reimbursement revenue for our testing could decline. If a third-party payer successfully proves that payment for prior testing was in breach of contract or otherwise contrary to law, they may recoup payment, which amounts could be significant and would impact our results of operations, and it may decrease reimbursement going forward. We may also decide to negotiate and settle with a third-party payer in order to resolve an allegation of overpayment. Any of these outcomes might require us to restate our financials from a prior period, which would likely cause our stock price to decline. As described in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Consolidated Financial Statements, in 2018 we reached a settlement with the United States Department of Justice to pay approximately $11.4 million to resolve claims under a qui tam complaint regarding past reimbursement submissions;

although the settlement involved no admission of fault by us and no corporate integrity agreement, we cannot guarantee that we will not be subject to similar claims, resulting in additional settlements or repayments, in the future.

Furthermore, some of our contracts with third-party payers contain so-called most favored nation provisions, pursuant to which we have agreed that we will not bill the third-party payer more than we bill any other third-party payer. We must therefore monitor our billing and claims submissions to ensure that we remain in compliance with these contractual requirements with third-party payers. If we do not successfully manage these most favored nation provisions, we may need to forego revenues from some third-party payers or reduce the amount we bill to each third-party payor with a most-favored nation clause in its contract that is violated, which would adversely affect our revenues. This situation could also subject us to claims for recoupment, which could require the time and attention of our management, require the expense of engaging outside counsel or consultants, and may be a distraction from development of our business, adversely impacting our operations. Such recoupment demands could also ultimately result in an obligation to repay amounts previously earned.

In addition, if a third-party payer denies coverage, it may be difficult for us to collect from the patient, and we may not be successful in doing so. In particular, we are often unable to collect the full amount of a patient's responsibility where we are an out-of-network provider and the patient is left with a large balance, despite our good faith efforts to collect. As a result, we cannot always collect the full amount due for our tests when third-party payers deny coverage, cover only a portion of the invoiced amount or the patient has a large deductible, which may cause payers to raise questions regarding our billing policies and patient collection practices. We believe that our billing policies and our patient collection practices are compliant with applicable laws. However, we have in the past received, and we may in the future receive, inquiries from third-party payers regarding our billing policies and collection practices. While we have addressed these inquiries as and when they have arisen, there is no guarantee that we will always be successful in addressing such concerns in the future, which may result in a third-party payer deciding to reimburse for our tests at a lower rate or not at all, seeking recoupment of amounts previously paid to us, or bringing legal action to seek reimbursement of previous amounts paid. Any of such occurrences could cause reimbursement revenue for our testing, which constitutes the large majority of our revenue, to decline. Additionally, if we were required to make a repayment, such repayment could be significant, this would impact our results of operations, and we might be required to restate our financials from a prior period, which would likely cause our stock price to decline.

We are aware of policies and practices of our competitors to offer patients a set cap on their out-of-pocket responsibility, waive patient responsibility altogether, and, in some cases, to not send patients a bill at all, all of which we believe is not in accordance with third-party payers' policies and, in many cases, not compliant with the law. In contrast, it is our policy not to offer such caps or waivers and to send bills to patients for services rendered. Because of this discrepancy, our offerings may be perceived as less attractive to patients and their healthcare providers, who are concerned about patients having a large financial responsibility for these products. As a result, we believe that our revenues and results of operations have been adversely affected, and may continue to be so affected to the extent that our competitors continue such practices.

Our revenues may be adversely affected if we are unable to successfully obtain reimbursement from the Medicare program and state Medicaid programs.

Our revenues from Medicare are currently very small, given the population that Medicare covers, and the fact that our testing generally is not received by Medicare beneficiaries. As a result, we do not expect our Medicare revenues to change materially with regard to NIPT. However, Medicare reimbursement can affect both Medicaid reimbursement, which is relevant to NIPT, and reimbursement from commercial third-party payers. Specifically, fee-for-service Medicaid programs generally do not reimburse at rates that exceed Medicare's fee-for-service rates, and many commercial third-party payers set their payment rates at a percentage of the amounts that Medicare pays for testing services. Medicare reimbursement rates are typically based on the Clinical Laboratory Fee Schedule, or CLFS, set by CMS. Our current Medicare Part B reimbursement was not set pursuant to a national coverage determination by CMS. Although we believe that coverage is available under Medicare Part B even without such a determination, we currently lack the certainty afforded by a formal national coverage determination by CMS. Thus, CMS could issue an adverse coverage determination as to Panorama which could influence other third-party payers, including Medicaid, and could have an adverse effect on our revenues. Furthermore, we expect that Medicare reimbursement will impact our future

revenue from our Signatera CLIA test, as well as our planned Prospera test, as the significant majority of transplant patients are covered by Medicare.

It is estimated that nearly half of all births in the United States are to state Medicaid program recipients. Each state's Medicaid program has its own coverage determinations related to our testing, and many state Medicaid programs do not provide their recipients with coverage for our testing. Even if our testing is covered by a state Medicaid program, we must be recognized as a Medicaid provider by the state in which the Medicaid recipient receiving the services resides in order for us to be reimbursed by a state's Medicaid program. In addition, many Medicaid programs have entered into agreements with managed care plans to have the managed care plans manage the provision of healthcare to that Medicaid program's beneficiaries, including exclusive arrangements with large national laboratory providers. In order for us to enter into contracts to provide our testing services to beneficiaries who are enrolled with a Medicaid managed care plan, we must first be recognized as a Medicaid provider in that state, and then contract with the applicable Medicaid managed care program. As of August 1, 2019, we are recognized by 47 states as a Medicaid provider. It is likely that we will not be able to be recognized as a provider by additional Medicaid programs because some states require that a provider maintain a physical laboratory in that state in order to be recognized; furthermore, some states have closed provider panels, which means that the state does not intend to expand its current provider network and therefore does not intend to recognize additional Medicaid providers. Even if we are recognized as a provider in a state, if Medicare's CLFS rate for our services and tests are low, the Medicaid reimbursement amounts are sometimes as low, or lower, than the Medicare reimbursement rate. In addition and as noted above, each state's Medicaid program has its own coverage determinations related to our testing, and many state Medicaid programs do not provide their recipients with coverage for our testing. In addition, from time to time we receive requests from state Medicaid programs seeking information or documents to determine eligibility for and the amount of Medicaid reimbursement. As a result of all of these factors, our testing is not reimbursed or only reimbursed at a very low dollar amount by many state Medicaid programs. In some cases, a state Medicaid program's reimbursement rate for our testing might be zero dollars. Low or zero dollar Medicaid reimbursement rates for our tests could have an adverse effect on our business and revenues.

Our revenues may be adversely impacted if third-party payers withdraw coverage or provide lower levels of reimbursement due to changing policies, billing complexities or other factors.

We are in network, or under contract, with the significant majority of third-party payers from whom we receive reimbursement; this means that we have agreements with most third-party payers that govern approval or payment terms. However, these contracts do not guarantee reimbursement for all testing we perform. For example, many third-party payers with whom we have written agreements have policies that state they will not reimburse for use of NIPTs for average-risk pregnancies or for the screening of microdeletions, or don't have a policy in place to reimburse for microdeletions screening. In addition, the terms of certain of our agreements require a physician or qualified practitioner's signature on test requisitions or require other controls and procedures prior to conducting a test. In particular, third-party payers have increasingly required prior authorization to be obtained prior to conducting a test, as a condition to reimbursing for the test. This has placed a burden on our billing operations as we have to dedicate resources to ensuring that these requirements are met and to conduct follow-up and address issues as they arise, and has also impacted our results of operations, including our gross margins, since the fourth quarter of 2017, when these requirements began to take effect. To the extent we or the physicians ordering our tests do not follow the prior authorization requirements, we may be subject to claims for recoupment of reimbursement amounts previously paid to us, or may not receive some or all of the reimbursement payments to which we would otherwise be entitled. This has occurred in some cases and may occur more frequently in the future, which does and would have an adverse impact on our revenues.

Where we are considered to be an out of network provider, which is the case with some third-party payers from whom we receive reimbursement, such third-party payers could withdraw coverage and decline to reimburse for our tests in the future, for any reason. Managing reimbursement on a case-by-case basis is time-consuming and contributes to an increase in the number of days it takes us to collect on accounts, which also increases our risk of non-payment. Negotiating reimbursement on a case-by-case basis also typically results in the receipt of reimbursement at a significant discount to the list price of our tests.

Even if we are being reimbursed for our tests, third-party payers may review and adjust the rate of reimbursement, require co-payments from patients or stop paying for our tests. Government healthcare programs and other third-party payers continue to increase their efforts to control the cost, utilization and delivery of healthcare services by demanding price discounts or rebates and limiting coverage of, and amounts they will pay for, molecular diagnostic tests. These measures have resulted in reduced payment rates and decreased utilization in the clinical laboratory industry. Because of these cost-containment measures, governmental and commercial third-party payers may reduce, suspend, revoke or discontinue payments or coverage at any time, including payors that currently provide reimbursement for our tests. Reduced reimbursement of our tests may harm our business, financial condition or results of operations.

Billing for clinical laboratory testing services is complex. We perform tests in advance of payment and without certainty as to the outcome of the billing process. In cases where we expect to receive a fixed fee per test due to our reimbursement arrangements, we may nevertheless encounter disputes over pricing and billing. Each third-party payer typically has different billing requirements, and the billing requirements of many payers have become increasingly difficult to meet. Among the factors complicating our billing of third-party payers are:

- disparity in coverage among various payers;
- disparity in information and billing requirements among payers, including with respect to prior authorization requirements and procedures and establishing medical necessity; and
- incorrect or missing billing information, which is required to be provided by the ordering healthcare practitioner.

These risks related to billing complexities, and the associated uncertainty in obtaining payment for our tests, could harm our business, financial condition and results of operations.

In the United States, the AMA generally assigns specific billing codes for laboratory tests under a coding system known as Current Procedure Terminology, or CPT, which we and our ordering healthcare providers must use to bill and receive reimbursement for our diagnostic tests. Once the CPT code is established by the AMA, CMS establishes payment levels and coverage rules under Medicare while private payers independently establish rates and coverage rules. A CPT code specific to NIPT for aneuploidies was implemented in January 2015, and a CPT code for microdeletions was implemented in January 2017. CMS has established a pricing benchmark of $802 for aneuploidy and microdeletions testing. However, our microdeletions reimbursement has decreased under the January 2017 code because third-party payers are declining to reimburse under this code or reimbursing at a much lower rate than we had previously received. Furthermore, we cannot guarantee that we will be able to negotiate favorable rates for this code or receive reimbursement at all if we are unable to collect and publish additional data and obtain positive coverage determinations for Panorama for microdeletions. In addition, the AMA has approved the use of a CPT code for expanded carrier screening tests, which may similarly cause reimbursement for our Horizon expanded carrier screening tests to decline. We do not currently have assay-specific CPT codes assigned for all of our tests, and there is a risk that we may not be able to obtain such codes or, if obtained, we may not be able to negotiate favorable rates for such codes. We currently submit for reimbursement using CPT codes based on the guidance of outside coding experts and legal counsel. There is a risk that the codes we currently submit may be rejected or withdrawn or that third-party payers will seek refunds of amounts that they claim were inappropriately billed based on either the CPT code used, or the number of units billed. In addition, third-party payers may not establish positive coverage policies for our tests or adequately reimburse for any CPT code we may use, or seek recoupment for testing previously performed, which have occurred in the past.

If the FDA were to begin actively regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval and incur costs associated with complying with post-market controls.

We currently offer a number of prenatal genetic tests, including Panorama, and each of those tests is an LDT. In addition, we are initially commercializing our Signatera CLIA laboratory test and our planned Prospera test as LDTs. An LDT is generally considered to be a test that is designed, developed, validated and used within a single laboratory. The FDA takes the position that it has the authority to regulate such tests as medical devices under the FDC Act, but it has generally exercised enforcement discretion with regard to LDTs. This means that even though the FDA believes it can

impose regulatory requirements on LDTs, such as requirements to obtain premarket approval or clearance of LDTs, it has generally chosen not to enforce those requirements to date.

The regulation by the FDA of LDTs remains uncertain. In October 2014, the FDA issued draft guidances outlining its plan to actively regulate LDTs using a risk-based approach. In November 2016, the FDA announced that it no longer plans to finalize the 2014 draft guidances. In January 2017, the FDA issued a discussion paper that laid out elements of a possible revised future LDT regulatory framework, but did not establish any regulatory requirements. The FDA's efforts to regulate LDTs prompted the drafting of legislation governing diagnostic products and services that sought to substantially revamp the regulation of both LDTs and IVDs. Congress may still act to provide further direction to the FDA on the regulation of LDTs and substantially modify the regulation of IVDs.

In the meantime, the FDA could require us to seek premarket clearance, approval or authorization to offer our tests for clinical use even before it finalizes any future guidance. If FDA premarket clearance, approval or authorization is required for any of our existing or future tests, we may be forced to stop selling our tests or we may be required to modify claims or make other changes to our tests while we work to obtain FDA clearance, approval or authorization. Our business would be adversely affected while such review is ongoing and if we are ultimately unable to obtain premarket clearance, approval or de novo authorization. For example, the regulatory premarket clearance, approval or de novo authorization process may involve, among other things, successfully completing analytical, pre-clinical and/or clinical studies beyond the studies we have already performed or plan to perform for each of our products and would involve submitting a premarket notification, or 510(k), a de novo application, or filing a PMA application with the FDA. As further described in the risk factor entitled "*Uncertainty in the development and commercialization of our enhanced or new tests or services could materially adversely affect our business, financial condition and results of operations,*" completing such studies requires the expenditure of time, attention and financial and other resources, and may not yield the desired results, which may delay, limit or prevent regulatory clearances, approvals or authorizations. In addition, we may require cooperation in our filings for FDA clearance, approval or authorization from third-party manufacturers of the components of our tests. If we are unable to obtain such required cooperation, we may be unable to achieve the desired regulatory clearances, approvals or authorizations, or may be delayed or be required to expend additional costs and other resources in doing so. For example, while we recently entered into a licensing, development and distribution agreement with Qiagen to develop NIPT and potentially other tests based on our technology, including for FDA approval, on Qiagen's sequencer, Illumina currently is our sole sequencer and sequencing reagent supplier. If we seek to achieve regulatory clearance, approval or authorization for Panorama, to the extent that Panorama incorporates Illumina's sequencer or sequencing reagents, we may require Illumina's cooperation in the regulatory process. We may face difficulty obtaining cooperation from Illumina because Illumina is the parent company of Verinata, a direct competitor of ours in the NIPT field. In addition, we are party to certain litigation with Illumina as described in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Consolidated Financial Statements. Furthermore, if FDA premarket clearance, approval or de novo authorization is required, our cash flows may be adversely affected until we obtain such clearance, approval or authorization, as most third-party payers, including Medicaid, will not reimburse for use of medical devices which are required to be cleared or approved but which have not been.

We cannot assure you that Panorama or any of our other tests for which we decide to pursue or are required to obtain premarket clearance, approval or de novo authorization by the FDA will be cleared, approved or authorized on a timely basis, if at all. In addition, if a test has been cleared, approved or authorized, certain changes that we may make to improve the test, or as a result of issues with suppliers of the components of the test or if a supplier modifies its component upon which our approval relies, may need to be cleared, approved or authorized by the FDA before we can implement them, which could increase the time and expense involved in rolling such changes out to the commercial market. Ongoing compliance with FDA regulations would increase the cost of conducting our business and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements, any of which may adversely impact our business and results of operations.

Furthermore, the FDA or the Federal Trade Commission, or FTC, may object to the materials and methods we use to promote the use of our current tests or other LDTs we may develop in the future, including with respect to the product claims in our promotional materials, and may initiate enforcement actions against us. Enforcement actions by the FDA may include, among others, untitled or warning letters; fines; injunctions; civil or criminal penalties; recall or seizure of current or future tests, products or services; operating restrictions and partial suspension or total shutdown of

production. Enforcement actions by the FTC may include, among others, injunctions, civil penalties, and equitable monetary relief.

Failure to obtain necessary regulatory approvals may adversely affect our ability to expand our operations internationally, including our ability to continue commercializing our cloud-based distribution model.

An important part of our business strategy is to expand and offer our tests internationally, either by providing our testing services directly or through our laboratory partners, or through our licensees under our Constellation cloud-based distribution model. As we do so, we will become increasingly subject to or impacted by the regulatory requirements of foreign jurisdictions, which are varied and complex. Our tests, and certain components of our tests, may be subject to the regulatory approval requirements in each foreign country in which they are sold by us or a laboratory partner, or by our licensees under our cloud-based distribution model, and our future performance would depend on us or our partners or licensees obtaining any necessary regulatory approvals in a timely manner. For example, while we have entered into a license agreement with BGI Genomics to commercialize our Signatera test in China and to develop reproductive health tests in select markets using BGI Genomics's sequencing instruments and platform, such commercialization and development activities will be subject to obtaining and maintaining necessary regulatory approvals in the relevant jurisdictions. In addition, while we have obtained a CE Mark from the European Commission for our Constellation software and the key reagents required for our licensees to run their NIPT based on our technology, we have not obtained a CE Mark for our Panorama test as a whole. Therefore, while we are able to offer Constellation in the European Union and other countries that accept a CE Mark, we are unable to offer Panorama as an IVD directly in these jurisdictions. This, coupled with our use of our Panorama brand name under our Constellation model, has caused regulatory authorities to question whether we, our laboratory partners or our licensees may be marketing, commercializing or otherwise offering our tests without required approvals. We are occasionally required to address inquiries from regulatory authorities in various countries, such as those in the European Union, regarding the regulatory status of our Panorama or Constellation offerings, and expect that we will continue to face similar inquiries. If we do not continue to satisfactorily address any such questions in the future, we may be required to cease offering our products, either directly or through our partners or licensees, in the relevant country. This may in turn result in similar concerns, and subsequent cessation of our sources of revenue, in other countries.

Our cloud-based distribution model has raised similar concerns in some countries outside of the European Union; as a result, we address inquiries from various international regulatory authorities from time to time, and it is likely that we will continue to do so in the future, regarding the regulatory status of Panorama and Constellation. We may also be at a competitive disadvantage in the European Union to our competitors who have obtained a CE Mark for their end to end NIPT. In addition, as further described in the risk factor entitled "*Risks Related to Our Business and Industry—We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers*," blood collection tubes sourced solely from Streck are required to run our tests. These blood collection tubes are CE Marked by the European Commission; however, if such blood collection tubes are not registered in jurisdictions that do not accept a CE Mark, we may be unable to expand our business in such jurisdictions.

We may also need to obtain regulatory clearance, approval or authorization in the United States for our Constellation software in order for it to be used by third parties in the development and commercialization of their diagnostic tests based on our technology. We have engaged in discussions with the FDA regarding the regulatory status of a portion of our Constellation software, the copy number calculator, or CNC, to make calls of copy number variants, which are genetic mutations in which relatively large regions of the genome have been deleted or duplicated. In those discussions, the FDA indicated that the CNC may be appropriate for review under the de novo classification process, which is less burdensome than the premarket approval, or PMA, process. The FDA stated that it would not prevent us from marketing Constellation in the United States while we discuss with the FDA how it will be regulated; however, it is possible that the FDA may reverse itself either on the appropriate regulatory review path or on the issue of our ability to continue to market Constellation. In addition, the 21st Century Cures Act, enacted in 2016, included a number of changes to the FDA's regulatory approach to software that may have bearing on the regulatory status of our Constellation software. If necessary, we intend to seek regulatory clearance, approval or authorization for our Constellation software; however, we cannot guarantee that we will obtain such clearance, approval or authorization. If clearance, approval or authorization is required by the FDA and we are unable to obtain it, we would be unable to commercialize our cloud-based distribution model in the United States.

If our Constellation software requires regulatory clearance, approval or authorization in the United States, we will be subject to ongoing FDA obligations and continued regulatory oversight and review, including compliance with requirements such as the quality system regulation, or QSR, which establishes extensive requirements for quality assurance and control as well as manufacturing procedures; the listing of our devices with the FDA; adverse event and malfunction reporting; corrections and removals reporting; and labeling and promotional requirements. We may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance to the extent required, we may not be permitted to offer our Constellation software and may be subject to enforcement action by the FDA, such as the issuance of warning or untitled letters, fines, injunctions and civil penalties; recall or seizure of products; operating restrictions and criminal prosecution. In addition, if a test developed by any of our licensees under our cloud-based distribution model in the United States is found not to be an LDT, or that licensee has difficulty obtaining the reagents and sequencing equipment for any regulatory, supply chain, or other reason, the licensee may not be able to market its test, we would not receive the anticipated revenues from that licensee, and potential or other current licensees may be dissuaded from utilizing our Constellation software.

Regulatory approval can be a lengthy, expensive and uncertain process. In addition, regulatory processes are subject to change, and new or changed regulations can result in unanticipated delays and cost increases. For example, the European Commission has published new directives regulating, among others, IVDs, which are expected to become effective in 2022. The new regulations will require companies providing genetic testing services to obtain a CE Mark for what will be considered IVDs, or a CE-IVD; in addition to requiring notified body approval for various classes of devices, including prenatal tests such as Panorama, companies will also be required to submit clinical evidence and post-market performance data to regulators after their tests have been approved and are commercialized. We or our partners or licensees may not be able to obtain regulatory approvals on a timely basis, if at all, which may cause us to incur additional costs or prevent us from marketing our tests in the United States or in foreign countries.

Changes in laws and regulations, or in their application, may adversely affect our business, financial condition and results of operations.

The clinical laboratory testing industry is highly regulated, and failure to comply with applicable regulatory, supervisory, accreditation, registration or licensing requirements may adversely affect our business, financial condition and results of operations. In particular, the laws and regulations governing the marketing and research of clinical diagnostic testing are extremely complex and in many instances there are no clear regulatory or judicial interpretations of these laws and regulations, increasing the risk that we may be found to be in violation of these laws.

Furthermore, the molecular diagnostics industry as a whole is a growing industry and regulatory agencies such as the United States Department of Health and Human Services, or HHS, or the FDA may apply heightened scrutiny to new developments in the field. While we have taken steps to ensure compliance with the current regulatory regime in all material respects, given its nature and our geographical diversity, there could be areas where we are non-compliant. Any change in the federal or state laws or regulations relating to our business may require us to implement changes to our business or practices, and we may not be able to do so in a timely or cost-effective manner. Should we be found to be non-compliant with current or future regulatory requirements, we may be subject to sanctions which could include changes to our operations, adverse publicity, substantial financial penalties and criminal proceedings, which may adversely affect our business, financial condition and results of operations by increasing our cost of compliance or limiting our ability to develop, market and commercialize our tests.

In addition, there has been a recent trend of increased U.S. federal and state regulation, scrutiny and enforcement relating to payments made to referral sources, which are governed by laws and regulations including the Stark law, the federal Anti-Kickback Statute, the federal False Claims Act, and EKRA as well as state equivalents of such laws. Among other requirements, the Stark law requires laboratories to track, and places a cap on, non-monetary compensation provided to referring physicians.

While we have a compliance plan to address compliance with government laws and regulations, including applicable fraud and abuse laws and regulations such as those described in this risk factor, the evolving commercial compliance environment and the need to build and maintain robust and scalable systems to comply with regulations in multiple jurisdictions with different compliance and reporting requirements increases the possibility that we could inadvertently violate one or more of these requirements.

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 require clinical laboratories to obtain a certificate and mandate specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management and quality assurance. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers, for our tests. Our laboratory located in San Carlos, California is CLIA certified, and is accredited by the College of American Pathologists, or CAP, a CMS-approved accreditation organization. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA and/or state inspectors may conduct random inspections of our clinical laboratory or conduct an inspection as a result of a complaint or reported incident, as has occurred. Any failure to address identified deficiencies, or to otherwise comply with CLIA, CAP or state requirements, can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA and/or CAP certificate of accreditation or state laboratory permit, as well as a directed plan of correction, on-site monitoring, civil monetary penalties, civil actions for injunctive relief, criminal penalties, suspension or exclusion from the Medicare and Medicaid programs and significant adverse publicity.

Some states require that we hold licenses or permits to test samples from patients in those states and as a result we are also required to maintain standards related to state licensure to conduct testing in our laboratories under state law. California state laboratory laws and regulations establish standards for the operation of our clinical laboratory and performance of test services in San Carlos, California, including the education and experience requirements for laboratory directors and personnel (including requirements for documentation of competency); equipment validations; and quality management practices. All personnel involved in testing must maintain a California state license or be supervised by licensed personnel. We maintain a license in good standing with the California Department of Public Health, or CAPH. In addition, because we receive test specimens originating from New York, we have obtained a state laboratory permit for our San Carlos laboratory from the New York Department of Health, or DOH, which mandates proficiency testing regardless of whether the laboratory is physically located in New York. The New York state laboratory laws, regulations and rules are at least as stringent than the CLIA regulations and establish standards for the operation of a clinical laboratory and performance of test services, including education and experience requirements for laboratory directors and personnel; physical requirements of a laboratory facility; equipment validations; and quality management practices. The laboratory director must maintain a Certificate of Qualification issued by New York's DOH in permitted categories. In addition, we are subject to routine on-site inspections or inspections in response to a complaint under both California and New York state laboratory laws and regulations. If we are found to be out of compliance with either California or New York requirements, CAPH or New York's DOH may suspend, restrict or revoke our license or laboratory permit, respectively (and, with respect to California, may exclude persons or entities from owning, operating or directing a laboratory for two years following such license revocation), assess civil monetary penalties, or impose specific corrective action plans, among other sanctions. Any such actions could materially and adversely affect our business by prohibiting or limiting our ability to offer testing.

As noted above, a number of states require that we hold licenses or permits to test samples from patients in those states. We have also obtained licenses from states that we believe require us to do so, including Pennsylvania, Maryland, and Rhode Island, and we intend to comply with similar requirements for other states of which we may become aware. However, we cannot assure you that the regulators in each state will at all times find us to be in compliance with the applicable laws of their respective state, which may result in suspension, limitation, revocation or annulment of our laboratory's license for that state or negative impact to our CLIA license, censure, or civil monetary penalties, and would result in our inability to test samples from patients in that state. Any such actions could materially and adversely affect our business.

CMS also has the authority to impose a wide range of sanctions, including revocation of a laboratory's CLIA certification along with a bar on the ownership or operation of any CLIA-certified laboratory by any owners or operators of the deficient laboratory. If we fail to maintain our CLIA certification or any required state license or accreditation, or if any sanction were imposed upon us under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, we would not be able to operate our clinical laboratory and offer our testing services in the affected

states or countries, which would materially and adversely impact our business and results of operations. Bringing our laboratory back into compliance with CLIA requirements could cause us to incur significant expenses and potentially lose revenues in order to address deficiencies and achieve compliance.

Our cord blood and tissue banking activities are subject to regulations that may impose significant costs and restrictions on us.

Our Evercord cord blood and tissue banking service is subject to FDA regulatory oversight. Pursuant to FDA regulations, an individual or entity that performs any of the manufacturing steps in banking cells or tissues, including peripheral and cord blood (such as recovery, processing, donor screening, donor testing, storage, labeling, packaging, or distribution) must register and list with the FDA unless an exception applies. Based on our activities, we are subject to FDA requirements and are also subject to FDA inspection. We have registered and listed with the FDA as an establishment engaged in specific manufacturing steps, including collecting cord blood and tissue samples, donor screening and distribution of cord blood hematopoietic progenitor cells, or HPCs, which are the blood-forming stem cells that are used to treat patients with cancers such as leukemia or lymphoma, and other disorders of the blood and immune systems. We have also registered with the FDA as an establishment engaged in the storage of cord blood HPCs. We have contracted with Bloodworks, another FDA-registered establishment, to perform other manufacturing steps on our behalf, which we may do as a registered establishment. As the contractor establishment, we remain responsible for ensuring that our subcontractors perform each manufacturing step in compliance with applicable requirements, and are required to terminate any arrangement if our subcontractor is non-compliant. While we are not required to validate and oversee the processes of our subcontractor registered establishments, we are required to make an initial determination that the subcontractor is compliant with the applicable current good tissue practice regulations, or cGTPs, and to have policies and procedures in place to ensure that the subcontractor remains compliant throughout the term of the arrangement. We have made this determination with respect to Bloodworks and have put such procedures in place. If at some point we determine that Bloodworks is not in compliance with the applicable cGTPs, then we will be required to terminate the contract with Bloodworks. We are also responsible for any manufacturing step performed on our behalf by an individual or entity that is not required to register with the FDA, such as the doctors and midwives who perform the collection of the cord blood and tissue.

We are also required to comply with cGTPs that establish a comprehensive regulatory program for human cellular and tissue-based products designed to prevent the introduction, transmission or spread of communicable disease. We believe that we currently comply with cGTP requirements. However, the FDA may determine that we are not compliant or, even if we are currently compliant, we may not be able to maintain this compliance or comply with future regulatory requirements that may be imposed on us. In addition, it is also possible that the FDA may determine that one or more of our products do not meet all the criteria for regulation exclusively under 21 CFR Part 1271, thereby requiring an Investigational New Drug Application and eventually licensure pursuant to a Biologics License Application for any such products.

In certain states, manufacturing steps in banking stem cells from cord blood and tissue are subject to state licensure or registration and compliance with state requirements. Certain states regulate private cord blood and/or tissue banking activities, and may require us and our subcontractors engaged in specific manufacturing steps to become licensed, permitted or registered in such states. We believe that we are licensed, permitted or registered to operate in such states as required. If other states adopt similar requirements, we would have to obtain licenses, permits or registrations to continue providing services in those states.

Changes in government healthcare policy could increase our costs and negatively impact coverage and reimbursement for our tests by governmental and other third-party payers.

The U.S. government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. Government healthcare policy has been and will likely continue to be a topic of extensive legislative and executive activity in the U.S. federal government and many U.S. state governments. As a result, our business could be affected by significant and potentially unanticipated changes in government healthcare policy, such as changes in reimbursement levels by government third-party payers. Any such changes could substantially impact our revenues, increase costs and divert management attention from our business strategy. Going forward, we cannot predict the full impact of governmental healthcare policy changes on our business, financial condition and results of operations.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, or collectively, the PPACA, was signed into law in March 2010 and significantly impacted the U.S. pharmaceutical and medical device industries, including the diagnostics sector, in a number of ways. Among other things, the PPACA expanded healthcare fraud and abuse laws such as the False Claims Act and the Anti-Kickback Statute, including but not limited to required disclosures of financial arrangements with physician customers, required reporting of discovered overpayments, lower thresholds for violations, new government investigative powers, and enhanced penalties for such violations. The PPACA restricts insurers from charging higher premiums or denying coverage to individuals with pre-existing conditions, and requires insurers to cover certain preventative services without charging any copayment or coinsurance, including screening for lung, breast, colorectal and cervical cancers. However, there have been multiple attempts to repeal PPACA or significantly scale back its applicability, which could negatively impact reimbursement for our testing. This could adversely affect our test volumes and adversely affect our business, financial condition, results of operations, and cash flows. An example of an attempt to scale back PPACA came through the passing of the Tax Cuts and Jobs Act of 2017, or the Tax Act. The Tax Act repeals the individual mandate under PPACA, which required consumers to buy insurance or pay a penalty unless they qualified for an applicable exemption. The repeal of this mandate means that fewer consumers may carry insurance coverage and therefore may be less likely to elect to receive our testing because they would be required to pay out of pocket for such tests, which could impact our test volumes and adversely affect our business, financial condition, results of operations, and cash flows. The PPACA also created a new system of health insurance "exchanges" designed to make health insurance available to individuals and certain groups through state- or federally-administered marketplaces in addition to existing channels for obtaining health insurance coverage. In connection with such exchanges, certain "essential health benefits" are intended to be made more consistent across plans, setting a baseline coverage level. The states (and the federal government) have some discretion in determining the definition of "essential health benefits" and we do not know whether Panorama or our other tests will fall into a benefit category deemed "essential" for coverage purposes across the plans offered in any or all of the exchanges. If Panorama or any of our other tests are not covered by plans offered in the health insurance exchanges, our business, financial condition and results of operations could be adversely affected. Furthermore, various proposed legislative initiatives with respect to the PPACA, including possible repeal of the PPACA, have resulted in considerable uncertainty and concern regarding, for example, a patient's election to undergo genetic screening and whether doing so may impact health insurance eligibility. Because it is unclear whether or how the PPACA may change, and whether and to what extent NIPT, cancer screening or other genetic screening may be affected, we are uncertain how our business may be impacted.

In addition to the PPACA, various healthcare reform proposals have also emerged from federal and state governments. The Protecting Access to Medicare Act of 2014, or PAMA, introduced a multi-year pricing program for services payable under the CLFS that is designed to bring Medicare allowable amounts in line with the amounts paid by private payers. The rule issued by CMS to implement PAMA required certain laboratories to report third-party payer rates and test volumes. Since January 1, 2018, the Medicare payment rate for these tests is equal to the weighted median private payer rate reported to CMS, which for many tests is lower than the previous CLFS payment rates due to the often lower negotiated private payer rates applicable to large commercial laboratories that were required to report data to CMS. While we continue to believe that the new rates will have minimal impact on our business, the rates continue to be the subject of controversy in the industry. The implementation of the PAMA rates have negatively impacted overall pricing and reimbursement for many clinical laboratory testing services. In addition, federal budgetary limitations and changes in healthcare policy, such as the creation of broad limits for our tests and requirements that beneficiaries of government health plans pay for, or pay for higher portions of, clinical laboratory tests or services received, could substantially diminish the utilization of our tests, increase costs and adversely affect our ability to generate revenues and achieve profitability.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or how any such future legislation, regulation or initiative may affect us. Current or potential future federal legislation and the expansion of government's role in the U.S. healthcare industry, as well as changes to the reimbursement amounts paid by third-party payers for our current and future tests, may adversely affect our test volumes and adversely affect our business, financial condition, results of operations, and cash flows.

If we or our laboratory distribution partners, consultants or commercial partners act in a manner that violates healthcare fraud and abuse laws or otherwise engage in misconduct, we may be subject to civil or criminal penalties.

We are subject to healthcare fraud and abuse regulation and enforcement by both the U.S. federal government and the states in which we conduct our business, including:

- HIPAA, which created federal civil and criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and also imposes significant obligations with respect to maintenance of the privacy and security, and transmission, of individually identifiable health information;
- federal and state laws and regulations governing informed consent for genetic testing and the use of genetic material;
- federal and state laws and regulations governing the submission of claims, as well as billing and collection practices, for healthcare services;
- the federal Anti-Kickback Statute, which prohibits, among other things, the knowing and willful solicitation, receipt, offer or payment of remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare;
- the federal False Claims Act which prohibits, among other things, the presentation of false or fraudulent claims for payment from Medicare, Medicaid, or other government-funded third-party payers;
- federal laws and regulations governing the Medicare program, providers of services covered by the Medicare program, and the submission of claims to the Medicare program, as well as the Medicare Manuals issued by CMS and the local medical policies promulgated by the Medicare Administrative Contractors with respect to the implementation and interpretation of such laws and regulations;
- the federal Stark law, also known as the physician self-referral law, which, subject to certain exceptions, prohibits a physician from making a referral for certain designated health services covered by the Medicare program (and according to case law in some jurisdictions, the Medicaid program as well), 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;
- the federal Civil Monetary Penalties Law, which, subject to certain exceptions, prohibits, among other things, the offer 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;
- the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which, among other things, prohibits the knowing or willful payment or offer, or the solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing;
- the prohibition on reassignment by the program beneficiary of Medicare claims to any party; and
- state law equivalents of the above U.S. federal laws, such as the Stark law, Anti-Kickback Statute and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state data privacy and security laws and which may be more stringent than HIPAA.

Furthermore, a development affecting our industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability for, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment by a federal governmental payer program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government for violations of the False Claims

Act and permit such individuals to share in any amounts paid by the defendant to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it is subject to mandatory damages of three times the actual damages sustained by the government, plus mandatory civil penalties of up to approximately $22,000 for each false claim. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, and in some cases go even further because many of these state laws apply where a claim is submitted to any third-party payer and not merely a governmental payer program. As described further in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Consolidated Financial Statements, in 2018 we reached a settlement with the United States Department of Justice to resolve claims under a qui tam complaint regarding past reimbursement submissions. Although the settlement involved no admission of fault by us and no corporate integrity agreement, we cannot guarantee that we will not be subject to similar claims in the future.

Many of these laws and regulations have not been fully interpreted by regulatory authorities or the courts, and their provisions are open to a variety of interpretations. We have adopted policies and procedures designed to comply with these laws, and in the ordinary course of our business, we conduct internal reviews of our compliance with these laws. However, the rapid growth and expansion of our business both within and outside of the United States may increase the potential for violating these laws or our internal policies and procedures, and the uncertainty around the interpretation of these laws and regulations increases the risk that we may be found in violation of these or other laws and regulations, or of allegations of such violations, including pursuant to private qui tam actions brought by individual whistleblowers in the name of the government as described above. If our operations, including the conduct of our employees, distributors, consultants and commercial partners, are found to be in violation of any laws or regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement of profits, exclusion from participation in government programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could materially and adversely affect our business, financial condition and results of operations.

Failure to comply with privacy and security laws and regulations could result in fines, penalties and damage to our reputation and have a material adverse effect on our business.

The federal HIPAA privacy and security regulations, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act, or HITECH, which was enacted as part of the American Recovery and Reinvestment Act of 2009, establish comprehensive federal standards with respect to the use and disclosure of protected health information by health plans, healthcare providers, and healthcare clearinghouses, in addition to setting standards to protect the confidentiality, integrity and security of protected health information. The regulations establish a complex regulatory framework on a variety of subjects, including patient authorization of the use and disclosure of, administrative, technical and physical safeguards for, and analysis of security incidents and breach notification requirements with respect to, protected health information.

We have implemented policies and procedures related to compliance with the HIPAA regulations. The HIPAA privacy and security regulations establish minimum requirements, and do not supersede state laws that are more stringent. A number of states include medical information in the definition of personal information and have implemented requirements or standards more stringent than HIPAA. Therefore, we are required to comply with federal as well as various state privacy and security laws and regulations. HIPAA, as amended by HITECH, provides for significant fines and other penalties for wrongful use or disclosure of protected health information in violation of privacy and security regulations, including potential civil and criminal fines and penalties. We could also incur penalties, compliance costs as a result of non-compliance or damages under state laws pursuant to an action brought by a private party for the wrongful use or disclosure of confidential health information or other private personal information. In addition, other federal and state laws that protect the privacy and security of patient information may be subject to enforcement and interpretation by various governmental authorities and courts, resulting in complex compliance issues.

The European Union's data privacy regulations, the General Data Protection Regulation, or GDPR, became subject to enforcement in May 2018. These regulations comprehensively reform the prior data protection rules of the European Union, and are more stringent, provide for higher potential liabilities, and apply to a broader range of personal data than those in the United States. The GDPR is applicable to U.S.-based companies, such as ours, that do business or offer services in, or that process or hold personal data of data subjects in, the European Union. Our current processes and practices comply with the GDPR, and we are currently expending considerable time and resources, including

management attention, to continue to revise our practices to ensure ongoing compliance with GDPR. Furthermore, the GDPR enables EU member states to enact jurisdiction-specific requirements in key areas, which could require us to modify our plans to comply with the GDPR, or otherwise to implement multiple policies unique to the jurisdictions in which we operate, which could make it more difficult and resource-intensive to continue to operate in the European Union.

As we continue to expand and grow our business, our overall compliance with applicable laws and regulations may result in increased costs and attention of management, and failure to comply may result in significant fines, penalties and damage to our reputation. Additionally, the interpretation and application of health-related, privacy and data protection laws are often uncertain, contradictory and in flux, and it is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. As a result, we could be subject to government-imposed fines or orders requiring that we change our practices, which could cause us to incur substantial costs and may adversely affect our business and our reputation.

Changes in the way the FDA regulates the reagents, other consumables, and testing equipment we use when developing, validating, and performing our tests could result in delay or additional expense in bringing our tests to market or performing such tests for our customers.

Many of the sequencers, reagents, kits and other consumable products used to perform our testing, as well as the instruments and other capital equipment that enable the testing, are offered for sale for research use only, or RUO. In addition, our Signatera (RUO) test is a research use only offering. Products that are intended for research use only and are labeled as RUO are exempt from compliance with FDA requirements, including the approval, clearance or authorization and other product quality requirements for medical devices. A product labeled RUO but which is actually intended for clinical diagnostic use may be viewed by the FDA as adulterated and misbranded under the FDC Act and subject to FDA enforcement action. The FDA has said that when determining the intended use of a product labeled RUO, it will consider the totality of the circumstances surrounding distribution of the product, including how the product is marketed and to whom. In addition, many of the reagents used to perform our testing are offered for sale as analyte specific reagents, or ASRs. ASRs are medical devices and must comply with QSR provisions and other device requirements, but most are exempt from 510(k) and PMA premarket review. The FDA could disagree with a supplier's assessment that the supplier's products are ASRs, or could conclude that products labeled as RUO are actually intended for clinical diagnostic use, and could take enforcement action against the supplier, such as us with respect to Signatera (RUO), including requiring the supplier to cease offering the product while it seeks clearance, approval or authorization. Suppliers of RUO products that we employ in our other tests may cease selling their respective products, and we may be unable to obtain an acceptable substitute on commercially reasonable terms or at all, which could significantly and adversely affect our ability to provide timely testing results to our customers or could significantly increase our costs of conducting business.

The sequencers and reagents supplied to us by Illumina and the blood collection tubes supplied to us by Streck are labeled as RUO in the United States. We are using these sequencers, reagents and blood collection tubes for clinical diagnostic use. If the FDA were to require clearance, approval or authorization for the sale of Illumina's sequencers and if Illumina does not obtain such clearance, approval or authorization, we would have to find an alternative sequencing platform for Panorama. We currently have not validated an alternative sequencing platform on which Panorama could be run in a commercially viable manner. If we were not successful in selecting, acquiring on commercially reasonable terms and implementing an alternative platform on a timely basis, our business, financial condition and results of operations would be adversely affected. Similarly, a decision by the FDA to require clearance, approval or authorization for the sale by Streck of the blood collection tubes used for Panorama, or a finding that any of our other suppliers failed to comply with applicable requirements, could result in interruptions in our ability to supply our products to the market and adversely affect our operations.

Our use of hazardous materials in the development of our tests exposes us to risks related to accidental contamination or injury and requires us to comply with regulations governing hazardous waste materials.

Our research and development activities involve the controlled use of hazardous materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. In addition,

we are subject on an ongoing basis to federal, state and local regulations governing the use, storage, handling and disposal of these materials and specified hazardous waste materials. An increase in the costs of compliance with such laws and regulations could harm our business and results of operations.

If the validity of an informed consent from a patient intake for Panorama or our other tests is challenged, we could be precluded from billing for such testing, forced to stop performing such tests, or required to repay amounts previously received, which would adversely affect our business and financial results.

All clinical data and blood samples that we receive are required to have been collected from individuals who have provided appropriate informed consent for us to perform our testing, both commercially and in clinical trials. We seek to ensure that the individuals from whom the data and samples are collected do not retain or have conferred any proprietary or commercial rights to the data or any discoveries derived from them. Our partners operate in a number of different countries in addition to the United States, and, to a large extent, we rely upon them to comply with the individual's informed consent and with U.S. and international laws and regulations. The collection of data and samples in many different states and foreign countries results in complex legal questions regarding the adequacy of informed consent and the status of genetic material under a large number of different legal systems. The individual's informed consent obtained in any particular country could be challenged in the future, and those informed consents could be deemed invalid, unlawful or otherwise inadequate for our purposes. Any findings against us, or our partners, could deny us access to, or force us to stop testing samples in, a particular country or could call into question the results of our clinical trials. We could also be precluded from billing third-party payers for tests for which informed consents are challenged, or could be requested to refund amounts previously paid by third-party payers for such tests. We could become involved in legal challenges, which could require significant management and financial resources and adversely affect our revenues and results of operations.

Risks Related to Our Intellectual Property

Third-party claims of intellectual property infringement could result in litigation or other proceedings, which would be costly and time-consuming, and could limit our ability to commercialize our products or services.

Our success depends in part on our non-infringement of the patents or intellectual property rights of third parties. We operate in a crowded technology area in which there has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the genetic diagnostics industry. Certain third parties, including our competitors, have asserted and may in the future assert that we are employing their proprietary technology without authorization or that we are otherwise infringing their intellectual property rights. In particular, Illumina has filed a patent infringement lawsuit against us alleging that our Panorama test infringes certain claims under U.S. Patent 9,493,831, as further described in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Consolidated Financial Statements.

In addition, as further described in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Consolidated Financial Statements, on or about March 26, 2019, CareDX, Inc., or CareDX, our primary competitor in the transplant rejection testing field, filed suit against us in the United States District Court for the District of Delaware. The suit alleges that we infringed two of CareDX's patents, 9,845,497 and 8,703,652. The complaint seeks unspecified damages and injunctive relief. On or about April 10, 2019 CareDX filed another suit against us in the United States District Court for the District of Delaware. This suit alleges false advertising, trademark disparagement, unfair competition, and unfair or deceptive trade practices based on statements we have made regarding our Prospera product and how it compares to CareDX's Allosure product. The complaint seeks unspecified damages and injunctive relief. We continue to defend both of these matters vigorously, but cannot provide any assurance as to the ultimate outcome of either matter or that an adverse resolution to either matter or both matters would not have a material adverse effect on our financial condition and results of operations. We are unable to predict the ultimate outcome of either matter and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome of either matter.

The number of contested intellectual property and other proceedings may increase as the number of products and the level of competition in our industry segments grows. Defending against these claims is costly and may divert the attention of our management and technical personnel. If we are unsuccessful in defending against these claims, we could be required to stop developing or commercializing products or services; change our marketing practices; pay potentially

substantial monetary damages; and/or, in the case of patent infringement claims, obtain licenses from third parties, which we may be unable to do on acceptable terms, if at all, and which may require us to make substantial royalty payments. In addition, we could encounter delays in product introductions or sales growth while we attempt to develop alternative non-infringing products or alternative product messaging campaigns. Any of these or other adverse outcomes could prevent us from offering our tests or otherwise have a material adverse effect on our business, financial condition and our results of operations.

As we move into new markets and applications for our products, competitors in such markets may assert their patents and other proprietary rights against us as a means of blocking or slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may have significantly stronger, larger and/or more mature patent portfolios than we have. In addition, future litigation may involve patent holding companies or other patent owners or licensees who have no relevant product revenues and against whom our own patents may provide little or no deterrence or protection.

In addition, our agreements with some of our customers, suppliers, and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties if we determine it to be in the best interests of our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, financial condition and results of operations.

Any inability to effectively protect our proprietary technologies could harm our competitive position.

Our success and ability to compete depend to a large extent on our ability to develop proprietary products and technologies and to maintain adequate protection of our intellectual property in the United States and other countries; this becomes increasingly important as we expand our operations and enter into strategic collaborations with partners to develop and commercialize products. 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 proprietary positions of companies developing and commercializing tools for molecular diagnostics, including ours, generally are uncertain and involve complex legal and factual questions. This uncertainty may materially affect our ability to defend or obtain patents or to address the patents and patent applications owned or controlled by our collaborators and licensors.

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. Any finding that our patents are invalid or unenforceable could harm our ability to prevent others from practicing the related technology. We cannot be certain that we were the first to invent the inventions covered by pending patent applications or that we were the first to file such applications, and a finding that others have claims of 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. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing similar or alternative competing products or design around our patented technologies, and may therefore fail to provide us with any competitive advantage. Furthermore, as our issued patents expire, we may lose some competitive advantage as others develop competing products that would have been covered by the expired patents, and, as a result, we may lose revenue.

We may be required to file infringement lawsuits to protect our interests, which can be expensive and time-consuming. For example, we filed a patent infringement lawsuit against Illumina alleging that alleging that certain of Illumina's tests infringe on our U.S. Patent No. 8,682,592, as further described in "Note 8—Commitments and Contingencies —Legal Proceedings" in the Notes to Consolidated Financial Statements. We cannot assure you that we would be successful in proving any such infringement by a third party, and we may become subject to counterclaims by such third parties. Our patents may be declared invalid or unenforceable, or narrowed in scope, as a result of such litigation. Some third-party infringers may have substantially greater resources than us and may be able to sustain the costs of complex infringement litigation more effectively than we can. Even if we prevail in an infringement action, we cannot assure you that we would be fully or partially financially compensated for any harm to our business. We may be

forced to enter into a license or other agreement with the infringing third party on terms less profitable or otherwise less commercially acceptable to us than those negotiated between a willing licensee and a willing licensor. Any inability to stop third-party infringement could result in loss in market share of some of our products or lead to a delay, reduction and/or inhibition of our development, manufacture or sale of some of our products. A product produced and sold by a third-party infringer may not meet our or other regulatory standards or may not be safe for use, which could cause irreparable harm to the reputation of our products, which in turn could result in substantial loss in our market share and profits.

There is also the risk that others may independently develop similar or alternative technologies or design around our patented technologies, and our competitors or others may have filed, and may in the future file, conflicting patent claims covering technology similar or identical to ours. The costs associated with challenging conflicting patent claims could be substantial, and it is possible that our efforts would be unsuccessful and may result in a loss of our patent position and the issuance or validation of the competing claims. Should such competing claims cover our technology, we could be required to obtain rights to those claims at substantial cost.

Certain of our intellectual property was partly supported by a U.S. government grant awarded by the National Institutes of Health, and the government accordingly has certain rights in this intellectual property, including a non-exclusive, non-transferable, irrevocable worldwide license to use applicable inventions for any governmental purpose. Such rights also include "march-in" rights, which refer to the right of the U.S. government to require us to grant a license to the technology to a responsible applicant if we fail to achieve practical application of the technology or if action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry.

Any of these factors could adversely affect our ability to obtain commercially relevant or competitively advantageous patent protection for our products.

If we are not able to adequately protect our trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

We rely on trade secret protection 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. For example, although we have a policy of requiring our consultants, advisors and collaborators, including, for example, our strategic collaborators with whom we seek to develop and commercialize products, to enter into confidentiality agreements and our employees to enter into invention, non-disclosure and non-compete agreements, we cannot assure you that such agreements will provide for a meaningful protection of our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of information, including as a result of breaches of our physical or electronic security systems, or as a result of our employees failing to abide by their confidentiality obligations during or upon termination of their employment with us. Any action to enforce our rights is likely to be time-consuming and expensive, and may ultimately be unsuccessful, or may result in a remedy that is not commercially valuable. These risks are heightened in countries where laws or law enforcement practices may not protect proprietary rights as fully as in the United States or Europe. Any unauthorized use or disclosure of, or access to, our trade secrets, know-how or other proprietary information, whether accidentally or through willful misconduct, could have a material adverse effect on our programs and our strategy, and on our ability to compete effectively.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

Failure to maintain our trademark registrations, or to obtain new trademark registrations in the future, could limit our ability to protect our trademarks and impede our marketing efforts in the countries in which we operate. We may not be able to protect our rights to trademarks and trade names which we may need to build name recognition with potential partners or customers in our markets of interest. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive, particularly for a company of our size, and time-consuming, and we may not be successful. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks.

Our pending trademark applications in the United States and in other foreign jurisdictions where we may file may not be allowed or may subsequently be opposed. Even if these applications result in registration of trademarks, third parties may challenge our use or registration of these trademarks in the future. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or diagnostic companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or willfully used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that our employees' former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims, and if we are unsuccessful, we could be required to pay substantial damages and could lose rights to important intellectual property. Even if we are successful, litigation could result in substantial costs to us and could divert the time and attention of our management and other employees.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has been and may be volatile, which could subject us to litigation.

The trading prices of the securities of life sciences companies, including ours, have been and may continue to be highly volatile. Accordingly, the market price of our common stock is likely to be subject to wide fluctuations in response to numerous factors, many of which are beyond our control, such as those in this "Risk Factors" section and others including:

- actual or anticipated variations in our and our competitors' results of operations, as well as how those results compare to analyst and investor expectations;
- announcements by us or our competitors of new products, significant acquisitions, other strategic transactions, including strategic and commercial partnerships and relationships, joint ventures, divestitures, collaborations or capital commitments;
- changes in reimbursement practices by current or potential payers; for example, third-party payers are increasingly requiring that prior authorization be obtained prior to conducting genetic testing as a condition to reimbursing for it, which has reduced and/or delayed the reimbursement amounts we receive for Panorama or our other tests, which has impacted our results of operations since the fourth quarter of 2017, when these requirements began to take effect;
- failure of analysts to initiate or maintain coverage of our company, issuance of new securities analysts' reports or changed recommendations for our stock;
- forward-looking statements related to our financial guidance or projections, our failure to meet or exceed our financial guidance or projections or changes in our financial guidance or projections;
- periodic fluctuations in our revenue, due in part to the way in which we recognized revenue prior to transitioning to accrual accounting under ASC 606;
- actual or anticipated changes in regulatory oversight of our products;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- any major change in our management; and

- general economic conditions and slow or negative growth of our markets.

In addition, if the market for life sciences stocks or the stock market in general experiences uneven investor confidence, the market price of our common stock could decline for reasons unrelated to our business, operating results or financial condition. The market price of our common stock might also decline in reaction to events that affect other companies within, or outside, our industry even if these events do not directly affect us. Some companies that have experienced volatility in the trading price of their stock have been the subject of securities class action litigation. For example, as described in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Consolidated Financial Statements, a purported securities class action lawsuit had been filed against us, our directors and certain of our officers and stockholders. Under certain circumstances, we have contractual and other legal obligations to indemnify and to incur legal expenses on behalf of current and former directors and officers, and on behalf of our current or former underwriters, in connection with the litigation described in Note 8 in the Notes to Consolidated Financial Statements and in connection with any future lawsuits. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the market price of our common stock.

As a public company, we will continue to incur significantly increased costs and devote substantial management time.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are required to comply with the applicable requirements of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC and the Nasdaq Global Select Market, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Our management and other personnel have limited experience managing a public company and preparing public filings. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we have incurred and expect to continue to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act, which will increase when we are no longer an emerging growth company, as defined by the Jumpstart Our Businesses Act of 2012, or the JOBS Act. We hired, and we expect that we will need to continue to hire, additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and may need to establish an internal audit function. We cannot predict or estimate the amount of additional costs we may incur as a public company or the timing of such costs. Additional compensation costs and any future equity awards will increase our compensation expense, which would increase our general and administrative expense and could adversely affect our profitability. Also, as a public company it is more expensive for us to obtain director and officer liability insurance on reasonable terms. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For as long as we continue to be an emerging growth company, we intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced

disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict whether investors will find our common stock less attractive because we rely on these exemptions, which could result in a less active trading market for our common stock and increased volatility in our stock price. We will remain an emerging growth company until December 31, 2019.

If we are unable to implement and maintain effective internal controls over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected.

As a public company, we are required to maintain internal controls over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal controls over financial reporting and provide a management report on internal controls over financial reporting. The Sarbanes-Oxley Act also requires that our management report on internal controls over financial reporting be attested to by our independent registered public accounting firm, beginning with our annual report on Form 10-K for the year ending December 31, 2019.

Although we determined that our internal control over financial reporting was effective as of December 31, 2018, we must continue to monitor and assess our internal controls over financial reporting. If we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. If we identify material weaknesses in our internal controls over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal controls over financial reporting are effective, or, when required in the future, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities.

We do not intend to pay dividends on our capital stock so any returns will be limited to changes in the value of our common stock.

We have never declared or paid any cash dividends on our capital stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends on our capital stock may be prohibited or limited by the terms of any current or future debt financing arrangement. Any return to stockholders will therefore be limited to the increase, if any, in the price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans or in connection with acquisitions or strategic or commercial transactions, could result in additional dilution of the percentage ownership of our stockholders and could cause the price of our common stock to decline.

From time to time, we may issue additional securities or sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine. We also expect to continue to issue common stock to employees and directors pursuant to our equity incentive plans. If we sell or issue common stock, convertible securities or other equity securities in subsequent transactions, or common stock is issued pursuant to equity incentive plans, investors may be materially diluted. We may decide to issue common stock or other equity securities in connection with an acquisition or a strategic or commercial transaction, which could cause dilution to our existing stockholders. New investors in such subsequent transactions could gain rights, preferences and privileges senior to those of holders of our common stock.

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

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

We may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investments or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. Currently, only a small number of securities analysts cover our stock. If more analysts do not commence coverage of us, or if industry analysts cease coverage of us or fail to publish reports on us regularly, the trading price for our common stock could be adversely affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline.

Insiders have substantial control over us and will be able to influence corporate matters.

As of June 30, 2019, our directors and executive officers and their affiliates beneficially owned, in the aggregate, approximately 23.06% of our outstanding capital stock. As a result, these stockholders are and will continue to be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or its assets. This concentration of ownership could limit stockholders' ability to influence corporate matters and may have the effect of delaying or preventing a third party from acquiring control over us.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- authorize the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings;
- establish a classified board of directors so that not all members of our board are elected at one time;
- permit the board of directors to establish the number of directors;
- provide that directors may only be removed "for cause" and only with the approval of 75% of our stockholders;

- require super-majority voting to amend some provisions in our amended and restated certificate of incorporation and amended and restated bylaws; and
- provide that the board of directors is expressly authorized to make, alter or repeal our amended and restated bylaws.

In addition, Section 203 of the Delaware General Corporation Law may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law or any action asserting a claim against us that is governed by the internal affairs doctrine. 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 and may discourage these types of lawsuits. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition and results of operations.

ITEM 2 UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) *Recent Sales of Unregistered Securities*

None.

(b) *Use of Proceeds*

Not applicable.

(c) *Purchases of Equity Securities by the Issuer and Affiliated Purchasers*

None.

ITEM 3 DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4 MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5 OTHER INFORMATION

None.

ITEM 6 EXHIBITS

INDEX TO EXHIBITS

		Incorporated by Reference				
Exhibit No.	**Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed Herewith**
3.1	Amended and Restated Certificate of Incorporation of Natera, Inc.	8-K	001-37478	3.1	7/9/2015	
3.2	Amended and Restated Bylaws of Natera, Inc.	8-K	001-37478	3.2	7/9/2015	
31.1	Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X

		Incorporated by Reference				
Exhibit No.	**Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed Herewith**
32.1†	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2†	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document.					X
101.SCH	XBRL Taxonomy Extension Schema Document.					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X

† The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are not to be incorporated by reference into any filing of Natera, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, regardless of any general incorporation language contained in any filing.

SIGNATURES

Pursuant to the requirements 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.

NATERA, INC.

Date: August 8, 2019

By: / s / *Steve Chapman*
Name: **Steve Chapman**
Title: **Chief Executive Officer, President, and Director (Principal Executive Officer)**

By: / s / *Michael Brophy*
Name: **Michael Brophy**
Title: **Chief Financial Officer (Principal Financial and Accounting Officer)**

Exhibit 31.1

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

I, Steve Chapman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Natera, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2019

By: */s/ Steve Chapman*
Name: **Steve Chapman**
Title: **Chief Executive Officer and President**
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER
PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Brophy, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Natera, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2019

By: */ s / Michael Brophy*
Name: **Michael Brophy**
Title: **Chief Financial Officer**
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

I, Steve Chapman, Chief Executive Officer and President of Natera, Inc. (the "Company"), certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The quarterly report on Form 10-Q for the Company for the quarter ended June 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: August 8, 2019

By: */s/ Steve Chapman*
Name: **Steve Chapman**
Title: **Chief Executive Officer and President**
(Principal Executive Officer)

Exhibit 32.2

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

I, Michael Brophy, Chief Financial Officer of Natera, Inc. (the "Company"), certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The quarterly report on Form 10-Q for the Company for the quarter ended June 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: August 8, 2019

By: */ s / Michael Brophy*
Name: **Michael Brophy**
Title: **Chief Financial Officer**
(Principal Financial and Accounting Officer)