



Conceive. Deliver. Thrive.

## **2018 ANNUAL REPORT**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2018

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

(State or Other Jurisdiction of Incorporation or Organization)

01-0894487

(I.R.S. Employer Identification No.)

201 Industrial Road, Suite 410

San Carlos, CA

(Address of Principal Executive Offices)

94070

(Zip Code)

(650) 249-9090

(Registrant's Telephone Number, Including Area Code)

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

Title of each class

Name of each exchange on which registered

Common Stock, par value \$0.0001 per share

The NASDAQ Stock Market LLC  
(NASDAQ Global Select Market)

**Securities registered pursuant to Section 12(g) of the Act: None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Act. Yes ☐ No ☒

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or 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

☐

Non-accelerated filer

☐

Accelerated filer

☒

Smaller reporting company

☐

Emerging growth company

☒

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

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant on June 29, 2018, based on the closing price of \$18.82 per share as reported on the NASDAQ was approximately \$0.62 billion.

As of February 28, 2019, the number of outstanding shares of the registrant's common stock, par value \$0.0001 per share, was 62,790,368.

**DOCUMENTS INCORPORATED BY REFERENCE**

Information required in response to Part III of this annual report on Form 10-K is hereby incorporated by reference to portions of the Registrant's proxy statement for its Annual Meeting of Stockholders to be held in 2019. The proxy statement will be filed by the Registrant with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2018.

**Natera, Inc.**

**FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2018**

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## 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 kidney 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 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;
- 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 reliance on collaborators such as medical institutions, contract laboratories, laboratory partners, and other third parties;
- our ability to operate our laboratory facility 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;
- 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 future tests, including 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 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.

As used in this annual report on Form 10-K, the terms “Natera”, “Registrant”, “we”, “us”, and “our” mean Natera, Inc. and its subsidiaries unless the context indicates otherwise.

## PART I

### Item 1. BUSINESS

Note: A glossary of terms used in this Form 10-K appears at the end of this Item 1.

#### Overview

We are a growing diagnostics company with proprietary molecular and bioinformatics technology that we are deploying to change the management of disease worldwide. Our novel molecular assays reliably measure many informative regions across the genome from samples as small as a single cell. Our statistical algorithms combine these measurements with data available from the broader scientific community to identify genetic variations covering a wide range of serious conditions with best-in-class accuracy and coverage. Our goal is to develop and commercialize non- or minimally-invasive tests to evaluate risk, and thereby enable early detection, for a wide range of genetic conditions, such as Down syndrome, as well as cancer and organ transplant rejection. 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, initially for research use and which we are developing as a Clinical Laboratory Improvement Amendments, or CLIA, test. We have also begun to develop products for applications in organ transplant rejection. 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 and distribution partners, including many of the largest international laboratories.

Since 2009, we have launched a comprehensive suite of ten products in reproductive health—nine molecular diagnostic tests and a newborn stem cell banking offering to complement our prenatal testing portfolio—and our personalized liquid biopsy technology for research use only in oncology applications. We are currently working towards commercial launch of our CLIA liquid biopsy test and of our transplant rejection test, and intend to continue to launch new products in the future.

We launched Panorama, our non-invasive prenatal test, or NIPT, in March 2013 and have since gone from being the fourth company to enter the NIPT market to being the market leader by volume in the United States. Panorama represented approximately 55% of our revenues, with approximately 429,600 Panorama tests accessioned, during the year ended December 31, 2018. Our revenues were \$257.7 million in 2018, compared to \$209.6 million in 2017, as revised under Accounting Standards Codification Topic 606 (“ASC 606”), and \$212.5 million in 2016, as revised. Our net losses decreased to \$128.2 million in 2018 from \$137.6 million in 2017, as revised, but increased from \$100.3 million in 2016, as revised.

In prenatal testing, oncology and transplant rejection, the use of blood-based tests offers significant advantages over older methods, but the significant technological challenge is that such testing requires the measurement of very small amounts of relevant genetic material circulating – fetal DNA in prenatal testing, tumor DNA in oncology, and donor DNA in transplant rejection – within a much larger blood sample. Our approach combines proprietary molecular biology and computational techniques to measure genomic variations in tiny amounts of DNA, as small as a single cell. Our molecular biology techniques are based on measuring thousands of single nucleotide polymorphisms, or SNPs, simultaneously using massively multiplexed polymerase chain reaction, or mmPCR, to multiplex, or target, many thousands of regions of the genome simultaneously in a single test reaction. Our method avoids losing molecules, which can happen when samples are split into separate reaction tubes, so that all relevant variants can be detected. We believe our approach represents a fundamental advance in molecular biology. In prenatal testing, this approach is distinct from the approach employed with other commercially available NIPTs, which use first-generation “quantitative”, or counting, methods to compare the relative number of sequence reads from a chromosome of interest to a reference chromosome. Based on extensive data published in the journals *Obstetrics & Gynecology*, *American Journal of Obstetrics & Gynecology*, *Prenatal Diagnosis*, and others, we believe Panorama is the most accurate NIPT commercially available in the United States. In oncology, our assay has demonstrated the ability to detect circulating tumor DNA, or ctDNA, with a high degree of sensitivity and

specificity. In transplant rejection, our test performance in both clinical and analytical validation achieved higher sensitivity and higher area under the curve, or AUC, than both the current standard of care and the current commercially available test. The current standard of care in transplant rejection monitoring is estimated glomerular filtration rate, or eGFR, which is a clinically accepted but inaccurate biomarker for active transplant rejection.

## Our Solution

Genetic inheritance is conveyed through DNA, a naturally occurring information storage system. DNA stores information in a linear sequence of the chemical bases adenine, cytosine, guanine and thymine, represented by the symbols A, C, G, and T. Billions of bases of A, C, G, and T link together inside living cells to form the genome, which can be read like a code or a molecular blueprint for life. While differences in the specific sequence and structure of this code drive biological diversity, certain variations can also cause disease. Examples of genetic diversity include CNVs and SNVs. A CNV is a genetic mutation in which relatively large regions of the genome have been deleted or duplicated, and an SNV is a mutation where a single base has changed. When single base changes are common in the population, that position on the chromosome, or loci, is called a single nucleotide polymorphism, or SNP.

To make sense of this deep and rich set of biological data and deliver a test result, we have developed computationally intensive algorithms that combine the data generated by mmPCR with the ever-expanding set of publicly available data on genetic variations. Our technology is compatible with standard equipment used globally and a range of NGS platforms, and we have optimized our algorithms to enable laboratories around the world to run tests locally and access our algorithms in the cloud.

We believe that our mmPCR technology and proprietary algorithms, which have been proven in the context of NIPT, can be a powerful tool for oncology applications such as molecular treatment monitoring and molecular residual disease, which we refer to as MRD, assessment, and in applications to monitor for organ transplant rejection.

In particular, we believe that our ability to interrogate DNA at tens of thousands of loci in parallel in a single reaction, at the scale of a single molecule, is well suited to the analysis of cancer-associated genetic mutations in ctDNA, in which many loci must be interrogated simultaneously without splitting a sample, and in which it is important to achieve sensitivity to tiny amounts of tumor DNA as low as a single copy. We are initially focused on treatment monitoring and MRD assessment in solid tumors, where we have generated data in over a dozen different cancer types and have published data in lung, bladder, colorectal and breast cancer. Based on our internal estimates, we believe that the total addressable market in the United States for MRD and recurrence monitoring for solid tumor cancers is over \$12 billion, and the market for molecular treatment monitoring in metastatic disease is an additional \$2 billion.

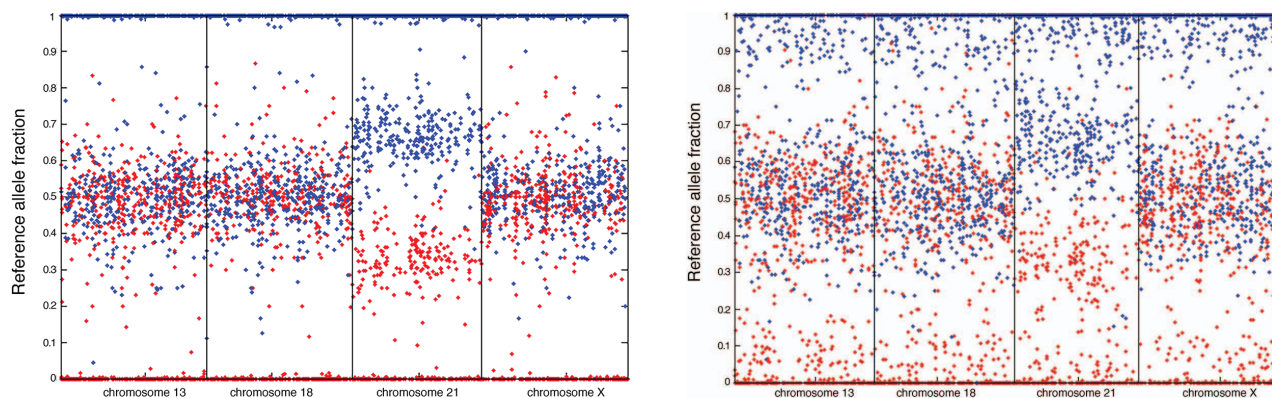
We have demonstrated our ability to detect both CNVs and SNVs from very low concentrations of ctDNA. Our technology was featured on the cover of the May 2017 issue of *Nature*, which highlighted our performance in detecting relapse early, and predicting patient response to adjuvant therapy, in patients with early stage non-small cell lung cancer. In August 2017, we launched Signatera™ (RUO), our first offering for oncology, for research use only, and we are working on developing this technology as a CLIA test. Signatera is a personalized assay that tests for the presence of ctDNA in a patient's blood, which is associated with micrometastatic disease that is often undetectable with standard imaging techniques. If left untreated, micrometastatic disease is likely to proliferate and cause relapse. Signatera is designed for optimal MRD analysis, targeting 16 clonal variants in each assay, and incorporating information obtained from analyzing mutations specific to an individual's tumor sample.

In transplant rejection, we have demonstrated the ability of our technology to measure the fraction of cell-free DNA that is donor-derived, or dd-cfDNA, which is DNA that is shed from a transplanted organ into circulation. We are working to commercialize a CLIA test based on this technology, which has been validated for detection of active rejection in renal transplant recipients, with test performance independent of donor type, rejection type, and clinical presentation.

Our technologies allow us to achieve a high signal-to-noise ratio when detecting fragments of DNA at frequencies as low as a single copy, which allows us to deliver tests with differentiated specificity and sensitivity. Furthermore, our current prenatal commercial tests assess the risk of a broad range of conditions, which we refer to as “clinical coverage,”

including common fetal aneuploidies, microdeletions, triploidy, and inherited genetic conditions that could be passed on from parent to child, from a single blood draw. We sell our tests directly and partner with other clinical laboratories to distribute our tests globally. Currently, all of our products other than our Constellation cloud software product and our Evercord newborn stem cell banking offering are laboratory developed tests, or LDTs. We perform commercial testing in our CLIA-certified laboratory.

An illustration of the resolution that can be achieved with our mmPCR capability is provided below. The figures display data from our approximately 20,000 primer mmPCR assay, where each primer targets one SNP. On the left, the assay is applied to a large genomic DNA sample from a child. On the right, the assay is applied to a single cell from the same child. Each dot represents data from a particular SNP location on a chromosome. The assay measures the amount of each of the two possible sequences of nucleotides, or alleles, at each SNP. The plots below show the relative proportion of the two alleles, plotted along the vertical axis, for each of the approximately 20,000 SNPs, arranged sequentially along the vertical axis. The two alleles are arbitrarily labeled A and B, and each dot is colored according to the allelic contribution of the mother—red (A) or blue (B). Those SNPs where both copies of DNA in the child contain only the A allele are red and are found at the very top of the plot, and those SNPs where both copies of DNA in the child contain only the B allele are blue and are found at the very bottom of the plot. The SNPs where the fetus contains at least one copy of the A allele and one copy of the B allele are found near the center of the plot. The four vertical bars separated by dotted lines display data from chromosomes 13, 18, 21 and X. For chromosomes 13, 18 and X, the middle band is centered on 0.5; which indicates that for those SNPs, the child has one copy of the A allele and one copy of a B allele (and therefore a relative proportion of 0.5), and, therefore, has the right number of chromosomes—two. In this sample, an additional chromosome is present at chromosome 21, which indicates the presence of trisomy 21. For chromosome 21, the bands centered at 0.33 and 0.66 signal the additional nucleotides contributed by the mother. The band centered at 0.33 represents SNPs where the child has two copies of the B allele and one copy of the A allele, and the band centered at 0.66 represents SNPs where the child has two copies of the A allele and one copy of the B allele. The assay clearly quantifies the difference between single molecules of a particular allele at each SNP. The images demonstrate our ability to derive actionable information from tiny quantities of DNA, as the data from a single cell in the image on the right is nearly as informative as the data from a large genomic sample in the image on the left.



Our bioinformatics technology complements our molecular technology to deliver a risk assessment with high sensitivity and specificity. We use proprietary statistical techniques to combine the measurements of our molecular assays with our internal databases and the vast and growing sources of publicly available genomic information to build highly detailed models of the genome of interest. This process includes the use of a statistical technique known as maximum likelihood estimation, or MLE, which is widely used in other industries, such as in the conversion of a noisy transmitted analog communications signal to a digital format. However, it is computationally complex to leverage this technique to combine genomic information from the patient's sample and information from the databases of the broader scientific community. We have issued U.S. patents claiming methods to do so and pending applications in the United States and abroad. We also maintain trade secrets on our processes and practices. Our proprietary solution using MLE enables us to continuously improve the performance of our existing tests and efficiently develop new ones. As our patient volumes grow,



our internal database of samples with genetic mutations and corresponding clinical outcomes further enhances our ability to interpret the clinical significance of complex genetic mutations. As the genomic data from the scientific community, such as from the Cosmic Database and the Cancer Genome Atlas, becomes richer, we can seamlessly integrate new clinical knowledge into our bioinformatics algorithm, driving further improvement in our tests.

## **Panorama**

We launched our Panorama NIPT in 2013, our microdeletions panel for Panorama in 2014 and our twins, egg donor, and surrogate screening capabilities in 2017. Panorama demonstrates the capabilities of our technology by employing our fundamentally unique approach of simultaneously measuring thousands of SNPs in a single test reaction to identify genetic variations in fetal DNA with a high degree of specificity and sensitivity.

Panorama helps physicians assess the risk of fetal genetic abnormalities by non-invasively screening for fetal chromosomal abnormalities, including Down syndrome, Edwards syndrome, Patau syndrome, Turner syndrome and triploidy, which often result in intellectual disability, severe organ abnormalities and miscarriage. Panorama can also identify fetal sex for single birth pregnancies as well as of each fetus in twin pregnancies. Panorama is also the only commercially available NIPT that can determine whether a set of twins is identical, or monozygotic, or fraternal, or dizygotic. Identifying a monozygotic twin pregnancy can prompt earlier, targeted ultrasound assessments for chorionicity and associated complications, while knowing that a twin pregnancy is dizygotic reduces concerns about certain complications, such as twin-twin transfusion syndrome.

Panorama is performed on a maternal blood sample and can be performed as early as nine weeks into a pregnancy, which is significantly earlier than traditional methods, such as serum protein measurement whereby doctors measure the presence and amount of certain hormones in the blood. Panorama starts with a simple blood draw from the mother, either in a doctor's office, in a laboratory or through a phlebotomist that may travel to the patient, and the sample is sent to our CLIA-certified and CAP-accredited laboratory in California. We extract DNA from each sample, amplify the specific SNPs that we are interested in measuring, and then sequence the DNA using NGS. Using our proprietary bioinformatics technology, we analyze the DNA sequences to assess the state of the fetal genome, focusing on the SNP data, while incorporating public information from the Human Genome Project. Our bioinformatics algorithm builds billions of detailed models of the potential genetic state of the sample to determine the most likely diagnosis. After Panorama generates its result, we provide the doctor or the laboratory with a simple report showing the risk that abnormalities are present in the fetus. In 2018, we averaged approximately 97% of Panorama results delivered within ten calendar days after we received the blood sample.

The analytic and clinical validity of our technology demonstrated in Panorama and our other products has been described in multiple peer-reviewed publications, including the journals *Clinical Embryology*, *Translational Oncology*, *Human Reproduction*, *Molecular Human Reproduction*, *Fertility and Sterility*, *PLOS ONE*, *Genetics in Medicine*, *Prenatal Diagnosis*, *Fetal Diagnosis and Therapy*, *Obstetrics & Gynecology*, *Genome Medicine*, and *American Journal of Obstetrics & Gynecology*. Based on data published in *Prenatal Diagnosis*, *Fetal Diagnosis and Therapy* and *Obstetrics & Gynecology*, Panorama demonstrated greater than 99% overall sensitivity for aneuploidies on chromosomes 13, 18 and 21 and triploidy and specificity of greater than 99.9% (less than 0.1% false positive rate) for each disorder, which we believe makes it overall the most accurate NIPT commercially available in the United States. A paper published in the August 2014 issue of *Obstetrics & Gynecology* reported that Panorama had a statistically significant lower false positive rate than other NIPT methods practiced by our U.S. competitors. Based on data published in *Obstetrics & Gynecology*, *Prenatal Diagnosis*, and *American Journal of Obstetrics & Gynecology*, we have also demonstrated the ability to identify fetal sex more accurately than competing NIPTs. This is partially a result of Panorama's unique ability to detect a vanishing twin, which is a known driver of fetal sex errors with quantitative methods used by our competitors. The October 2014 issue of the *American Journal of Obstetrics & Gynecology* noted that the ability of Panorama to identify additional fetal haplotypes is expected to result in fewer false positive calls and prevent incorrect fetal sex calls. A study reporting on the use of Panorama in over 30,000 women, published in the *American Journal of Obstetrics & Gynecology*, supported the use of NIPT as a first-line screening test for aneuploidy.

We believe Panorama's specificity and sensitivity can give patients and their physicians a greater degree of comfort in choosing to forego unnecessary invasive procedures, limiting the resulting risk of spontaneous miscarriage associated with invasive procedures and lowering the total cost to the healthcare system of these procedures.

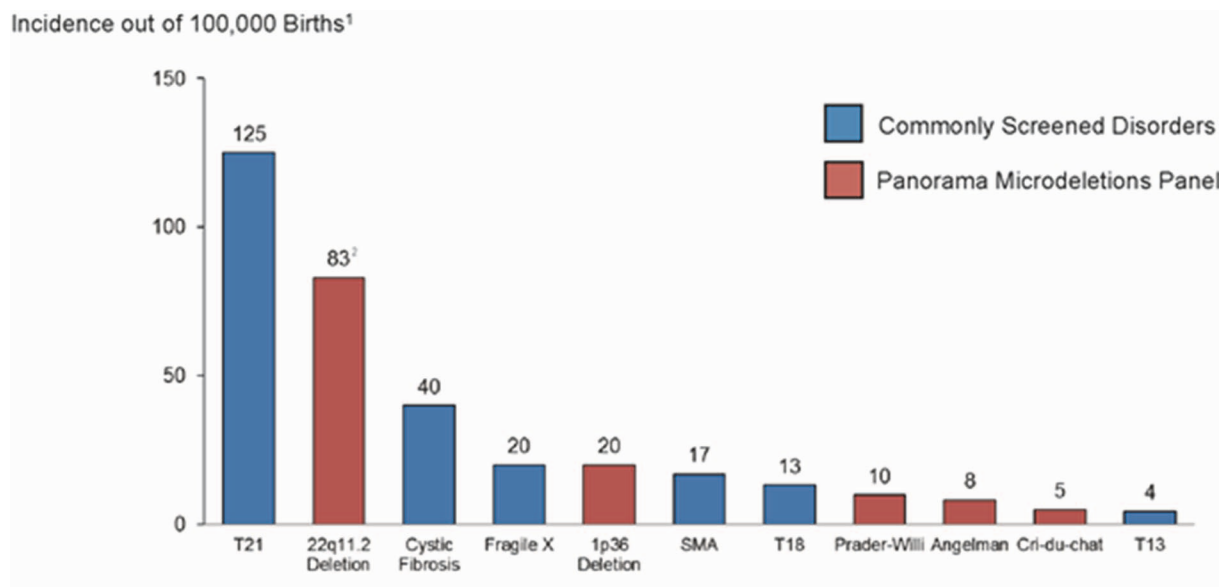
Panorama screens for common genetic conditions that affect both high-risk pregnancies, where maternal age is over 35 and which we estimate represent approximately 20% of the over 6 million pregnancies in the United States, or over 1.2 million pregnancies, and average-risk pregnancies, which we estimate represent approximately 4.9 million pregnancies in the United States. By recognizing early on the importance of NIPT to average-risk pregnancies and maintaining a focus on this market, we are strategically positioned to capitalize on what we believe will be increased penetration and reimbursement of NIPT in all risk categories. NIPT has not historically been well reimbursed for the average-risk population; however, commercial payers representing close to half of all commercial covered lives in the United States now have a positive coverage determination for NIPT for average-risk pregnancies, and we believe that this momentum will continue consistent with the growing consensus among physicians, professional societies, and third-party payers that NIPT is an appropriate screening tool for all pregnant women. ACMG is the most recent professional society that has advocated for broader adoption of NIPT, including 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 CNVs in the context of counseling that includes the risks/benefits and limitations of screening for CNVs. Furthermore, we believe that 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, can help to drive further progress in average-risk NIPT reimbursement. These results were published in January 2017 in *Genetics in Medicine*. As part of this trial, we ran the Panorama test on over 2,600 pregnant women through Women and Infants Hospital in Rhode Island. DNAFirst was the first study demonstrating routine clinical use of cfDNA-based prenatal screening for common aneuploidies in a general U.S. population, offered through primary obstetric care providers.

Our Panorama microdeletions panel screens for five of the most common genetic diseases caused by microdeletions – 22q11.2 deletion syndrome (DiGeorge syndrome), 1p36 deletion, Angelman syndrome, Cri-du-chat syndrome and Prader-Willi syndrome. Microdeletions are missing sub-chromosomal pieces of DNA, and can have serious health implications depending on the location of the deletion. Unlike Down syndrome, where the risk increases with maternal age, the risk of these five microdeletions is independent of maternal age. Based on data published in *Prenatal Diagnosis* and *American Journal of Obstetrics & Gynecology*, the combined prevalence of these targeted microdeletions is approximately one in 1,000 pregnancies, which collectively makes them more common than Down syndrome for women younger than approximately 28 years of age. Diseases caused by microdeletions are often not detected via common screening techniques such as ultrasound or hormone-based screening, yet the presence of a microdeletion can critically impact postnatal treatment. For example, when learning prior to birth that a newborn has 22q11.2 deletion syndrome, doctors will know to monitor the infant and administer calcium if needed to avoid seizures and permanent cognitive impairment, and will know to avoid administering routine vaccinations due to the immunodeficiency frequently associated with this condition.

Panorama has demonstrated best-in-class performance in screening for microdeletions. Panorama achieved sensitivity of 90% for deletions of approximately 2.9Mb for 22q11.2 deletion syndrome, based on a validation study that contained 10 positives. It has also been validated to perform at low fetal fractions, which refers to the percentage of fetal DNA in a maternal plasma sample. Based on data published in the February 2018 issue of *Clinical Genetics*, Panorama demonstrated a PPV of 44.2% and false positive rate of 0.07% for 22q11.2 deletion syndrome. Furthermore, we have completed enrollment in our 20,000-patient SNP-based Microdeletions and Aneuploidy RegisTry (SMART) observational study to evaluate the performance of SNP-based NIPT for 22q11.2 deletion syndrome by tracking birth outcomes in the general population among women who present clinically and elect Panorama microdeletion and aneuploidy screening as part of their routine care. We expect to review perinatal medical records and collect postnatal DNA in order to perform genetic diagnostic testing for 22q11.2 deletion syndrome. Results from the follow-up specimens will be compared to those obtained by the Panorama screening test to determine test performance, particularly PPV.

The graph below summarizes the incidence of genetic diseases for which prenatal screening is relatively common, as well as the incidence of genetic diseases caused by microdeletions that are screened by the Panorama microdeletions

panel. Incidence rates are higher than that of many commonly tested disorders, such as Cystic Fibrosis and Spinal Muscular Atrophy. We estimate that triploidy and the aneuploidy and microdeletion conditions that we screen for combined are more than three times as prevalent in the general population as the three most common autosomal aneuploidies, trisomies 13 (Patau syndrome), 18 (Edwards syndrome), and 21 (Down syndrome), alone.

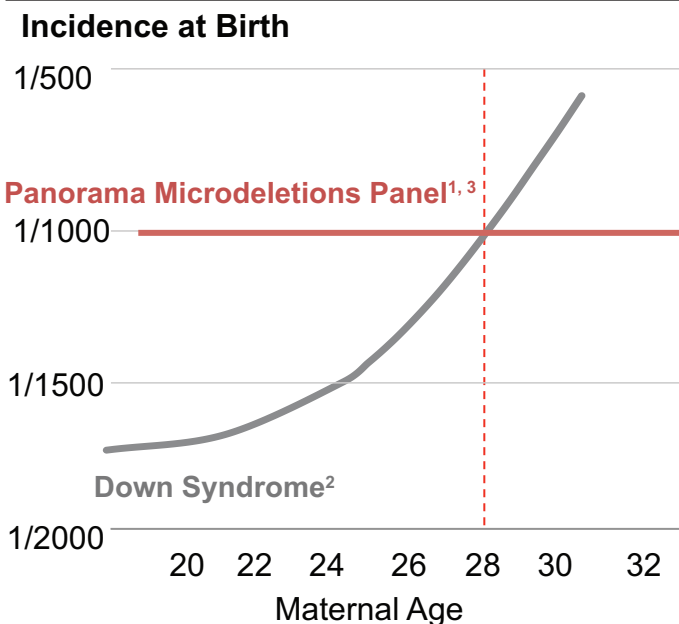


1. Hall. Panorama™ Non-invasive Prenatal Screening for Microdeletion Syndromes. 2013.

2. Gross, et al. Clinical experience with single-nucleotide polymorphism-based non-invasive prenatal screening for 22q11.2 deletion syndrome. Ultrasound Ob Gyn, 2016.

The graph below demonstrates how the relative incidence of Down syndrome and genetic diseases caused by the microdeletions screened for by the Panorama microdeletions panel varies with maternal age.

## Prevalence: Incidence Does Not Change with Age<sup>3</sup>



1 Grati, et al. Prevalence of recurrent pathogenic microdeletions and microduplications in over 9,500 pregnancies. *Prenatal Diagnosis*. 2015.

2 Snijders, et al. Maternal age and gestational age-specific risk for chromosomal defects. *Fetal Design Ther.* 1995.

3 Hall, Panorama™ Non-Invasive Prenatal Screening for Microdeletion Syndromes. 2013.

Because the microdeletions that we screen for are more common at birth than fetal aneuploidies for children born to younger women, and based on the performance of Panorama on microdeletions, we believe our microdeletions testing capability is a significant driver of Panorama adoption in all risk categories, including those who are traditionally considered average-risk. We intend to continue to work closely with physicians, medical societies, payers, patient advocacy groups such as the International 22q11.2 Deletion Syndrome Foundation, Inc., and our laboratory partners to demonstrate that Panorama's sensitivity and specificity across a range of chromosomal abnormalities and superior false positive rates, coupled with disease coverage for conditions for which prevalence does not vary with maternal age, represent a compelling case for a continued shift towards broad adoption in the average-risk population.

Furthermore, we believe that we are well-positioned for what we anticipate will be stable reimbursement for NIPT for microdeletions over the long term. A CPT code for use in billing and reimbursement for microdeletions testing went into effect in January 2017, and CMS provided a pricing benchmark for aneuploidy and microdeletions testing. See “—Reimbursement.” Since there are some Medicaid programs that haven't yet priced aneuploidy testing, we expect the pricing of aneuploidy testing set by CMS will further increase the number of Medicaid programs that price the test and may result in Medicaid plans pricing microdeletions testing at a faster pace. In addition, although most commercial insurances have already priced aneuploidy testing, the price established by CMS for microdeletions testing can serve as a relevant benchmark for pricing discussions with commercial insurance plans to begin reimbursement for microdeletions testing. Our microdeletions reimbursement has been, and we expect that it will, at least in the near term, remain low under the CPT code, either due to reduced reimbursement or third-party payers declining to reimburse under the code; however, we believe that growing recognition from professional societies, combined with the performance of our microdeletions

test and the additional validation data from our SMART study that we expect to report on the sensitivity and specificity of our tests, will drive broader reimbursement in the future.

Panorama is also validated to screen twin pregnancies, as well as egg donor and surrogate pregnancies. Our unique SNP technology makes Panorama the only commercially available NIPT that can distinguish between each twin's DNA, and therefore can determine zygosity, or whether the twins are identical or fraternal, and the fetal sex of each twin. Determining zygosity early in a pregnancy can help guide the management of a pregnancy, as certain monozygotic, or identical twin, pregnancies are at higher risk for various complications such as twin-twin transfusion syndrome, where there is an unequal sharing of blood, and therefore unequal growth, between the twins. Panorama screens twin pregnancies for Down, Edwards and Patau syndromes and, for identical twins, Turner syndrome and 22q11.2 deletion syndrome. In validation studies, Panorama identified identical twins with >99% sensitivity and specificity and achieved a combined sensitivity of >99% and specificity of >99% for Down, Edwards and Patau syndromes in twin pregnancies.

Since launching Panorama, we have implemented various updates to both the molecular and computational portions of Panorama, continuing to improve performance and efficiency, and reduce the cost of running the test, for example by incorporating screening for 22q11.2 deletion syndrome in our base Panorama panel. Previous updates have significantly reduced Panorama's no-call rate, improved sensitivity at lower fetal fractions, and simplified sample collection for clinics, and we've improved our microdeletions testing protocol to increase PPVs and reduce false positive rates. In validation studies, Panorama has demonstrated greater than 99% sensitivity and specificity for Down syndrome, and a combined sensitivity and specificity of greater than 99% across Down, Edwards, Patau and Turner syndromes. Furthermore, Panorama continues to maintain the highest commercially available sensitivity (90%) for deletions of approximately 2.9Mb for 22q11.2 deletion syndrome, based on a validation study that contained 10 positives.

Panorama's commercial performance has been consistent with our initial validation data. Data published in the *American Journal of Obstetrics & Gynecology* on 28,739 commercial cases of Panorama that were screened for Down, Edwards, Patau and Turner syndromes demonstrated an overall PPV of 83% for all indications combined. We believe Panorama's performance in commercial practice represents a significant improvement over first-generation NIPTs that rely on quantitative methods. Because Panorama does not require a reference chromosome, it is uniquely able to detect triploidy as well as full molar pregnancies. Panorama's ability to differentiate between maternal and fetal DNA also allows Panorama to identify the presence of a vanishing twin, as well as maternal abnormalities, which have been shown in multiple studies to lead to false positives when using quantitative methods, particularly in the sex chromosomes where maternal abnormalities are common.

Panorama has demonstrated substantial commercial success to date. We believe our test performance has allowed us to command a price premium compared to low-cost NIPTs while continuing to maintain growth in volume and revenue from Panorama.

## ***Horizon***

We launched our Horizon carrier screening test in 2012. Horizon helps couples determine if they are carriers of genetic mutations that cause specific diseases. Depending on the specific disease, if one or both parents are carriers for a specific disease, it could result in a child affected with the disease. Many people do not know they are a carrier for an inherited genetic disease until they have an affected child. These diseases are rare and usually there is no family history, although certain disorders are more common in certain ethnic groups. However, ethnicity may no longer be a reliable predictor of carrier status, as patients are increasingly of mixed or uncertain ethnicities. Accordingly, the industry's approach to carrier screening has evolved over time, from ethnic-based screening targeting specific ethnicities with a higher incidence of screened conditions, to pan-ethnic screening for certain recommended conditions available to all patients, and most recently to expanded screening for many conditions simultaneously. In early 2017, ACOG expanded its guidelines on carrier screening, recommending universal screening for Spinal Muscular Atrophy in addition to Cystic Fibrosis, as many genetic conditions are not limited to any specific ethnic group, and providing guidance on expanded carrier screening.

Horizon was created based on recommended screening guidelines from ACOG, ACMG, and the Victor Center for the Prevention of Jewish Genetic Diseases. Horizon screens for up to 274 inherited diseases, including Cystic Fibrosis, Duchenne Muscular Dystrophy, or DMD, Spinal Muscular Atrophy, Fragile X Syndrome and other conditions. Most conditions on the Horizon panel are autosomal recessive disorders, which means that both parents must be carriers for their children to be at risk. Some conditions are X-linked disorders, which are inherited from a mother who is a carrier and primarily affect male children. If both partners are carriers for the same recessive genetic disease, the couple has a 25% chance of having an affected child in each pregnancy. If a woman is a carrier of an X-linked disease, she has up to a 50% chance of having an affected child in each pregnancy. DMD, an X-linked condition, affects approximately 1/3500 male births, an incidence similar to Cystic Fibrosis and to Fragile X Syndrome in males. DMD is the most common muscular dystrophy in children and affects families of all ethnicities. Approximately 2/3 of clinically diagnosed cases of DMD are attributable to a carrier mother, who is likely unaware that she is a carrier. In addition to providing information about reproductive risks, carrier screening can identify women who are, themselves, at risk of health effects caused by defects in the DMD gene.

The blood or saliva sample required for Horizon can be obtained simultaneously with the blood sample required for Panorama, which makes it easier for us to offer, and for patients to take, both tests. Horizon employs various methodologies, including next generation sequencing and copy number analysis, often in combination in order to increase test sensitivity, to analyze the DNA from the individual's blood or saliva sample to determine if the individual is a carrier for the genetic diseases being screened. Horizon test results are generally returned to the ordering physician in ten to 15 business days from the day we receive the sample, depending on the number of conditions the patient has requested to be screened.

### ***Vistara***

We launched Vistara, an NIPT that screens for single-gene disorders across 30 genes, in 2017. Vistara is a complement to Panorama, and screens for severe skeletal, cardiac and neurological conditions which are often associated with cognitive disabilities or require surgical intervention. The conditions screened by Vistara have a combined incidence of approximately 1 in 600, which is higher than that of Down syndrome as well as Cystic Fibrosis, and are associated with advanced paternal age. Other NIPTs do not screen for these conditions, and prenatal ultrasounds may either fail to detect these disorders or the disorders may not present until much later in the pregnancy, after birth or even into childhood. Furthermore, family history is not a good indicator of risk for these conditions, which are commonly caused by *de novo*, or new and not inherited, mutations. Screening for these conditions early in the pregnancy can facilitate early diagnosis, enable patients to be referred to MFMs and other specialists for targeted evaluations, guide labor and delivery management, and allow families to mobilize resources, ask questions and anticipate future needs. We have received a CE Mark for Vistara from the European Commission.

In validation studies, Vistara demonstrated a combined analytical sensitivity and analytical specificity of greater than 99%.

### ***Other reproductive health products***

Our preimplantation genetic test for aneuploidy, or PGT-A, which we market under the Spectrum brand, are for couples undergoing IVF. Spectrum can improve the chance of a successful pregnancy while reducing the chance of miscarriage or of having a child with a chromosome condition, by helping to identify the healthiest embryos during an IVF cycle. Spectrum evaluates the number of chromosomes in embryos to detect extra or missing pieces of chromosomes prior to transfer of embryos created through IVF procedures, which have a high rate of non-viable chromosomal abnormalities, known as aneuploidy, and screens for inherited genetic disorders. This allows IVF physicians to select and transfer chromosomally normal embryos. Aneuploidy is common in human embryos—particularly as women age—and is the primary cause of failed IVF. PGT-A has been shown to improve IVF outcomes for all women, regardless of maternal age. In a study published in April 2018, a retrospective analysis of pregnancy outcomes demonstrated that use of Spectrum during IVF led to increased rates of implantation, including in older women, clinical pregnancy, and live births. The study findings also demonstrated that use of PGT-A can increase the use of single embryo transfer, which can reduce the risks of multiple pregnancies. Spectrum incorporates our proprietary technology to further screen for uniparental disomy, in

which two copies of a chromosome come from the same parent; confirm parentage; and determine the parental origin of the chromosomal abnormality.

Anora is our products of conception, or POC, test, which analyzes miscarriage tissue from women who have experienced one or more pregnancy losses to determine whether there was an underlying chromosomal reason for the loss. The Anora test is helpful to obstetricians, gynecologists and IVF physicians in supporting their patients' reproductive goals. Anora can help couples understand the likelihood of another miscarriage, their future reproductive options, and whether there are any steps that may help them avoid a miscarriage in future pregnancies.

Our non-invasive prenatal paternity product allows a couple to safely establish paternity without waiting for the child to be born. Testing can be done as early as nine weeks in gestation using a blood draw from the pregnant mother and alleged father. Our internal data indicates that the accuracy of this test is greater than 99.99%. We have licensed this technology to a third party to perform the test in its clinical laboratory.

### ***Constellation***

Our Constellation software forms the core of our cloud-based distribution model. Through this model, we have been able to expand access to our molecular and bioinformatics capabilities worldwide, enabling laboratories, under a license from us, to run the molecular workflows themselves and then access our computation-intensive bioinformatics algorithms through Constellation, which runs in the cloud, to analyze the results. As of March 1, 2019, 15 licensees are using our Constellation platform commercially, including 14 in NIPT and one in prenatal paternity testing. We have licensing contracts with various other laboratories in the United States and internationally to develop products in both NIPT and oncology. Our licensees are in various stages of development and implementation of an NIPT product. We leverage Constellation to enhance adoption of our tests among laboratory licensees globally, and to perform our internal commercial laboratory activities and research and development of our products.

We have received CE Marks from the European Commission for our Constellation software and for the key reagents that our laboratory licensees need to run their portion of the Panorama test prior to accessing our algorithms through Constellation. These CE Marks enable us to offer Constellation in the European Union and other countries that accept a CE Mark. We are pursuing other regulatory approvals, as needed, to allow the international roll out of Constellation in regions that do not accept a CE Mark.

We believe that our cloud-based distribution model provides us with a competitive advantage by allowing us to, among others, accelerate international adoption by leveraging our licensees' existing capabilities, efficiently achieve scale, and reduce costs.

### ***Evercord***

We launched Evercord, a private cord blood and tissue banking service, in 2017. This offering enables expecting parents to collect, store and potentially retrieve their newborn's stem cells for therapeutic use in transplantation and regenerative medicine applications for the child or related family members. Cord blood, which is the blood contained in the placental blood vessels and umbilical cord, contains HPCs, which are the blood-forming stem cells that are routinely used to treat patients with cancers such as leukemia or lymphoma, and other disorders of the blood and immune systems. Other sources of HPCs include bone marrow and peripheral blood, which is blood circulating in the body. Scientific literature has shown that in successful transplants, cord blood HPCs may not require as exact a match as HPCs from bone marrow or the bloodstream do, and, as a result, there is a higher chance of finding a cord blood stem cell match for transplant. Cord tissue, which is the tissue surrounding the umbilical vein and blood vessels in the umbilical cord, contains mesenchymal stem cells, or MSCs. MSCs can inhibit inflammation following tissue damage, secrete growth factors that aid in tissue repair, and develop into many different cell types such as bone, cartilage, muscle and nerve cells. Although there are no proven medical treatments currently available using cord tissue or MSCs, MSCs have the potential to treat more conditions than HPCs alone, such as heart disease, Parkinson's disease and lung cancer. Published data suggests that one in three people in the United States, or 128 million people, could potentially benefit from regenerative medicine applications of cord blood and tissue if they are proven effective. More than 300 clinical trials involving cord blood and

tissue stem cells are currently underway, including studies focused on regenerative medicine. More than 30,000 cord blood stem cell treatments have been conducted worldwide. Based on the advances in research focused on stem cells and regenerative medicine, it is anticipated that number may continue to grow.

We believe that our Evercord offering is a natural extension of our mission and our experience in genetic testing, and ties in well to our other offerings. Our Horizon carrier screening test includes 35 of the nearly 80 diseases for which cord blood stem cell treatment has been administered. This complementary product offering also allows us to optimize our sales and marketing strategy and engage with potential customers earlier than our competitors in this space, through our patient and provider interactions early in their pregnancies facilitated by our NIPT and carrier screening offerings.

Our Evercord service was created in partnership with Bloodworks Northwest, or Bloodworks, which operates a public cord blood bank at one of only seven FDA-licensed cord blood banking facilities. Bloodworks has 20 years of cord blood banking experience and has released over 1,000 cord blood units for transplants. Under our service agreement with Bloodworks, Bloodworks performs processing and infectious disease testing services on blood samples submitted by Evercord customers and cryo-preserved the cord blood and tissue samples at its Seattle, Washington-based storage facility. We are also in the process of building out our own storage facility in the Seattle area, and expect to begin storing samples cryo-preserved by Bloodworks in our facility in mid-2019. We believe that we are well positioned to leverage our established commercial capabilities for Evercord because we already engage with potential Evercord customers through our offering of Panorama and Horizon products. Also, we believe that our patient portal and healthcare provider digital services through Natera Connect help us to establish a relationship and level of familiarity and trust, which puts us at a competitive advantage over other cord blood banking providers.

### *Signatera*

MRD assessment has become a standard of care in the management of patients with hematological malignancies, but until now it has not been possible in solid cancers due to technical limitations. Accurate MRD testing and molecular monitoring offers the potential for physicians to change or escalate treatment in patients who are MRD-positive, and to de-escalate or avoid unnecessary treatment in patients who are MRD-negative. It also holds potential as a surrogate endpoint in clinical trials.

In 2017 we launched Signatera (RUO), our first oncology offering, for research use only to cancer researchers and biopharmaceutical companies. Signatera (RUO) is a personalized circulating tumor DNA (ctDNA) assay that analyzes blood for the presence of mutations specific to an individual's tumor. Each patient receives a custom assay, designed and manufactured on an individual basis based on the mutational signature found in that patient's tumor. Signatera (RUO) is designed to screen for an average of 16 tumor-derived targets with each assay, and is able to detect mutations at concentrations as low as 0.01% fraction of cfDNA. We believe this approach is optimal in the MRD setting, in which it is common for tumor DNA to be present only at low frequencies immediately after treatment. In comparison, static liquid biopsy panels screen for a generic set of mutations independent of an individual's tumor, generally covering fewer than five mutations for each patient and resulting in sensitivity that may suffer at low frequencies. The static approach also becomes economically inefficient in a commercial setting when scaling up to build larger panels that cover more mutations. We believe that Signatera's approach, however, would be cost-effective and a compelling tool for repeat testing over a period of time. Signatera is also optimized to achieve high specificity on a sample level by requiring detection of multiple mutations in order for a plasma sample to be considered ctDNA positive. We expect to commercialize this technology for clinical use as an LDT in our own CLIA-certified and CAP-accredited laboratory in 2019.

Our technology was selected for use in Cancer Research UK/University College London's Tracking Cancer Evolution through Therapy (TRACERx) clinical trial for the multi-year monitoring of patient-specific SNVs in plasma, to understand the evolution of cancer mutations over time, and to monitor patients for disease recurrence. Results from the first 100 early-stage lung cancer patients analyzed as part of the study were featured on the cover of the May 2017 issue of *Nature* and showed that an early prototype version of Signatera identified 43% more ctDNA-positive early-stage lung cancer cases than a generic lung cancer panel and demonstrated its potential to detect residual disease, measure treatment response, and identify recurrence up to 11 months earlier than the standard of care, with a sensitivity of 93% at time of relapse.



We have also completed research collaborations with Aarhus University in Denmark in locally advanced muscle invasive bladder cancer and in colorectal cancer. In both the bladder study and the colon study, blood was drawn prospectively at regular intervals over more than two years from initial diagnosis. The studies demonstrated the ability of our Signatera (RUO) test to stratify patients by whether they are MRD positive or negative based on post-treatment presence or absence of ctDNA in the blood. Signatera (RUO) detected molecular relapse an average of four months prior to clinical relapse in bladder cancer, and an average of over seven months in colorectal cancer. In addition to the data in MRD and recurrence monitoring, our Signatera technology showed promise in treatment response monitoring. In addition, in the bladder study, ctDNA analysis using Signatera (RUO) at the time of diagnosis predicted treatment outcome more accurately than all other variables traditionally used for clinical staging.

We have also completed two studies in breast cancer. In our study with Cancer Research UK-funded researchers at Imperial College London and the University of Leicester, U.K., which included patients with all three of the key breast cancer subtypes (ER+, HER2+, and Triple Negative), blood was prospectively collected every six months from patients who were relapse-free for at least three years after the completion of adjuvant treatment. Signatera (RUO) detected molecular residual disease with a lead time of up to two years prior to clinical or radiological detection, and overall detected clinical relapse with a sensitivity of 89% at time of relapse. Our second study in breast cancer, the Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging and Molecular Analysis 2 (I-SPY 2) trial with the University of California, San Francisco and QuantumLeap Healthcare Collaborative, launched in 2010, was a multi-center study evaluating the safety and efficacy of investigational therapies combined with early treatment in women with newly diagnosed, locally advanced breast cancer. As part of this trial, we analyzed blood samples at various points throughout patient treatment to evaluate the effectiveness of Signatera in monitoring disease burden, treatment response, and residual disease, as compared to traditional imaging methods. The results of this trial demonstrated that the change of measurable ctDNA from positive to negative during neoadjuvant treatment predicted therapeutic response, while failure to clear ctDNA after neoadjuvant treatment correlated with poor clinical outcomes. ctDNA levels were also associated with disease burden as determined by imaging.

We are currently participating in research collaborations with various cancer centers and pharmaceutical companies in multiple cancer types, such as with Institut Jules Bordet, a multidisciplinary cancer reference center in Belgium, using our Signatera (RUO) assay to evaluate molecular response and minimal residual disease in women with early stage breast cancer, and Fox Chase Cancer Center, a leading cancer center in the United States, to assess our Signatera (RUO) assay for recurrence monitoring in kidney cancer.

### ***Transplant Rejection***

We are working to commercialize our technology for application in organ transplant rejection, and are initially focused on kidney transplants. The current tools for diagnosing organ transplant rejection are either invasive (biopsies) or inaccurate (serum creatinine), resulting in an unmet need for better diagnostic tools to monitor for allograft rejection and improve patient management and outcomes. Our assay is designed to detect active rejection in patients who have undergone kidney transplantation by measuring the fraction of dd-cfDNA in the recipient's blood, which can spike relative to background cfDNA when the transplanted organ is injured due to immune rejection. Our goal is to help physicians detect rejection events earlier, avoid unnecessary biopsies, and safely optimize immunosuppression levels, potentially lowering the overall costs associated with transplant care and improving graft survival. Based on our internal estimates, we believe the total addressable market in the United States for tests such as ours that predict kidney transplant rejection is over \$2 billion.

In June 2018, we announced study results in collaboration with the University of California, San Francisco, a recognized leader in transplantation care, demonstrating strong performance of our mmPCR technology for detecting active rejection in patients with kidney transplants. In the blinded, retrospective study, we leveraged our validated SNP technology to measure dd-cfDNA levels in plasma samples from kidney transplant patients, including patients experiencing active rejection. Our assay demonstrated 89% sensitivity in detecting active rejection, with specificity of 73%, based on a cutoff of 1% dd-cfDNA. The assay performed particularly well in detecting T-cell mediated rejection (TCMR) and subclinical rejection, both of which we believe are areas of unmet need.

In an analytical validation study published in the February 2019 issue of *Transplantation*, our assay demonstrated superior precision, up to 5 times better than the competing dd-cfDNA assay. Precision is a measure of the test's ability to give the same result when a single sample is tested repeatedly. This study also included donor-recipient pairs that were related, such as parents or siblings, as well as non-related. This is significant because an estimated 52% of live kidney donations are from a biological relative of the patient, but it is technically challenging to differentiate between DNA patterns of close relatives. We were able to achieve a high degree of accuracy in these challenging cases by leveraging our experience with SNP-based methods in the prenatal setting.

## **Direct Sales Force and Global Distribution Network**

Through our direct sales efforts and worldwide network of over 100 laboratory and distribution partners, we have established a broad distribution channel. Our own direct sales force and managed care teams, which include approximately 150 genetics-focused sales representatives, anchor our commercial engagement with physicians, laboratory partners, and payers, and sell directly to MFMs, OB/GYNs, physicians or physician practices, IVF centers, or integrated health systems. In the NIPT market, Panorama is typically ordered for a patient by an MFM or OB/GYN. There are over 37,000 OB/GYNs in the United States and most of them practice generalist medicine for women's health. They typically only assist women with average risk pregnancies and will refer women with high risk pregnancies to one of the more than 2,000 MFMs in the United States. We believe that Panorama will continue to be adopted by physicians for broader use in average risk pregnancies, and therefore anticipate that we will continue to see an increasing proportion of Panorama orders in the future from OB/GYNs.

Where our sales force can access physician offices directly, as in the U.S. market, we are able to maximize cross-selling opportunities by offering the full portfolio of our products. For example, we are promoting the use of Panorama NIPT, our Panorama microdeletions panel, and Horizon together for pregnant women who have not had a CS test at the time they are ready to have an NIPT performed. These tests can all be run using one blood draw from the mother and can be ordered on one requisition form and with one shipment of the patient's samples by the physician. Also, because of the importance and demand for screening for 22q11.2 deletion syndrome, we have included that feature as part of our basic Panorama panel, unless the patient or physician ordering the test opts out of the 22q11.2 deletion syndrome screen. In the year ended December 31, 2018, approximately 68% of customers who ordered the basic Panorama panel directly from us also ordered screening for 22q11.2 deletion syndrome or the full microdeletions panel, and approximately 33% of customers who ordered Panorama directly from us also ordered Horizon carrier screening.

In our Evercord business, in addition to promoting to physician practices directly through our sales force, we have a unique opportunity to engage with potential Evercord customers early in their pregnancies as we build a relationship with them through our prenatal tests. We are able to leverage this early engagement to sell newborn stem cell banking directly to our existing patients. Other cord blood service providers typically market to potential customers much later in pregnancy.

We plan to market our Signatera CLIA test to oncologists through our direct sales force. We have entered into an agreement with a transplant diagnostics company to co-market our kidney transplant rejection test in the United States in conjunction with our direct sales force.

We generate a higher gross margin when we sell testing services directly, compared to when our products are distributed by laboratory partners to be performed at our CLIA-certified laboratory. The percentage of our revenues generated through the higher margin U.S. direct sales force channel was approximately 83% in 2018, down from approximately 84% in 2017 and up from approximately 78% in 2016. In January 2017, we terminated our licensing and distribution agreement with Bio-Reference Laboratories, Inc., or Bio-Reference, a laboratory distribution partner that accounted for approximately 7% of our revenues in 2016, and began directly servicing the accounts that were previously ordering through Bio-Reference.

In addition to our sales force, we market to physicians through clinical journals, educational webinars, conferences, tradeshows and e-mail marketing campaigns. While we do not sell directly to patients other than for our Evercord offering, we do engage in brand awareness campaigns directed at patients to highlight our products. Our

marketing and medical science liaison teams work extensively with key opinion leaders in the prenatal genetic testing field. We also dedicate resources to assist our laboratory partner network in marketing Panorama and our other products by conducting joint events, joint advertising and developing joint tools with our partner network.

We generate the highest gross margins on royalty revenue collected from laboratories that run tests in their own facilities and have the sequencing data analyzed by our Constellation software under our cloud-based distribution model. As of March 1, 2019, 15 signed licensees are commercializing products using our Constellation platform. We have licensing contracts with other laboratory licensees, both in the United States and internationally, to develop their own NIPT LDTs and access our algorithm through our Constellation platform.

Our partners' capabilities augment our direct sales capabilities, and where we have identified laboratory or distribution partners who share our focus on premium quality and service, we also contract with them to distribute our tests. In NIPT, we have partnered with leading academic and commercial laboratories and hospital systems in the United States to capitalize on their relationships with MFMs and OB/GYNs, large distribution capabilities, and commercial infrastructure. These distribution partners also frequently have in-network contracts with key third party payers. As of December 31, 2018, we had in-network contracts with insurance providers that accounted for over 209 million, out of a total of approximately 294 million, covered lives in the United States. We continue our efforts to increase the number of our in-network contracts with payers. Our target market for NIPT is a much smaller subset of these covered lives, because it excludes men, children and post-menopausal women who would not be users of the majority of our products. Outside of the United States, where our products are sold in over 80 countries, we currently sell predominantly through partner laboratories.

## **Enhanced User Experience**

### ***Natera Digital Services***

We have created an integrated platform encompassing various digital services designed to enhance the patient and provider experience.

Our patient portal is a one-stop resource for patients to access information and services throughout their experience with our products, from pre-test to post-test. After logging on to the patient portal, patients are able to easily access information about our tests and services, order tests, track their status and access results, and pay their bill. We have recently implemented a price transparency tool whereby patients can receive an estimate of their test cost and out of pocket responsibility, and have initially launched on a pilot basis a pre-test cost estimator whereby patients can receive a personalized cost estimate prior to a blood draw. We believe that these cost estimation features provide peace of mind to patients and providers and helps to mitigate cost concerns as a barrier to NIPT adoption.

Natera Connect is our physician portal, which enables physicians to easily complete various tasks online including ordering tests, tracking the status of a patient's test, reviewing patient results online, sharing results with patients, connecting with genetic counselors, ordering supplies and educational materials, and offering live chat support. We also provide a service to integrate with our customers' Electronic Medical Records, or EMR, systems to provide physicians a seamless experience of ordering tests and reviewing patient test results directly through their EMR systems.

### ***Access to Genetic Counselors***

After receiving a report with results from any of our products, doctors have access by phone to our team of genetic counselors should they have any questions or require any guidance in interpreting the results. Patients themselves may contact our genetic counselors for information by phone either before or after taking one of our tests, with direct access provided to all patients who are tested with Spectrum or Anora and patients who have a high-risk result for a genetic disease based on Horizon screening or for a microdeletion syndrome based on Panorama screening.

## ***Phlebotomy Services***

We have a network of over 2,000 phlebotomy centers in the United States. We also offer mobile phlebotomy services whereby a patient can request and schedule a phlebotomist visit at the patient's home or office.

## **Other Future Applications of our Technology**

We intend to refine and expand our offering in prenatal diagnostics by leveraging our core technology and the data we gather as our sample volumes grow. For example, the microdeletion samples that we gather through Panorama NIPT or through Anora POC testing help us to refine the algorithms that detect these anomalies, determine the exact genetic regions where these anomalies are sought, and increase the accuracy with which they are reported. We have substantial intellectual property covering the analysis of single cells, an approach we use to analyze embryos with our Spectrum products to improve the success of IVF. We believe that our technology may allow us to capitalize on future advances in isolating fetal cells from a mother's blood, which could allow us to measure more of the fetal genome non-invasively and with even higher accuracy, and potentially enable us to replace invasive confirmatory procedures, such as amniocentesis, over time. Importantly, we believe that we have a distinct advantage in our opportunity in single-cell isolation because our technology can not only analyze very small samples, but can also confirm that the cells are fetal as opposed to maternal.

We believe that, in the future, our informatics technology may have the ability to generate a nearly full genome of an individual, roughly nine weeks after the individual is conceived. Publications in *Genome Medicine*, *Science* and *PLoS Genetics* highlight the ability of our informatics technology to determine which chromosome segments from the parent contributed to the DNA of the fetus and hence to substantially reconstruct the genome of the fetus using only a tiny amount of fetal DNA. This enhanced view of the full genome early in life, combined with knowledge of the parent DNA, has the potential to substantially impact the management of many aspects of an individual's health, from birth through adulthood. Future applications of such an offering may include prediction of disease susceptibilities and appropriate interventions, selection of drugs and drug dosages, nutrition guidance and many other emerging applications.

We believe that our ability to design custom panels and targeted assays can be utilized in various research applications such as variant discovery and mechanism of action studies, among others, and clinical applications in diagnostics and therapeutics. Some areas that we believe other researchers and laboratories may be interested in applying this technology are: forensic identity analysis in mixtures for law enforcement, agricultural sample screening for patented lines, prenatal relationship testing for veterinary breeding and cell line purity testing for cell repositories. We are also investigating the potential application of our technology to other specimen types beyond blood, such as urine or sputum, which may have applications in the oncology diagnostics field.

## **Key Relationships**

### ***Illumina***

We are party to a supply agreement with Illumina, Inc., or Illumina, for the supply of Illumina genetic sequencing instruments and reagents for NIPT, oncology and transplant diagnostic testing. For oncology, we also received rights to develop and sell in vitro diagnostic kits and services worldwide, in exchange for which we agreed to make certain milestone and royalty payments to Illumina. During the term of the supply agreement, which expires in June 2026, Illumina has agreed to supply us with sequencers, reagents and other consumables for use with the Illumina sequencers, and we must provide a forecast, on a monthly basis, detailing our needs for certain of the Illumina products. The first four calendar months of each forecast are binding and the fourth month can vary by only up to 25% more or less than what was forecasted for that month in the prior month's forecast. In addition, during each calendar quarter, we must spend a minimum amount on reagents under this agreement. We and Illumina have agreed on prices for the sequencers and reagents, for which we are entitled to certain discounts based on total spend and other factors. Illumina has the right to adjust these prices under certain conditions. In addition, we must pay a fee to Illumina for each clinical NIPT test that we perform using Illumina reagents. Illumina is currently the sole supplier of our sequencers and related reagents for Panorama, along with certain hardware and software; we are not bound to use exclusively Illumina's sequencing instruments and reagents for conducting

our sequencing, but if we use other sequencing instruments and reagents for NIPT clinical use, we may no longer be entitled to discounts from Illumina.

Illumina may terminate the agreement upon the following circumstances: if we materially breach the agreement and fail to cure such breach within 30 days after receiving written notice of such breach, and only after complying with additional notice provisions; if we become the subject of certain bankruptcy or insolvency proceedings or in connection with certain changes of control of Natera. Illumina also has the right to terminate: (a) certain rights under the agreement upon two years' prior notice, but no earlier than June 8, 2021; and (b) our rights with respect to IVDs if we have not obtained a premarket approval for at least one IVD from the United States Food and Drug Administration by June 8, 2021, unless we are diligently pursuing approval of an active PMA application at such time. We may terminate the agreement: if Illumina materially breaches the agreement and fails to cure such breach within 30 days after receiving written notice of such breach, and only after complying with additional notice provisions; if Illumina becomes the subject of certain bankruptcy or insolvency proceedings; in connection with certain supply failures by Illumina or for convenience with four months written notice. The agreement also contains use limitations, representations and warranties, indemnification, limitations of liability and other provisions.

### ***Qiagen***

We are party to a license, distribution and development agreement with QIAGEN LLC (the "Agreement") for the development and distribution of NGS-based genetic tests on our proprietary technology for use on QIAGEN's proprietary GeneReader® NGS sequencing platform in certain countries globally. Under the Agreement, which has a ten (10) year term, we will receive an upfront license fee and prepaid royalties totaling \$40 million. QIAGEN will owe us tiered royalties on a percentage basis based on net sales of its sequencers and reagent kits that are distributed by QIAGEN, as enabled by our technology. The tiers increase after the first and second years after commercial launch of such products. These royalties will initially be credited against the prepaid royalties and then paid quarterly to us once the prepaid royalties have been fully credited. QIAGEN has also committed to a minimum net sales requirement. We are also entitled to milestone payments from QIAGEN totaling \$10 million upon the achievement of certain volume, regulatory, and commercial milestones.

For a certain period, QIAGEN is restricted from developing assays in prenatal screening competitive to the ones being developed based on our technology under this Agreement, and we are restricted from developing and selling certain *in vitro* diagnostic kits in prenatal screening independent of QIAGEN, unless such kits have been approved by regulatory authorities separately from a sequencing platform. These restrictions could be removed if QIAGEN fails to satisfy certain requirements related to the development and performance of its sequencing platform and to sales of the assays that are subject to the Agreement. In addition, if, in the future, QIAGEN satisfies certain requirements related to the development and performance of its sequencing platform for use with our prenatal screening assays, additional provisions related to an extended cooperation between both parties will apply.

The Agreement contains representations, warranties, covenants, termination provisions, and indemnification provisions that are generally customary for a transaction of this type.

We must return up to \$15 million of the prepaid royalties if the Agreement expires, or under termination of the Agreement in most circumstances, without such prepaid royalties having been earned. The remainder of the prepaid royalties, to the extent not yet earned, and the technology access fee, are subject to return to QIAGEN by us only in the event of certain terminations of the Agreement.

### **Competition**

The markets in which we operate are characterized by innovation and rapid change, and we primarily face competition from various companies that develop and commercialize molecular diagnostic tests in prenatal health, oncology, and organ transplant rejection. Our competitors in the NIPT space include Sequenom, Inc., or Sequenom, which was acquired by Laboratory Corporation of America Holdings, or LabCorp; Illumina, through its subsidiary Verinata; Ariosa, Inc., a subsidiary of F. Hoffman La-Roche Ltd, or Roche; Myriad Genetics, Inc., which has acquired Counsyl, Inc.;

Quest Diagnostics Incorporated, or Quest; Premaitha Health PLC; BGI; Progenity, Inc., or Progenity; LifeCodexx AG; Bio-Reference, a business unit of OPKO Health, Inc. and which was previously a laboratory distribution partner of ours; and Multiplicom N.V., which was acquired by Agilent Technologies Inc. We also compete against companies providing carrier screening tests such as LabCorp; Myriad Genetics, Inc. through its acquisition of Counsyl, Inc.; Invitae Corp. through its acquisition of Good Start Genetics, Inc.; Progenity; Recombine Inc.; Quest; and GenPath Diagnostics, a business unit of Bio-Reference. Each of these companies offers comprehensive CS panels.

In the field of cancer diagnostics, and liquid biopsy tests specifically, we expect to compete with various companies that offer or seek to offer competing solutions, such as Roche Molecular Systems Inc., a subsidiary of Roche, Guardant Health, Inc., Adaptive Biotechnologies, Personal Genome Diagnostics, Inc., Foundation Medicine, Inc., which is also a subsidiary of Roche, and Genomic Health Inc.

In organ transplant rejection, we anticipate that our primary competitor will be CareDx, Inc.

We expect additional competition as other established and emerging companies enter these markets, including through business combinations, and as new tests and technologies are introduced. These competitors could have greater technological, financial, reputational and market access resources than us.

We believe the principal competitive factors in our molecular diagnostic testing markets include the following:

- test performance, as demonstrated in clinical and analytical studies and clinical trials as well as in commercial experience;
- for prenatal testing, comprehensiveness of coverage of diseases and ability to conveniently test for multiple conditions;
- for cancer diagnostics, comprehensiveness of coverage of cancer types and indications;
- value of product offerings, including pricing and impact on other healthcare spending;
- scope and extent of reimbursement and payer coverage;
- effectiveness of sales and marketing efforts;
- breadth of distribution of products and partnership base;
- reputation among patients and providers for development and introduction of new, innovative products;
- operational execution, including test turn-around time and test failures;
- key opinion leader support;
- brand awareness; and
- ease of integration for laboratories, including for cloud-based distribution models.

Specific market share data regarding our products is not publicly available, and consumers may choose to use competing products for a variety of reasons, including lower cost. We believe, however, that we compete favorably in the prenatal testing market on the basis of several factors, particularly test performance, comprehensiveness of coverage of diseases, ability to conveniently test for multiple conditions, value of product offerings and effectiveness of sales and marketing efforts. In oncology, we believe that the sensitivity and specificity of our technology compare favorably to generic panel-based ctDNA assays due to our individualized approach.

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. We believe the principal competitive factors in this market include quality, measured by number and stature of accreditations; experience in transplants; stability and longevity; price, for example promotions, coupons and benefits such as referral programs; services offered, such as designated transplant programs and extra services such as access to genetic counselors; ease of customer experience, including process, communication, kit shipping and availability, and timely notifications. We believe that we compete favorably in this market based on all of these factors.

## **Intellectual Property**

Our success and ability to compete depend in part on securing and preserving enforceable patent, trade secret, trademark and other intellectual property rights; operating without having competitors infringe, misappropriate or otherwise circumvent these rights; operating without infringing the proprietary rights of others; and obtaining and maintaining licenses for technology development and/or product commercialization. As of December 31, 2018, we held 54 issued U.S. and foreign patents, which expire between November 2026 and December 2036, and over 100 pending U.S. and foreign patent applications. Our patents and patent applications relate generally to molecular diagnostics, and more specifically to biochemical and analytical techniques for obtaining and analyzing genetic information to detect genetic abnormalities in relatively small complex samples, such as cell free fetal DNA or circulating tumor DNA. We intend to seek patent protection as we develop new technologies and products in this area.

In the past, parties have filed, and in the future parties may file, claims asserting that our technologies or products infringe on their intellectual property. For example, we are currently involved in patent infringement litigation with Illumina and have in the past been involved in patent infringement litigation with Sequenom. We cannot predict whether other parties will assert such claims against us, or whether those claims will harm our business. The field of molecular diagnostics is complex and rapidly evolving, and we expect that we and others in our industry will continue to be subject to third-party infringement claims.

## **Reimbursement**

We receive reimbursement from commercial third-party payers and from government health benefits programs such as Medicare and Medicaid. We receive reimbursement for our Panorama, Horizon, Vistara, Anora and Spectrum tests, and are in the process of pursuing reimbursement for our Signatera CLIA test and transplant rejection test, both of which we are currently developing for commercialization.

Laboratory tests, as with most other healthcare services, are classified for reimbursement purposes under a coding system known as Current Procedure Terminology, or CPT, which we and our customers must use to bill and receive reimbursement for our diagnostic tests. These CPT codes are associated with the particular test that we have provided to the patient. Once the American Medical Association establishes a CPT code, the Centers for Medicare & Medicaid Services, or CMS, establishes payment levels and coverage rules under Medicare while private payers establish rates and coverage rules independently. For most of the tests performed for Medicare or Medicaid beneficiaries, laboratories are required to bill Medicare or Medicaid directly, and to accept Medicare or Medicaid reimbursement as payment in full. Prior to 2015, CMS had implemented a set of CPT codes without a fee schedule for most codes specific to NIPTs; however, a CPT code specific to NIPT for aneuploidies has been effective since January 2015, and a CPT code for microdeletions has been effective since January 2017. CMS has established a pricing benchmark of \$802 for aneuploidy and microdeletions testing. In addition, a CPT code for expanded carrier screening tests went into effect in January of this year, for which CMS has established a pricing benchmark of approximately \$2,450.

We currently submit for reimbursement using CPT codes based on the guidance of coding experts and outside legal counsel. There is a risk that these codes may be rejected or withdrawn or that payers will seek refunds of amounts that they claim were inappropriately billed to a specific CPT code. We do not currently have a specific CPT code assigned for all of our tests, and there is a risk that we may not be able to obtain specific codes for such tests, or if obtained, we may not be able to negotiate favorable rates for one or more of these codes. In particular, while we have obtained a CPT code for microdeletions and CMS has set a price for microdeletions testing, we expect that our microdeletions reimbursement

will decline, at least in the near term, because third-party payers are declining to reimburse under the new code or reimbursing at a much lower rate than we had previously received before the CPT code was established. The reimbursement rates for our broader Horizon screening panel may also decline as a result of the new CPT code becoming effective in 2019, as carrier screening tests that had previously been reimbursed on a per-condition basis may be reimbursed as a combined single panel instead of as multiple individual tests.

NIPT has received positive coverage determinations for high-risk pregnancies and are reimbursed by most private payers, including United Healthcare, AETNA, Anthem, Humana, CIGNA and others. Reimbursement policies for the use of NIPT for average-risk pregnancies have not been widely established, but recent publications have analyzed the use of NIPT in the average-risk population and certain medical societies have supported such use. In particular, ACMG has issued guidelines recommending that pregnant women be informed 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 CNVs in the context of counseling that includes the risks/benefits and limitations of screening for CNVs. ISPD has issued guidelines that are supportive of NIPT in average-risk pregnancies as well as high-risk pregnancies. However, SMFM has issued a guideline stating that while all pregnant women should be informed of the option to receive NIPT, conventional screening methods, rather than NIPT, remain the most appropriate choice for first-line screening for average-risk pregnancies. ACOG has withdrawn its previous guideline, which was consistent with SMFM's guideline, and it remains uncertain when ACOG will issue a new guideline as well as whether and to what extent such guideline may be supportive of NIPT in the average-risk setting. Private payers are moving towards reimbursing for average-risk NIPT. Fifty-nine commercial payers in the United States, representing close to half of all commercial covered lives in the United States, and several state Medicaid programs, have a positive coverage determination for NIPT for average-risk pregnancies.

Based on Health Leaders publication data, as of December 31, 2018 we and our laboratory partners had in-network contracts with insurance providers that accounted for over 209 million covered lives, out of a total of approximately 294 million covered lives, in the United States. Our target market for NIPT is a much smaller subset of these covered lives, because it excludes men, children and post-menopausal women who would not be users of our products.

## **Government Regulations**

Our business is subject to and impacted by extensive and frequently changing laws and regulations in the United States (at both the federal and state levels) and internationally. These laws and regulations include regulations particular to our business and laws and regulations relating to conducting business generally (e.g., export controls laws, U.S. Foreign Corrupt Practices Act and similar laws of other jurisdictions). We also are subject to inspections and audits by governmental agencies. Set forth below are highlights of certain key regulatory schemes applicable to our business.

### ***Clinical Laboratory Improvement Amendments of 1988 and State Regulation***

As a clinical laboratory, we are required to hold certain federal and state licenses, certifications and permits to conduct our business. As to federal certifications, in 1988, Congress passed the Clinical Laboratory Improvement Amendments of 1988, or CLIA, establishing more rigorous quality standards for all laboratories that perform testing on human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of disease. CLIA requires such laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure the accuracy, reliability and timeliness of patient test results. CLIA certification is also a prerequisite to be eligible to bill state and federal healthcare programs, as well as many commercial third-party payers, for laboratory testing services.

Our laboratory located in San Carlos, California is CLIA certified. Our laboratory must comply with all applicable CLIA requirements. If a clinical laboratory is found to be out of compliance with CLIA standards, CMS may impose sanctions, limit or revoke the laboratory's CLIA certificate (and prohibit the owner, operator or laboratory director from owning, operating, or directing a laboratory for two years following license revocation), a directed plan of correction, on-site monitoring, civil monetary penalties, civil actions for injunctive relief, criminal penalties, or suspension or exclusion from the Medicare and Medicaid programs.



CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory requirements. State laws may require that laboratory personnel meet certain qualifications, specify certain quality control procedures or facility requirements, or prescribe record maintenance requirements. We are required to meet certain laboratory licensing requirements for those states in which we offer services or from which we accept specimens and that have adopted regulations beyond CLIA. For more information on state licensing requirements, see “—California Laboratory Licensing”, “—New York Laboratory Licensing,” and “—Other State Laboratory Licensing Laws.”

Our laboratory has also been accredited by the College of American Pathologists, or CAP, which means that our laboratory has been certified as following CAP guidelines in operating the laboratory and in performing tests that ensure the quality of our results.

## **FDA**

In the United States, medical devices are subject to extensive regulation by the Food and Drug Administration, or FDA, under the Federal Food, Drug, and Cosmetic Act, or FDC Act, and its implementing regulations, and other federal and state statutes and regulations. The laws and regulations govern, among other things, medical device development, testing, labeling, storage, premarket clearance or approval, advertising and promotion and product sales and distribution. To be commercially distributed in the United States, medical devices must receive from the FDA prior to marketing, unless subject to an exemption, clearance of a premarket notification, or 510(k), premarket approval, or a PMA, or a de novo authorization.

IVDs are a type of medical device that can be used in the diagnosis or detection of diseases, conditions or infections, including, without limitation, the presence of certain chemicals, genetic information or other biomarkers. Predictive, prognostic and screening tests, such as carrier screening tests, can also be IVDs. A subset of IVDs are known as analyte specific reagents, or ASRs. ASRs consist of single reagents, and are intended for use in a diagnostic application for the identification and quantification of an individual chemical substance in biological specimens. ASRs are medical devices, but most are exempt from the premarket review processes. As medical devices, ASRs have to comply with some quality system regulation, or QSR, provisions and other device requirements.

The FDC Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Many Class I devices are exempt from FDA premarket review requirements. Class II devices, including some software products to the extent that they qualify as a device, are deemed to be moderate risk, and generally require clearance through the premarket notification, or 510(k) clearance, process. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices typically require a PMA by the FDA before they are marketed. A clinical trial is almost always required to support a PMA application and is sometimes required for 510(k) clearance. All clinical studies of investigational devices must be conducted in compliance with any applicable FDA and Institutional Review Board requirements. Devices that are exempt from FDA premarket review requirements must nonetheless comply with post-market general controls as described below, unless the FDA has chosen otherwise.

*510(k) clearance pathway.* To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating to the FDA's satisfaction that the proposed device is substantially equivalent to a previously 510(k)-cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for submission of PMA applications. The previously cleared device is known as a predicate. The FDA's 510(k) clearance pathway usually takes from three to 12 months from submission, but it can take longer, particularly for a novel type of product.

*PMA pathway.* The PMA pathway requires proof of the safety and effectiveness of the device to the FDA's satisfaction. The PMA pathway is costly, lengthy, and uncertain. A PMA application must provide extensive preclinical and clinical trial data as well as information about the device and its components regarding, among other things, device

design, manufacturing, and labeling. As part of its PMA review process, the FDA will typically inspect the manufacturer's facilities for compliance with QSR requirements, which impose elaborate testing, control, documentation, and other quality assurance procedures. The PMA review process typically takes one to three years from submission but can take longer.

*De novo pathway.* If no predicate device can be identified, the product is automatically classified as Class III, requiring a PMA application. However, the FDA can reclassify, or use "de novo classification," for a device for which there was no predicate device if the device is low- or moderate-risk. If the device is deemed Class II, the FDA will identify "special controls" that the manufacturer must implement, which often include labeling and other restrictions. Subsequent applicants can rely upon the de novo product as a predicate for a 510(k) clearance, unless FDA exempts subsequent devices from the need for a 510(k). The de novo route is less burdensome than the PMA process, but FDA has issued a proposed regulation that, if adopted as written, would increase the regulatory burden in obtaining a de novo authorization. A device company can ask the FDA at the outset if the de novo route is available and submit the application as one requesting de novo classification. The de novo route has been used for many IVD products. The FDA has indicated to us that our software that enables our cloud-based distribution model may be appropriate for review under the de novo classification process. However, the FDA has not committed to this position and may take a different position in the future.

*Post-market general controls.* After a device, including a device exempt from FDA premarket review, is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, registration and listing, the Medical Device Reporting regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act).

The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from an untitled or public warning letter to more severe sanctions such as fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMAs already granted; and criminal prosecution. For additional information, see "Risk Factors—Reimbursement and Regulatory Risks Related to Our Business."

*Research use only.* Research use only, or RUO, products belong to a separate regulatory classification under a long-standing FDA regulation. RUO products are not regulated as medical devices and are therefore not subject to the regulatory requirements discussed above. The products must bear the statement: "For Research Use Only. Not for Use in Diagnostic Procedures." RUO products cannot make any claims related to safety, effectiveness or diagnostic utility, and they cannot be intended for human clinical diagnostic use. A product labeled RUO but intended to be used diagnostically may be viewed by the FDA as adulterated and misbranded under the FDC Act and is subject to FDA enforcement activities, including requiring the supplier to seek clearance, approval or authorization for the products. Our LDT uses instruments and reagents labeled as RUO.

*Laboratory-developed tests.* LDTs have generally been considered to be tests that are 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. The FDA has historically exercised enforcement discretion and has not required clearance or approval of LDTs prior to marketing.

On October 3, 2014, the FDA issued two draft guidance documents regarding oversight of LDTs. These draft guidance documents proposed more active review of LDTs. The draft guidances were the subject of considerable controversy, and in November 2016, the FDA announced that it would not be finalizing the 2014 draft guidance documents. On January 13, 2017, the FDA issued a discussion paper which 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 have 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.

We believe that other than the RUO version of Signatera, all of the tests we currently offer, including Panorama, meet the definition of LDTs, as they have been designed, developed, and validated for use in a single CLIA-certified laboratory. If our tests are LDTs, they are currently not subject to FDA regulation as medical devices.

### ***California Laboratory Licensing***

In addition to federal certification requirements for laboratories under CLIA, we are required under California law to maintain a California state license for our San Carlos clinical laboratory and comply with California state laboratory laws and regulations. Similar to the federal CLIA regulations, the California state laboratory laws and regulations establish standards for the operation of a clinical laboratory and performance of test services, including the education and experience requirements of a laboratory director and personnel (including requirements for documentation of competency); equipment validations; and quality management practices. All testing personnel must maintain a California state license or be supervised by licensed personnel.

Clinical laboratories are subject to routine on-site inspections by the state. If a clinical laboratory is found to be out of compliance with California standards, the California Department of Public Health, or CAPH, may suspend, restrict or revoke the California state laboratory license to operate the clinical laboratory (and exclude persons or entities from owning, operating, or directing a laboratory for two years following license revocation), assess civil money penalties, and impose specific corrective action plans, among other sanctions.

### ***New York Laboratory Licensing***

Because we receive test specimens originating from New York State, our San Carlos clinical laboratory is required to obtain a New York state laboratory permit and comply with New York state laboratory laws and regulations. The New York state laboratory laws, regulations and rules are equal to or more 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 of a laboratory director 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 the New York State Department of Health, or DOH, in the permitted categories.

Our clinical laboratory is subject to proficiency testing and on-site survey inspections conducted by the Clinical Laboratory Evaluation Program, or CLEP, of the DOH. If a laboratory is found to be out of compliance with New York's CLEP standards, the DOH, may suspend, limit, revoke or annul the New York laboratory permit, censure the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory's operator, owners and/or laboratory director being found guilty of a misdemeanor under New York law.

Our clinical laboratory maintains a valid permit in the State of New York for the molecular genetic testing services furnished by our clinical laboratory.

The DOH also must approve each LDT before the test is offered to patients located in New York. Our clinical laboratory has received approval from New York's DOH to offer our basic Panorama test to women with high-risk pregnancies and a conditional approval to offer both our basic Panorama and Panorama with the microdeletions panel to all pregnant women, regardless of risk. Our clinical laboratory also holds a permit from New York's DOH to offer our Horizon, Spectrum, Anora and non-invasive prenatal paternity tests, and provisional approval is pending for our Horizon test under our recently updated workflow.

### ***Other State Laboratory Licensing Laws***

In addition to New York and California, other states, including Maryland, Pennsylvania and Rhode Island, require licensing of out-of-state laboratories under certain circumstances. We have obtained licenses in these three additional states and believe we are in compliance with applicable state laboratory licensing laws.

Potential sanctions for violation of state statutes and regulations include significant fines, the rejection of license applications, the suspension or loss of various licenses, certificates and authorizations, and in some cases criminal penalties, which could harm our business. CLIA does not preempt state laws that have established laboratory quality standards that are at least as stringent as federal law.

### ***State Genetic Testing Laws***

Many states have implemented genetic testing and privacy laws imposing specific patient consent requirements and protecting test results. In some cases, we are prohibited from conducting certain tests without appropriate documentation of patient consent by the physician ordering the test. Requirements of these laws and penalties for violations vary widely.

### ***Cord Blood and Tissue Banking***

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 from 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, and is 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. 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. 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. Cord blood and tissue stored for autologous use and for use in first- or second-degree relatives are generally regulated under 21 CFR Part 1271 as Human Cells, Tissues, and Cellular and Tissue-Based Products and do not require approval before use. Cord blood and tissue stored for potential future allogeneic use not in a first- or second-degree relative meets the definition of “drug” under the FDC Act and “biological product” under Section 351 of the Public Health Service Act. Cord blood and tissue in this category must meet additional requirements, including conducting clinical trials pursuant to an Investigational New Drug Application and obtaining licensure pursuant to a Biologics License Application prior to marketing.

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.

## *HIPAA and Other Privacy Laws*

The privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, establish uniform standards governing the conduct of certain electronic healthcare transactions and require certain entities, called covered entities, to comply with standards that include the privacy and security of protected health information, or PHI. HIPAA further requires business associates of covered entities—independent contractors or agents of covered entities that have access to protected health information in connection with providing a service to or on behalf of a covered entity—to enter into business associate agreements with the covered entity and to safeguard the covered entity's PHI against improper use and disclosure. In addition, certain of HIPAA's privacy and security standards are directly applicable to business associates.

As a covered entity and as a business associate of other covered entities (with whom we have therefore entered into business associate agreements), we have certain obligations regarding the use and disclosure of any PHI that may be provided to us, and we could incur significant liability if we fail to meet such obligations or if our business associates fail to meet such obligations. Among other things, HITECH imposes civil and criminal penalties against covered entities and business associates for noncompliance with privacy and security requirements and authorizes states' attorneys general to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

As noted above, we are required to comply with HIPAA standards promulgated by the U.S. Department of Health and Human Services, or HHS. First, we must comply with HIPAA's standards for electronic transactions, which establish standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures. We must also comply with the standards for the privacy of individually identifiable health information, which limit the use and disclosure of most paper and oral communications, as well as those in electronic form, regarding an individual's past, present or future physical or mental health or condition, or relating to the provision of healthcare to the individual or payment for that healthcare, if the individual can or may be identified by such information. Additionally, we must comply with HIPAA's security standards, which require us to ensure the confidentiality, integrity and availability of all electronic protected health information that we create, receive, maintain or transmit, to protect against reasonably anticipated threats or hazards to the security of such information, and to protect such information from unauthorized use or disclosure.

Various states in the United States have implemented similar restrictive requirements regulating the use and disclosure of health information and other personally identifiable information that are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. For example, Massachusetts law requires that any company that obtains personal information of any resident of the Commonwealth of Massachusetts implement and maintain a security program that adequately protects such information from unauthorized use or disclosure.

There are also foreign privacy and security laws and regulations that impose restrictions on the access, use and disclosure of health information. In particular, the EU's General Data Protection Regulation, or GDPR, became effective in May 2018. The GDPR applies not only to organizations within the EU, but also applies to organizations outside of the EU, such as Natera, that offer goods or services to EU data subjects or that process or hold personal data of EU data subjects. The regulation specifies higher potential liabilities for certain data protection violations, and we anticipate that it will result in a greater compliance burden for us as we conduct our business, particularly through our Constellation cloud-based distribution model, in the European Union. Fines for non-compliance can range from the greater of 2% of annual global revenues or €10 million, up to the greater of 4% of annual global revenues or €20 million.

As a business that operates both internationally and throughout the United States, any unauthorized use or disclosure of personally identifiable information, even if it does not constitute PHI, by us or our third-party contractors, including disclosure due to data theft or unauthorized access to our or our third-party contractors' computer networks, could subject us to costs, fines or penalties that could adversely affect our business and results of operations, including the cost of providing notice, credit monitoring and identity theft prevention services to affected consumers.

## ***Healthcare Fraud and Abuse Laws***

The federal Anti-Kickback Statute makes it a felony for a provider or supplier, including a laboratory, to knowingly and willfully offer, pay, solicit or receive remuneration, directly or indirectly, in order to induce business that is reimbursable under any federal healthcare program. A violation of the federal Anti-Kickback Statute may result in imprisonment for up to five years and/or criminal fines of up to \$25,000, civil assessments and fines up to \$50,000, and exclusion from participation in Medicare, Medicaid and other federal healthcare programs. Although the federal Anti-Kickback Statute applies only to federal healthcare programs, a number of states have passed laws substantially similar to the federal Anti-Kickback Statute pursuant to which similar types of prohibitions are made applicable to all other health plans and third-party payers. Actions which violate the federal Anti-Kickback Statute or similar laws may also involve liability under the Federal False Claims Act, which prohibits knowingly presenting or causing to be presented a false, fictitious or fraudulent claim for payment to the U.S. Government.

Federal and state law enforcement authorities scrutinize arrangements between healthcare providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals and opportunities. Law enforcement authorities, courts and Congress have demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of payments between healthcare providers and actual or potential referral sources. Generally, courts have taken a broad interpretation of the scope of the federal Anti-Kickback Statute, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce future referrals.

The HHS Office of Inspector General, or OIG, has issued Special Fraud Alerts on arrangements for the provision of clinical laboratory services and relationships between laboratories and referring physicians. The Fraud Alerts set forth a number of practices allegedly engaged in by some clinical laboratories and healthcare providers that raise issues under the federal fraud and abuse laws, including the federal Anti-Kickback Statute. The OIG emphasized in the Special Fraud Alerts that when one purpose of such arrangements is to induce referrals of government program-reimbursed laboratory testing, both the clinical laboratory and the healthcare provider (e.g., physician) may be liable under the federal Anti-Kickback Statute, and may be subject to civil and/or criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.

Recognizing that the federal Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, HHS has issued a series of regulatory “safe harbors” which provide confidence to healthcare providers and other parties that they may not be prosecuted under the federal Anti-Kickback Statute if they can demonstrate compliance with each element of the safe harbor. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued.

While we believe that we are in compliance with the federal Anti-Kickback Statute or similar laws, there can be no assurance that our relationships with physicians, hospitals and other customers will not be subject to scrutiny or will survive regulatory challenge under such laws. If imposed for any reason, sanctions under the federal Anti-Kickback Statute or any similar state statute could have a negative effect on our business.

Because our laboratory is located in California and licensed by California’s DHS, California law is applicable to our business arrangements. California’s state anti-kickback statutes, Business and Professions Code Section 650 (which applies to all categories of payors) and Insurance Code Section 754, and its Medi-Cal anti-kickback statute, Welfare and Institutions Code Section 14107.2, are analogous to, and have been interpreted by the California Attorney General and California courts in substantially the same way as the federal government and the courts have interpreted, the federal Anti-Kickback Statute. A violation of Section 650 is punishable by up to one year of imprisonment, a fine up to \$50,000, or both imprisonment and a fine. A violation of Section 14107.2 is punishable by imprisonment and fines of up to \$10,000. The California Insurance Code includes similar prohibitions against any consideration for the referral or procurement of patients if a claim is submitted to a commercial insurer, CA Ins. Code § 750, which is punishable by criminal penalties mirroring those that apply to violations of Business and Professions Code Section 650.

Because our laboratory holds a New York CLEP permit, we must comply with New York state laboratory statutes and regulations, which include anti-kickback provisions, Public Health Law Section 587, and Medicaid anti-kickback provisions, 18 NYCRR Section 515.2, related to laboratory services. The New York DOH may suspend, limit, revoke or annul the New York laboratory permit or otherwise discipline the permit holder for a violation.

In addition to the requirements that are discussed above, there are other healthcare fraud and abuse laws that could have an impact on our business. The federal False Claims Act prohibits a person from knowingly submitting or causing to be submitted false claims or making a false record or statement in order to secure payment by the federal government. Actions which violate another law in this section may also result in liability under the Federal False Claims Act as a result of the submission of claims pursuant to a prohibited arrangement. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud sometimes referred to as a “whistleblower”.

Because the complaints are initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government is ultimately successful in obtaining redress in the matter or if the private party plaintiff succeeds in obtaining redress without the government’s involvement, then the private party plaintiff will receive a percentage of the recovery. Violation of the federal False Claims Act may result in fines of up to three times the actual damages sustained by the government, plus mandatory civil penalties of up to approximately \$22,000 for each separate false claim, imprisonment or both, and possible exclusion from Medicare or Medicaid.

In October of 2018, the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, was passed as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (referred to as the SUPPORT Act). Similar to the federal Anti-Kickback statute, EKRA creates criminal penalties for knowing or willful payment or offer, or 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 unless a specific exception applies. Unlike the federal Anti-Kickback Statute, EKRA is not limited to government health care benefit programs, so the prohibitions extend to services covered by private payors. Additionally, most of the safe harbors available under the federal Anti-Kickback Statute are not reiterated under EKRA. Therefore, compliance with a federal Anti-Kickback safe harbor does not guarantee protection under EKRA. As currently drafted, EKRA potentially expands the universe of arrangements that could be subject to government enforcement under federal fraud and abuse laws. Violation of EKRA carries potential penalties of up to \$200,000 in fines and imprisonment of up to 10 years for each occurrence. Because EKRA is a new law, there is very little additional guidance to indicate how and to what extent it will be applied and enforced by government agencies in our industry. We cannot assure you that our relationships with physicians, sales representatives, hospitals or customers will not be subject to scrutiny or will survive regulatory challenge under such laws. If imposed for any reason, sanctions under the EKRA could have a negative effect on our business.

We are also subject to a federal law directed at “self-referrals,” commonly known as the Stark Law, which prohibits, with certain exceptions, payments made by a laboratory to a physician in exchange for the referral of clinical laboratory services, or presenting or causing to be presented claims to Medicare and Medicaid for laboratory tests referred by physicians who personally, or through a family member, have an investment interest in, or a compensation arrangement with, the clinical laboratory performing the tests. A person who engages in a scheme to circumvent the Stark Law’s referral prohibition may be fined up to \$100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties of up to \$15,000 per claim submission, an assessment of up to three times the amount claimed, and possible exclusion from participation in federal governmental payer programs. Claims submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited claim is obligated to refund such amounts.

Many states, including California, also have state “physician self-referral” prohibitions and other laws that are not limited to Medicare and Medicaid referrals, with which we must comply. We are subject to California’s Physician Ownership and Referral Act, or PORA, under Article 6 of the California Business & Professions Code. PORA generally prohibits us from billing a patient or any governmental or private payer for any laboratory services when the physician ordering the service, or any member of such physician’s immediate family, has a “financial interest” with us, unless the

arrangement meets an exception. The term “financial interest” is defined broadly and includes any type of ownership interest, debt, loan, lease, compensation, remuneration, discount, rebate, refund, etc. between the ordering physician and the entity receiving the referral. The exceptions to PORA track certain of the Stark Law exceptions, including an exception for personal service arrangements and for ownership of publicly traded entities. A violation of PORA is punishable by civil and criminal penalties (civil penalties and criminal fines vary depending on the nature of the violation, but may reach up to \$15,000 per violation).

Other states may have self-referral restrictions with which we have to comply that differ from those imposed by federal and California law.

We are also subject to applicable state client billing laws (also known as “pass through billing”), which specify whether a provider that did not perform the service is permitted to submit the claim for payment and if so, whether the non-performing provider is permitted to mark up the cost of the services in excess of the price the purchasing provider paid for such services. California has an anti-markup statute with which we must comply, which prohibits providers from charging for a laboratory test that it did not perform unless the provider (a) notifies the patient of the name, address, and charges of the laboratory performing the test, and (b) charges no more than what he or she was charged by the clinical laboratory which performed the test except for any other service actually rendered to the patient by the provider (Business and Professions Code Section 655.5). A violation of this provision can lead to imprisonment and/or a fine of up to \$10,000. Other states have similar anti-markup prohibitions with which we must comply. In addition, many states also have “direct-bill” laws, which means that the services actually performed by an individual or entity must be billed by such individual or entity, thus preventing ordering physicians from purchasing services from a laboratory and billing for the services they order. For example, California has a direct bill rule specific to anatomic pathology services that prohibits any provider from billing for anatomic pathology services if those services were not actually rendered by that person or under his or her direct supervision with some exemptions (Business and Professions Code Section 655.7).

While we have attempted to comply with the federal fraud and abuse laws, California and New York fraud and abuse laws and similar laws of other states and non-U.S. jurisdictions, it is possible that some of our arrangements could be subject to regulatory scrutiny at some point in the future, and we cannot provide assurance that we will be found to be in compliance with these laws following any such regulatory review.

Further, in addition to the privacy and security regulations stated above, HIPAA created two federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

Finally, federal law prohibits any entity from offering or transferring to a Medicare or Medicaid beneficiary any remuneration that the entity knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services, including waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. Entities found in violation may be liable for civil monetary penalties of up to \$10,000 for each wrongful act. Although we believe that our practices, including our sales and marketing practices, are in material compliance with all applicable federal and state laws and regulations, relevant regulatory authorities may disagree, and violation of these laws or our exclusion from such programs as Medicaid and other governmental programs as a result of a violation of such laws could have a material adverse effect on our business, results of operations, financial condition and cash flows.

## **Employees**

As of December 31, 2018, we had 975 employees, including 310 in laboratory operations and manufacturing administration, 148 in research and development and 517 in sales, general and administrative functions. We have not been subject to labor action or union activities, and our management considers its relationships with employees to be good.



## **Glossary of Terms**

ACOG – the American Congress of Obstetricians and Gynecologists.

ACMG – the American College of Medical Genetics and Genomics.

Allograft – the transplant of an organ or tissue from one individual to another individual of the same species who is not genetically identical.

AMA – American Medical Association.

AUC – area under the receiver operating curve; a measure of the diagnostic performance of a test, based on sensitivity and specificity.

CMS – Centers for Medicare and Medicaid Services.

CNV – copy number variation; a genetic mutation in which relatively large regions of the genome have been deleted or duplicated.

CPT – Current Procedure Terminology.

ctDNA – circulating tumor DNA; tumor DNA circulating in a blood sample.

CS test – carrier screening test.

dd-cfDNA – donor-derived cell-free DNA; DNA that is shed from a transplanted organ undergoing rejection.

DNA – deoxyribonucleic acid.

Fetal aneuploidy – an inherited genetic condition in which a fetus has a different number of chromosomes than are typical.

Gene fusion – an abnormality in which DNA segments from two different genes are exchanged, forming one fused gene. Gene fusions have been implicated in the development of cancer tumors.

HPC – hematopoietic progenitor cells.

ISPD – the International Society for Prenatal Diagnosis.

IVD – in vitro diagnostic; tests that can be used in any laboratory that has the appropriate qualifications and authorizations.

IVF – in vitro fertilization.

LDT – laboratory developed test; tests that are designed, developed, validated and used within a single laboratory.

MFM – maternal fetal medicine.

Microdeletion – a deletion of a region of DNA from one copy of one chromosome.

Micro-metastatic disease – a subclinical disease state in which small numbers of cancer cells have spread from the primary tumor to other parts of the body and are too few to be picked up in a screening or diagnostic test.

mmPCR – massively multiplexed polymerase chain reaction.

NGS – next-generation sequencing; a DNA sequencing technology.

No-call – the inability to update the prior risk, or the standard risk assigned based on maternal and gestational age, in order to provide a high-risk or low-risk test result due to insufficient information in the sample.

PPV – positive predictive value; the likelihood that a positive result on a test indicates a true positive result in the patient.

Sensitivity – the likelihood that an individual with a condition will be correctly found to have that condition. Sensitivity is calculated as the ratio between the number of individuals that test positive for the condition over the total number of individuals in the tested cohort who actually have the condition.

Signal to noise ratio – the ratio of useful information to irrelevant data.

SMFM – the Society for Maternal Fetal Medicine.

SNP – single nucleotide polymorphism; a position on the chromosome at which single DNA base changes are common in the population.

SNV – single nucleotide variant; a genetic mutation in which a single chemical base in DNA has changed.

Specificity – the likelihood that an individual without a condition will be correctly found not to have that condition. Specificity is calculated as the ratio between the number of individuals that test negative for a condition over the total number of individuals in the tested cohort who do not have the condition.

Triploidy – a type of fetal aneuploidy in which an individual has three copies of every chromosome instead of two.

## **Corporate Information**

We were initially formed in California as Gene Security Network, LLC in November 2003. We were incorporated in Delaware in January 2007, and we changed our name to Natera, Inc. in January 2012. Our principal executive offices are located at 201 Industrial Road, Suite 410, San Carlos, California 94070, and our telephone number is (650) 249-9090. Our website address is [www.natera.com](http://www.natera.com). We do not incorporate the information on, or accessible through, our website into this annual report on Form 10-K, and you should not consider any information on, or accessible through, our website as part of this annual report on Form 10-K.

## **Available Information**

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended. Copies of our reports on Form 10-K, Form 10-Q and Form 8-K, may be obtained, free of charge, electronically through our Internet website, <http://investor.natera.com>.

## 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 in this report, including the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our 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. If any of the following risks actually occurs, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the price of our common stock could decline and you could lose part or all 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 years ended December 31, 2018, 2017 and 2016, 55%, 62% and 66%, 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 7—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 7—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 (RUO) cancer screening offering and the CLIA version currently in development, our Evercord cord blood banking service, and our planned organ 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 years ended December 31, 2018, 2017 and 2016 was, respectively, \$128.2 million; \$137.6 million, as revised under ASC 606; and \$100.3 million, as revised under ASC 606. As of December 31, 2018, we had an accumulated deficit of \$574.6 million. 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 new products, an increasing proportion of which are in industries that are new to us, including oncology and transplant rejection products.

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 continues to be 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 if we are unable to continue 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 may 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 tests. We continue to focus our research and development efforts on prenatal products, and are now expanding our platform and 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 for research use only, 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 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, profitability 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 have 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; Counsyl, Inc., which has been acquired by Myriad Genetics, Inc.; Bio-Reference, a business unit of OKPO Health, Inc.; Quest; Premaitha Health PLC; BGI; Progenity; LifeCodexx AG; and Multiplicom N.V., which was acquired by Agilent Technologies Inc. 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; Counsyl, 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.; and Genomic Health 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 as we conduct our development and commercialization activities.

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. 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 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 March 1, 2019, only 14 licensees are using Constellation commercially to market NIPT products. One 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 83% of our revenues for the year ended December 31, 2018 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 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 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 (RUO), and certain of our research and development activities, and we plan to utilize the platform for additional applications in the future, including our Signatera CLIA test and our 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, including to various other applications such as cancer diagnostics and transplant rejection. 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 or technological 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 and technical 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 have only recently launched our Evercord service, which is in an industry in which we previously had no experience; we also recently launched our Vistara NIPT and our Signatera (RUO) liquid biopsy technology for research use only. 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. 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 (RUO) 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 our planned transplant rejection test, 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. 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; and we began to focus research, development and commercialization efforts on our planned Signatera CLIA test and 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 (RUO) offering, and our planned Signatera CLIA test and transplant rejection 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 transplant rejection 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. We 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 (RUO) test is currently performed at this facility, and we also plan to perform our Signatera CLIA test and our transplant rejection 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 (RUO) 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 (RUO) 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 7—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. 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.

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 7—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 are working to launch an additional two offerings in 2019. In addition, we regularly evaluate and refine our testing process, often significantly updating our workflows, as with Panorama in 2017 and our 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 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 are beginning the process of transitioning 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, and are working to launch 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 kidney transplant rejection 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 in the process of pursuing additional 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 profitability.

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 that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.***

In the future, we may enter into transactions to acquire other businesses, products or technologies. Because we have not made any acquisitions to date, our ability to do so successfully is unproven. Even if we identify suitable targets, we may not be able to make such acquisitions on favorable terms or at all. Any acquisitions we make 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 undiscovered liabilities of the 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 the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions 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 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 December 31, 2018, we had approximately \$127.3 million of debt outstanding with accrued interest. In August 2017, we completed our 2017 Term Loan under which we borrowed \$75.0 million, with unpaid interest totaling \$2.1 million at December 31, 2018. In addition, we have \$50.2 million outstanding under our Credit Line with UBS. 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.

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, our Signatera cancer diagnostic test, 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 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.***

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 December 31, 2018. In addition, we are working to develop our Signatera (RUO) liquid biopsy technology, which is an 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 develop a 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 continued to experience 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 may 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 7—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 7—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 those revenues to increase materially with regard to NIPT. However, we expect our Medicare revenues to increase as we move into the oncology and transplant rejection fields. Additionally, 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 ability to receive future revenue from our planned Signatera CLIA test, as well as our transplant rejection test currently in development, 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 March 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. 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 increasingly require 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 anticipate initially commercializing our planned Signatera CLIA laboratory test, and our transplant rejection test that we are developing, 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 7—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 less consumers will 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. This could also 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 7—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, we have recently launched Signatera (RUO) as 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 7—Commitments and Contingencies—Legal Proceedings" in the Notes to Consolidated Financial Statements. We have in the past also been engaged in patent infringement litigation with Sequenom. The number of contested intellectual property proceedings may increase as the number of products and the level of competition in our industry segments grows. Defending against infringement claims is costly and may divert the attention of our management and technical personnel. If we are unsuccessful in defending against patent infringement claims, we could be required to stop developing or commercializing products or services; pay potentially substantial monetary damages; and/or 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 while we attempt to develop alternative non-infringing products. Any of these or other adverse outcomes could prevent us from offering our tests, which would 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 certain of Illumina's tests infringe on our U.S. Patent No. 8,682,592, as further described in "Note 7—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, strategic and commercial partnerships and relationships, joint ventures, 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 7—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 7 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 the earliest of (a) the end of the fiscal year (i) following the fifth anniversary of the closing of our IPO, or December 31, 2020, (ii) in which the market value of our common stock that is held by non-affiliates exceeds \$700 million and (iii) in which we have total annual gross revenues of \$1.07 billion or more during such fiscal year, and (b) the date on which we issue more than \$1 billion in non-convertible debt in a three-year period.

***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, to the extent we are no longer an emerging growth company. We do not expect to have our independent registered public accounting firm attest to our management report on internal controls over financial reporting for so long as we are an emerging growth company.

Although we have 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.***

In the future, 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 from time to time. We also expect 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 December 31, 2018, our directors and executive officers and their affiliates beneficially own, in the aggregate, approximately 34.4% of our outstanding capital stock. As a result, these stockholders will 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 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 2. PROPERTIES**

Our corporate headquarters are located in San Carlos, California. We lease office facilities under non-cancelable operating lease agreements. We currently occupy approximately 136,000 square feet of laboratory and office space at 201 Industrial Road in San Carlos pursuant to a lease that we directly entered into with our landlord in October 2016. This lease covers two office spaces (the "First Space" and the "Second Space"). The First Space covers approximately 88,000 square feet at a base rent of \$319,095 per month. The Second Space covers approximately 48,000 square feet at a base rent of \$190,424 per month. The lease term is approximately 84 months and expires in October 2023.

In Tukwila, Washington, we lease a facility to provide storage of our cord blood tissue units. The facility covers approximately 10,000 square feet, with a lease term of 62 months beginning in June 2018 and expiring in July 2023.

Our subsidiary leases laboratory and office space in Austin, Texas, comprising approximately 94,000 square feet pursuant to a lease expiring in November 2026.

We may expand our facilities capacity as our employee base and laboratory processing needs grow. We believe that we will be able to obtain additional space on commercially reasonable terms.

### **ITEM 3. 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 7—Commitments and Contingencies—Legal Proceedings” in the Notes to Consolidated Financial Statements, which is incorporated herein by reference.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## **PART II**

### **ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

#### ***Market Price of Our Common Stock***

Our common stock is listed on the Nasdaq Global Select Market under the symbol "NTRA".

#### ***Holders***

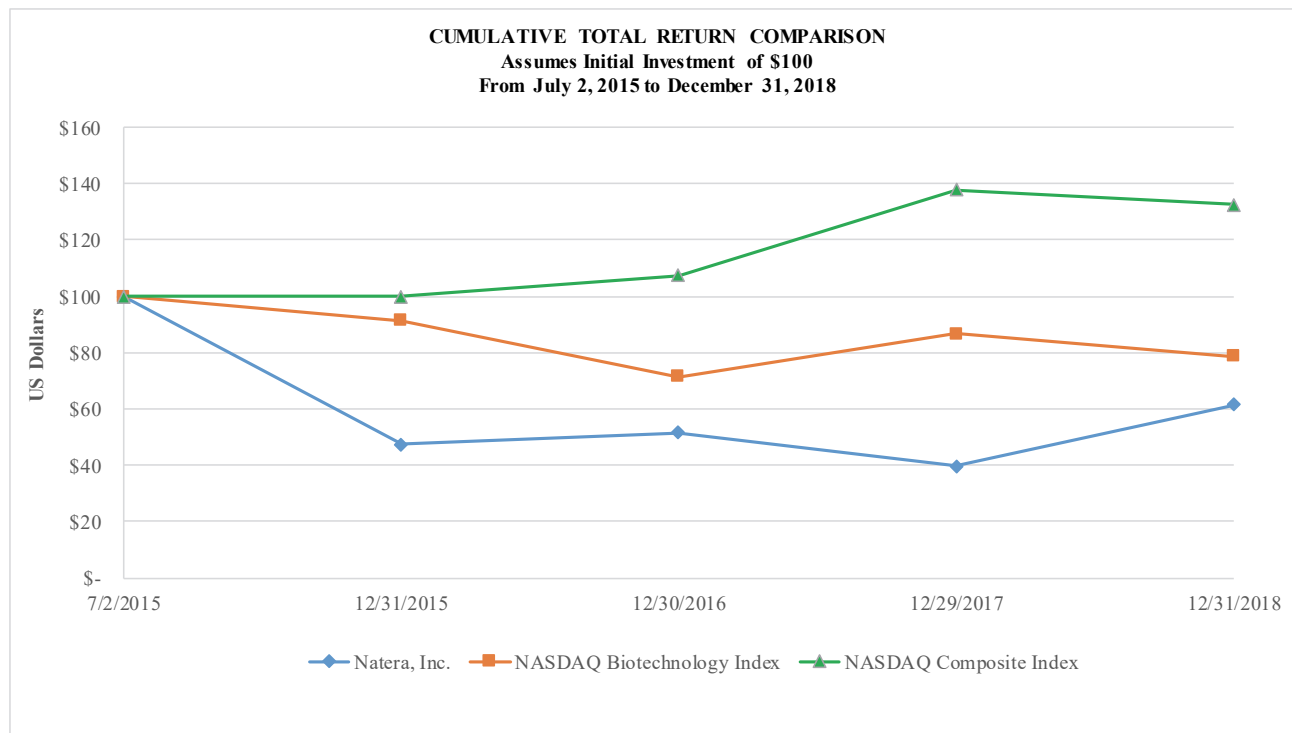
As of December 31, 2018, we had 20 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

#### ***Dividends***

No cash dividends have ever been paid or declared on our common stock. We currently intend to retain all future earnings, if any, for use in our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors our board of directors may deem relevant. Our credit agreement with OrbiMed Royalty Opportunities II, LP, or OrbiMed, restricts our ability to pay cash dividends on our common stock, and we may also enter into credit agreements or other borrowing arrangements in the future that may further restrict our ability to declare or pay cash dividends on our common stock.

## Performance Graph

This performance graph shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our other filings under the Exchange Act or the Securities Act except to the extent we specifically incorporate it by reference into such filing. The following graph compares the cumulative total stockholder return on our common stock between our initial public offering on July 2, 2015 and December 31, 2018 with the cumulative total return of (i) the NASDAQ Biotechnology Index and (ii) the NASDAQ Composite Index over the same period. The chart assumes \$100 was invested at the close of market on July 2, 2015, and assumes the reinvestment of any dividends. The stock price performance on the following graph is not necessarily indicative of future stock price performance.



Trade Date	Natera, Inc.	Nasdaq Biotechnology	Nasdaq Composite
Base period 7/2/2015 .....	\$ 100.00	\$ 100.00	\$ 100.00
12/31/2015 .....	\$ 47.49	\$ 91.34	\$ 99.96
12/31/2016 .....	\$ 51.50	\$ 71.53	\$ 107.46
12/31/2017 .....	\$ 39.53	\$ 86.60	\$ 137.81
12/31/2018 .....	\$ 61.39	\$ 78.52	\$ 132.46

## Recent Sales of Unregistered Securities

None.

## Purchases of Equity Securities by the Issuer and Affiliated Parties

None.

## ITEM 6. SELECTED FINANCIAL DATA

The following table presents our selected historical consolidated financial data. The consolidated statements of operations data for the three fiscal years ended December 31, 2018, 2017 and 2016 and the consolidated balance sheet data as of December 31, 2018 and 2017 are derived from our audited consolidated financial statements included elsewhere in this annual report on Form 10-K.

The consolidated statements of operations data for the years ended December 31, 2015 and 2014, and the balance sheet data as of December 31, 2016, 2015 and 2014 are derived from audited financial statements that are not included in this annual report on Form 10-K.

The selected historical consolidated balance sheet and operating data presented below should be read in conjunction with the consolidated financial statements and the notes to such statements and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this annual report on Form 10-K. Historical results are not necessarily indicative of the results to be expected in the future.

(in thousands, except per share data)	Year ended December 31,				
	2018	2017 (As Revised)(1)	2016 (As Revised)(1)	2015 (1)	2014 (1)
<b>Selected Statement of Operations Data:</b>					
Total revenues . . . . .	\$ 257,654	\$ 209,625	\$ 212,512	\$ 190,355	\$ 159,289
Total cost and expenses . . . . .	372,282	344,966	313,562	250,193	158,624
Interest expense and other (expense) income, net . . . . .	(13,205)	(1,833)	865	(10,437)	(5,817)
Income tax expense . . . . .	(321)	(454)	(142)	—	—
Net loss . . . . .	<u>\$ (128,154)</u>	<u>\$ (137,628)</u>	<u>\$ (100,327)</u>	<u>\$ (70,275)</u>	<u>\$ (5,152)</u>
Net loss per share, basic . . . . .	<u>\$ (2.22)</u>	<u>\$ (2.58)</u>	<u>\$ (1.95)</u>	<u>\$ (2.68)</u>	<u>\$ (1.07)</u>
Net loss per share, diluted . . . . .	<u>\$ (2.22)</u>	<u>\$ (2.59)</u>	<u>\$ (1.95)</u>	<u>\$ (2.68)</u>	<u>\$ (1.07)</u>

(in thousands)	As of December 31,				
	2018	2017 (As Revised)(1)	2016 (As Revised)(1)	2015 (1)	2014 (1)
<b>Selected Balance Sheet Data:</b>					
Cash, cash equivalents and restricted cash. . . . .	\$ 51,004	\$ 13,021	\$ 16,690	\$ 30,531	\$ 88,487
Short-term investments . . . . .	107,461	106,247	130,860	201,586	—
Inventory . . . . .	13,633	8,998	6,414	8,093	11,542
Property and equipment, net . . . . .	24,336	29,667	32,289	12,710	14,574
Total assets . . . . .	268,171	214,613	247,781	265,240	123,623
Debt . . . . .	123,510	123,177	49,624	42,090	26,814
Total liabilities . . . . .	236,009	189,196	104,204	80,475	54,346
Convertible preferred stock . . . . .	—	—	—	—	240,612
Total stockholders' equity (deficit) . . . . .	32,162	25,417	143,577	184,765	(171,335)

- (1) The summary consolidated financial data for the years ended December 31, 2018, 2017 and 2016, and as of December 31, 2018, 2017, and 2016 reflects the adoption of Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (“ASU 2014-09”). See Note 2 to the consolidated financial statements for a summary of adjustments. The summary consolidated financial data for the years ended December 31, 2015 and 2014, and as of December 31, 2015 and 2014 does not reflect the adoption of ASU 2014-09.

## ITEM 7. 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 consolidated financial statements and related notes included in Part II, Item 8 of this report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in "Risk Factors" included elsewhere in 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 and 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 \$257.7 million for the year ended December 31, 2018, and \$209.6 million and \$212.5 million, as revised, for the years ended December 31, 2017 and 2016, 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 Screening in 2012; Panorama NIPT in 2013; our microdeletions panel for Panorama in 2014; Constellation in 2015; and Evercord, Vistara, Signatera (RUO) and our new Panorama test offered to screen twin pregnancies for zygosity and chromosomal abnormalities in 2017.

In the year ended December 31, 2018, 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 direct sales force and through 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 revenue 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 December 31, 2018, we have in-network contracts with insurance providers that account for approximately 209 million 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 also reimburse for our products through out-of-network claims submission processes 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 our direct sales force, our 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. 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 year ended December 31, 2018, we processed approximately 668,600 tests, comprised of approximately 625,900 tests accessioned in our laboratory and 39,100 processed through our Constellation software platform, or Constellation units, compared to approximately 515,200 tests processed during the year ended December 31, 2017, comprised of approximately 486,000 tests accessioned and 29,200 Constellation units; and approximately 447,600 tests processed during the year ended December 31, 2016, comprised of approximately 430,600 tests accessioned and 17,000 Constellation units. This increase in volume 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 429,600 Panorama tests during the year ended December 31, 2018, which represents an increase of approximately 25% over 2017 and an increase of approximately 29% over 2016. We accessioned approximately 173,800 HCS tests during the year ended December 31, 2018, which represents an increase of approximately 39% over 2017 and an increase of approximately 115% over 2016.

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 year ended December 31, 2018 was 83%, down from 84% when compared to the year ended December 31, 2017, but up from 78% when compared to the year ended December 31, 2016. The percent of our revenues attributable to U.S. laboratory partners for the year ended December 31, 2018 was 5%, which was flat when compared to the year ended December 31, 2017 and down from 11% when compared to the year ended December 31, 2016. 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 partners and other international sales for the years ended December 31, 2018 was 12%, up from 11% for the year ended December 31, 2017 and 11% for the year ended December 31, 2016.

In addition to distributing molecular diagnostic tests to be performed at our laboratory, either directly or through our laboratory partners, we also establish licensing arrangements with laboratories under our cloud-based distribution model, whereby our laboratory licensees run the molecular workflows themselves and then access 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 ourselves, our costs per test under this model are also lower. In February 2014, we entered into 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. Starting the fourth quarter of 2015, we began entering into other licensing arrangements. For the years ended December 31, 2018, 2017 and 2016, we have recognized revenues of \$2.4 million, \$2.4 million and \$2.2 million from the DDC arrangement, respectively. Regarding revenues recognized from our licensing arrangements, we have recognized \$2.4 million, \$1.8 million and \$0.9 million during the years ended December 31, 2018, 2017 and 2016, 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 and 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 to 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, which is an NIPT that screens for single-gene disorders and offered as 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 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 year ended December 31, 2018, total revenues were \$257.7 million, compared to \$209.6 million and \$212.5 million, respectively, in the years ended December 31, 2017 and 2016, as revised. Panorama revenues accounted for \$140.9 million, or 55%, of total revenues for the year ended December 31, 2018; \$128.9 million, or 62%, of total revenues for the year ended December 31, 2017, as revised; and \$140.6 million, or 66%, of total revenues for the year ended December 31, 2016, as revised. HCS revenues accounted for \$87.2 million, or 34% of total revenues for the year ended December 31, 2018; \$63.5 million, or 30%, of total revenues for the year ended December 31, 2017, as revised; \$56.4 million, or 27% of our revenues for the year ended December 31, 2016, as revised. For the years ended December 31, 2018, 2017 and 2016, there were no customers exceeding 10% of the total revenues on an individual basis. In January 2017, we terminated our licensing and distribution agreement with Bio-Reference, which represented less than 1% and 7% of total revenues, as revised, for the years ended December 31, 2017 and 2016, respectively. Revenues from customers outside the United States were \$31.7 million, representing 12% of total revenues for the year ended December 31, 2018. For the years ended December 31, 2017 and 2016, revenues from customers outside the United States were \$24.1 million and \$24.0 million, representing approximately 11% and 11%, respectively, of total revenues, as revised. 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.

Our net losses for the years ended December 31, 2018, 2017 and 2016 were, respectively, \$128.2 million, \$137.6 million and \$100.3 million, as revised. This included non-cash stock compensation expense of \$14.2 million, \$11.4 million and \$10.6 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of \$574.6 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 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 our cloud-based distribution model licensees. Starting the second quarter of 2017, we began recognizing revenues from Evercord offering.

Sales of Panorama and HCS 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 December 31, 2018, we have commercially launched 15 licensing and service arrangements with laboratories under our cloud-based distribution model from which we recognized revenue from in 2018.

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 Topic 606, *Revenue from Contracts with Customers* (“ASC 606”), using the full retrospective approach. In accordance with ASC 606, the total consideration we expect to collect from insurance carriers, clinics, 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 some 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 on 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 took effect beginning January 1, 2019, and may 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.

Our financial performance is also impacted by our increase in 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, we expect its associated gross margin to be higher.

### ***Cost of Product Revenues***

The components of our cost of product revenues are materials 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 record, 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 to be higher. While costs associated with our licensing arrangements have become steady over time, we expect additional costs associated with Evercord 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 record set up costs; and 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 the near term, we expect general and administrative expenses related to compliance with the rules and regulations of the Securities and Exchange Commission and the Nasdaq Global Select Market, additional insurance expenses, investor relations activities and other administrative and professional services to become steady, whereas selling and marketing related expenses 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 Income and Other (Expense) Income, Net***

Interest income and other (expense) income, net is comprised of 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.

Our significant accounting policies are described in Note 2 to our audited financial statements included elsewhere in this Annual Report. Some of these accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. We consider the following critical accounting policies to reflect the more significant estimates and assumptions used in the preparation of our financial statements.

### ***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 consolidated 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 is 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 third-party payers on behalf of the patients, and the patients are considered 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 a 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 years ended December 31, 2018 and 2017, \$3.3 million and \$4.9 million were released from amounts previously held in reserves in other accrued liabilities and recognized as product revenue. There were no amounts released from our reserves during the year ended December 31, 2016.

### ***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 License, Development and Distribution Agreement with Qiagen ("the Qiagen Agreement").

### ***Income Taxes***

We account for income taxes in accordance with ASC 740, *Income Taxes* ("ASC 740"), which requires recognition of deferred tax assets and liabilities for the expected tax consequences of our future financial and operating activities. Under ASC 740, we determine deferred tax assets and liabilities based on the temporary difference between the financial statement and tax bases of assets and liabilities using the tax rates in effect for the year in which we expect such differences to reverse. If we determine that it is more likely than not that we will not generate sufficient taxable income to realize the value of some or all of our deferred tax assets (net of our deferred tax liabilities), we establish a valuation allowance offsetting the amount we do not expect to realize. We perform this analysis each reporting period and reduce our measurement of deferred taxes, if the likelihood we will realize them becomes uncertain.

We also account for uncertain tax positions in accordance with ASC 740, which requires us to adjust our financial statements to reflect only those tax positions that are more-likely-than-not to be sustained upon review by federal or state examiners. We may recognize a tax benefit only if it is more likely than not the tax position will be sustained on

examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon settlement. Our policy is to report interest and penalties related to unrecognized tax benefits as income tax expenses.

On December 22, 2017, President Donald Trump signed into U.S. law the Tax Cuts and Jobs Act of 2017 (“Tax Act”). The Tax Act reduced the corporate income tax rate from 34% to 21% effective January 1, 2018. ASC 740 required 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 the 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. We made provisional adjustments to reduce our deferred tax assets and liabilities as of December 31, 2017, based on the reduction of the U.S. federal corporate tax rate and assessed the realizability of our deferred tax assets based on our current understanding of the provisions of the new law. As of December 31, 2018, we completed our assessment of the tax rate change and determined no additional adjustments were required.

### ***Stock-Based Compensation***

We have included stock-based compensation as part of our cost of revenues and our operating expenses in our statements of operations as follows:

	Year ended December 31,								
	2018			2017			2016		
	Employee	Non-Employee	Total	Employee	Non-Employee (in thousands)	Total	Employee	Non-Employee	Total
Cost of revenues . . . . .	\$ 564	\$ 5	\$ 569	\$ 544	\$ —	\$ 544	\$ 651	\$ (10)	\$ 641
Research and development . . . . .	4,043	—	4,043	3,214	—	3,214	2,829	24	2,853
Selling, general and administrative . . . . .	9,474	112	9,586	7,644	—	7,644	6,837	270	7,107
Total . . . . .	<u>\$ 14,081</u>	<u>\$ 117</u>	<u>\$ 14,198</u>	<u>\$ 11,402</u>	<u>\$ —</u>	<u>\$ 11,402</u>	<u>\$ 10,317</u>	<u>\$ 284</u>	<u>\$ 10,601</u>

Stock-based compensation related to stock options granted to our employees and non-employees is measured at the grant date based on the fair value of the award, which is determined by the Black-Scholes option-pricing model. The fair value is recognized as expense over the requisite service period, which is generally the vesting period of the respective awards. No compensation cost is recognized on stock options for employees and non-employees who do not render the requisite service and therefore forfeit their rights to the stock options. The measurement of stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest, and the resulting change in value, if any, is recognized in our statements of operations and comprehensive loss during the period that the related services are rendered.

### ***Impairment of Long-lived Assets***

We evaluate our 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. We then compare the carrying amounts of the 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.

For the year ended December 31, 2018, an asset impairment charge of \$1.5 million was recorded in research and development expenses in the statements of operations and comprehensive loss. This charge was recorded to write off certain project development costs that were previously capitalized.

For the year ended December 31, 2017, we recorded asset impairment charges totaling \$0.6 million in cost of product revenues. The charges were recorded after we fully decommissioned certain sequencing and automation equipment in January 2017. For the year ended December 31, 2016, we performed an impairment analysis on a number of sequencing and automation equipment, and their service lives were accelerated as we determined that they were significantly shorter than we had initially expected. As a result, we recorded an asset impairment charge of \$2.1 million.

## Results of operations

### Comparison of the years ended December 31, 2018, 2017 and 2016

(in thousands)	Year Ended December 31,			Changes			
	2018	2017	2016	2018 - 2017		2017 - 2016	
		(As Revised)	(As Revised)	Amount	Percent	Amount	Percent
<b>Revenues:</b>							
Product revenues . . . . .	\$ 240,366	\$ 203,777	\$ 209,406	\$ 36,589	18.0 %	\$ (5,629)	(2.7)%
Licensing and other revenues . . . . .	17,288	5,848	3,106	11,440	195.6	2,742	88.3
Total revenues . . . . .	257,654	209,625	212,512	48,029	22.9	(2,887)	(1.4)
<b>Cost and expenses:</b>							
Cost of product revenues . . .	158,081	135,508	134,494	22,573	16.7	1,014	0.8
Cost of licensing and other revenues . . . . .	7,974	4,088	1,080	3,886	95.1	3,008	278.5
Research and development ..	51,355	50,064	41,862	1,291	2.6	8,202	19.6
Selling, general and administrative . . . . .	154,872	155,306	136,126	(434)	(0.3)	19,180	14.1
Total cost and expenses ..	372,282	344,966	313,562	27,316	7.9	31,404	10.0
<b>Loss from operations</b> . . . . .	(114,628)	(135,341)	(101,050)	20,713	(15.3)	(34,291)	33.9
Interest expense . . . . .	(10,476)	(4,213)	(533)	(6,263)	148.7	(3,680)	690.4
Interest and other (expense) income, net . . . . .	(2,729)	2,380	1,398	(5,109)	(214.7)	982	70.2
Loss before income taxes . . . . .	(127,833)	(137,174)	(100,185)	9,341	(6.8)	(36,989)	36.9
Income tax expense . . . . .	(321)	(454)	(142)	133	(29.3)	(312)	219.7
<b>Net loss</b> . . . . .	<u>\$ (128,154)</u>	<u>\$ (137,628)</u>	<u>\$ (100,327)</u>	<u>\$ 9,474</u>	<u>(6.9)%</u>	<u>\$ (37,301)</u>	<u>37.2 %</u>

## 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 \$48.0 million, or 22.9%, when compared to the year ended December 31, 2017. Total revenues declined by \$2.9 million, or 1.4%, in the year ended December 31, 2017 when compared to the year ended December 31, 2016. We transitioned to the new revenue recognition standard, ASC 606, as of January 1, 2018 on a full retrospective basis, and total revenues for the years ended December 31, 2017 and 2016 were impacted by this transition.

### Product revenues

During the year ended December 31, 2018, product revenues increased \$36.6 million, or 18.0%, as a result of continued revenue growth in Panorama and HCS tests. Panorama and HCS revenues had a net increase of \$12.0 million and \$23.7 million, respectively. A portion of the net increase in Panorama and HCS revenues pertained to cumulative catch-up revenue adjustments totaling approximately \$7.0 million and \$3.1 million recognized in the current period, respectively, due to collections from appeals on claims in the prior periods. Revenues from other tests increased by \$0.8 million. The number of Panorama and HCS tests accessioned continued to grow during the year ended December 31, 2018

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, and negative coverage determinations for our microdeletions screening.

During the year ended December 31, 2017, product revenues decreased \$5.6 million, or 2.7%. The decrease was the combined effect of reductions in Panorama and other test revenues, along with higher HCS revenues. From a volume perspective, the number of Panorama tests accessioned grew when compared to the year ended December 31, 2016, however, factors such as erosion in collection trends related to prior authorization requirements, reduced reimbursement for our microdeletions screening, and, to a smaller extent, our termination of a distribution agreement in January 2017 caused Panorama revenues to decrease by \$11.7 million. Such decrease was impacted by a favorable movement of \$4.1 million of revenues recognized from the release of certain amounts previously held in reserves from third-party payers. Our HCS test volumes increased in the year ended December 31, 2017, resulting in a corresponding increase in revenues from that test by \$7.1 million. The increase in HCS revenues included \$0.8 million of revenues recognized from the release of certain amounts previously held in reserves from third-party payers. As for other product revenues, the decrease was primarily attributable to erosion in collection trends.

#### *Licensing and other revenues*

Licensing and other revenues increased \$11.4 million, or 195.6%, during the year ended December 31, 2018 when compared to the same period in the prior year due to additional revenues of \$4.0 million from our Evercord business, \$1.1 million from Constellation software licensing arrangements with our licensees and the associated IVD kits. We also recognized revenues totaling \$5.8 million from the agreement with Qiagen that we entered into in March 2018.

Licensing and other revenues increased by \$2.7 million, or 88.3%, in the year ended December 31, 2017 when compared to the year ended December 31, 2016, due to the additional revenues of \$1.7 million from our Constellation software licensing arrangements with our licensees and the associated IVD kits, and \$1.0 million of revenues recognized from our Evercord business.

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 year ended December 31, 2018, total reported units were approximately 628,600, comprising of approximately 591,200 reported units that were accessioned and 37,400 Constellation units. Within this period, we recognized revenues on approximately 412,200 Panorama tests accessioned and 31,300 Panorama Constellation units, and approximately 164,000 HCS tests accessioned. During year ended December 31, 2017, total reported units were approximately 488,500, comprising of approximately 460,400 reported units that were accessioned and 28,100 Constellation units. Within that period, we recognized revenues on approximately 328,800 Panorama tests accessioned and 21,500 Panorama Constellation units, and approximately 117,800 HCS tests accessioned.

Revenues from customers outside the United States were \$31.7 million for the year ended December 31, 2018, and \$24.1 million and \$24.0 million, as revised, for the year ended December 31, 2017 and 2016, respectively.

#### *Cost of product revenues*

During the year ended December 31, 2018, cost of product revenues increased \$22.6 million, or 16.7%, when compared to the year ended December 31, 2017 primarily due to \$10.0 million of additional costs incurred from increased volume of HCS tests accessioned and materials acquired for our in-house HCS automation, higher material and service costs of \$9.0 million associated with increased volume of our Panorama test, with the remainder of the increase attributable to labor and overhead allocation driven by resources dedicated to our HCS automation process and depreciation of automation and sequencing equipment utilized for our Panorama test.

Cost of product revenues increased by \$1.0 million, or 0.8%, in the year ended December 31, 2017 compared to the year ended December 31, 2016 due to \$15.7 million of additional costs incurred in connection with the increased volume of HCS tests accessioned and higher freight charges of \$1.3 million associated with overall volume increase in the year ended December 31, 2017, offset by cost savings of \$9.6 million resulting from our transition to Version 3 of



Panorama, lower overhead of \$3.1 million, and lower material costs of \$0.3 million related to other products. Further, we benefitted from a decrease of \$1.6 million due to lower inventory reserves recorded in the current period, and a decrease of \$1.4 million in asset impairment charges after we fully decommissioned our previous generation of sequencing and automation equipment in January 2017. As a percentage of product revenues, cost of product revenues was 66.0% for the year ended December 31, 2017 compared to 62.9% in the prior year, which was the result of the additional costs incurred due to the higher volume of HCS tests accessioned.

### ***Cost of licensing and other revenues***

Cost of licensing and other revenues increased by \$3.9 million, or 95.1%, during the year ended December 31, 2018 compared to the year ended December 31, 2017 primarily due to the launch of our Evercord business in April 2017, and costs incurred in connection with Signatera (RUO) which we launched in August 2017. During the year ended December 31, 2018, costs incurred from our Evercord business increased \$3.7 million, and costs associated with Signatera (RUO) were \$1.0 million, while costs associated with the improvement and maintenance of our Constellation software platform decreased by \$0.8 million when compared to the same period in the prior year. We expect the reduction in costs required to improve and maintain our Constellation software platform to continue as its design and functionality matures over time.

Cost of licensing and other revenues increased by \$3.0 million, or 278.5%, in the year ended December 31, 2017 compared to the prior year as the number of licensees under our Constellation cloud-based distribution model increased, and as we continued to improve and maintain our Constellation software platform. Costs allocated to Constellation software platform increased approximately \$1.3 million, of which \$0.8 million was related to engineering and maintenance of our software platform, and \$0.5 million was related to the amortization of the Constellation software development and other related material costs. Costs of licensing and other revenues also included \$1.7 million in costs associated with Evercord, which we launched in April 2017. Such costs were related to materials consumed in connection with the collection and processing of cord blood samples, fees paid to our partner and medical doctors for sample processing and storage services, and freight charged to transport the samples to the storage facility.

### ***Research and development***

Research and development expenses increased \$1.3 million, or 2.6%, in the year ended December 31, 2018 compared to the year ended December 31, 2017. The increase was primarily the result of higher salaries and employee benefits of \$0.7 million caused by stock-based compensation expense for additional awards granted and bonuses accrued, higher consulting fees of \$0.3 million, higher facilities-related and office expenses of \$0.7 million, an impairment charge of \$1.5 million recognized for writing off the project development costs previously capitalized; offset by a \$1.7 million decrease in depreciation and overhead allocated to research and development and a \$0.4 million decrease in laboratory supplies as upon completion of the development of our HCS automation workflow, which expenses then shifted to cost of product revenues as we implemented the new workflow, while we expanded our research and development activities in support of transplant and oncology product offerings.

Research and development expenses increased by \$8.2 million, or 19.6%, in the year ended December 31, 2017 compared to the year ended December 31, 2016. The increase was primarily attributable to higher salaries and benefit costs of \$2.7 million as a result of our annual merit adjustments, higher costs of employee benefits and average headcount growth, facilities-related costs and office expenses of \$1.9 million associated with higher repairs and maintenance expenses, and the expansion of our lease premises, along with higher allocation of rent and property management fees for our headquarters in San Carlos, California. Expenses associated with clinical trials and research and related laboratory supplies increased by \$3.3 million related to our existing and newly launched products, including the launch of our Signatera (RUO) liquid biopsy offering in August 2017. Depreciation and overhead increased by \$1.1 million as a result of testing and validation work performed on our HCS automation equipment. These were offset by a decrease in outside services of \$0.8 million following the completion of certain research projects.

### ***Selling, general and administrative***

Selling, general and administrative expenses decreased by \$0.4 million, or 0.3%, in the year ended December 31, 2018 compared to the year ended December 31, 2017. The primary factors causing the decrease were an \$11.4 million decrease in legal settlement expenses accrued compared to the same period of the prior year, and a \$3.1 million reduction in selling and marketing and travel related expenses. These decreases were offset by higher salaries and employee benefits of \$7.6 million associated with stock-based compensation expense for additional awards granted and bonuses accrued, higher fees of \$4.2 million paid to third party vendors for collections from insurance carriers and consulting fees for work performed by outside legal counsel, higher facilities-related and office expenses of \$1.0 million due to the expansion of occupancy in our San Carlos, California headquarters, higher administration fees \$0.5 million charged for our self-funded health insurance plans, and an increase in other corporate-related expenses of \$0.7 million.

Selling, general and administrative expenses increased by \$19.2 million, or 14.1%, in the year ended December 31, 2017 compared to the year ended December 31, 2016. The increase was primarily due to a \$11.4 million in legal settlement expenses accrued for reimbursement related claims, as further discussed in Note 7 of our Notes to Consolidated Financial Statements, higher salaries and employee benefit costs of \$8.5 million associated with headcount growth, annual merit salary adjustments, higher health insurance premiums charged, and higher stock-based compensation expense. Outside services increased by \$0.5 million primarily due to fees paid to consultants hired for technical accounting projects and internal controls assessment, and audit and related fees incurred by our annual audit, quarterly reviews and corporate tax related work. Additionally, facilities, office and other corporate related expenses increased \$1.5 million primarily attributable to higher spending on supplies and software subscription, higher depreciation resulting from leasehold improvements made in our Austin, Texas location, and higher rent and property management fees charged for our headquarters in San Carlos, California. These were offset by a \$2.7 million decrease in selling and marketing related expenses as we scaled back on speaker conferences, public relations and promotional events.

### ***Interest expense***

Interest expense increased by \$6.3 million, or 148.7%, in the year ended December 31, 2018 compared to the prior year. The increase was the combined result of \$5.4 million of additional interest incurred and debt discount amortized in connection with our 2017 Term Loan; \$0.6 million of interest charged at the variable interest rate on the Credit Line, which was higher in the year ended December 31, 2018, and \$0.3 million of interest incurred from the quarterly installments we paid under the settlement agreement for reimbursement related claims.

Interest expense increased by \$3.7 million, or 690.4%, in the year ended December 31, 2017 compared to the prior year. The increase was the combined result of \$3.2 million of interest incurred and debt discount amortized in connection with our 2017 Term Loan and \$0.5 million of interest charged at the variable interest rate on our Credit Line, which was higher in the year ended December 31, 2017.

### ***Interest and other (expense) income, net***

Interest and other expense, net was \$2.7 million for the year ended December 31, 2018, compared to interest and other income of \$2.4 million in the same period of the prior year, which represented a net increase in expenses of \$5.1 million. This net increase in expenses was primarily due to a \$5.3 million unfavorable movement on the fair value remeasurement of our warrant liability and a \$0.4 million unfavorable change in exchange rates for our foreign currency transactions, offset by higher interest income of \$0.6 million related to purchases of new securities for our investment portfolio during the third and fourth quarters of 2018.

Interest and other income, net was \$2.4 million in the year ended December 31, 2017, compared to interest and other income of \$1.4 in the prior year, which represented an increase of \$1.0 million. The increase was primarily due to a \$1.3 million increase in the fair value of our warrant liability, and a decrease in interest income and other expenses of approximately \$0.3 million primarily attributable to a reduction of our investment portfolio.

## **Liquidity and Capital Resources**

We have incurred net losses each year since our inception. For the years ended December 31, 2018, 2017 and 2016, we had net losses of \$128.2 million; \$137.6 million and \$100.3 million, as revised, respectively, and we expect to incur additional losses in the future as we continue to devote a substantial portion of our resources to our research and development and commercialization efforts of our existing and new products. As of December 31, 2018, we had \$46.4 million in cash and cash equivalents, \$107.5 million in marketable securities, \$50.2 million of outstanding balance of the Credit Line including accrued interest, and \$73.4 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 July 12, 2018, we completed an equity offering to sell 4,500,000 shares of our common stock to the public at a price of \$20 per share, along with the sale of 675,000 additional shares of our common stock to the underwriters upon their exercise of the option to purchase those shares. Upon the closing of the equity offering on July 16, 2018, we received proceeds of \$97.3 million before offering expenses, which totaled approximately \$0.5 million.

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 March 15, 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 which can be drawn in increments at any time. The Credit Line bears interest at 30-day LIBOR plus 1.10%, and it is secured by a first priority lien and security interest in our money market and marketable securities 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 it, in its discretion and without cause, at any time.

### ***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 to borrow at our option at any time through December 31, 2018, subject to standard conditions. The amounts borrowed under the 2017 Term Loan will primarily be used for general corporate purposes and to fund and support our business and operations. Interest accrues 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 on a quarterly basis, 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 additional 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.

## Cash Flows

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

	Year Ended December 31,		
	2018	2017 (As Revised)	2016 (As Revised)
(in thousands)			
Cash used in operating activities . . . . .	\$ (70,581)	\$ (97,825)	\$ (74,052)
Cash (used in) provided by investing activities . . . . .	(5,161)	13,784	47,027
Cash provided by financing activities . . . . .	113,725	80,372	13,184
Net increase (decrease) in cash, cash equivalents and restricted cash . . . . .	37,983	(3,669)	(13,841)
Cash, cash equivalents and restricted cash, beginning of period . . . . .	13,021	16,690	30,531
Cash, cash equivalents and restricted cash, end of year . .	<u>\$ 51,004</u>	<u>\$ 13,021</u>	<u>\$ 16,690</u>

### Cash Used in Operating Activities

Cash used in operating activities during the year ended December 31, 2018 was \$70.6 million. The net loss of \$128.2 million includes \$30.4 million in non-cash benefits resulting from \$7.5 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 an automation project, \$14.2 million of stock-based compensation expense, \$0.3 million of inventory excess adjustments, \$0.2 million of premium amortization and discount accretion on investment securities, \$4.1 million of remeasurement loss on changes in the fair value of our warrant liability; \$2.6 million of interest accrued on our Credit Line and under our settlement agreement related to reimbursement claims, as well as amortization of debt discount in connection with our 2017 Term Loan, and other insignificant items. Operating assets generated cash outflows of \$20.0 million primarily due to an \$18.1 million increase in accounts receivable and a \$4.9 million increase in inventory, offset by a \$2.7 million reduction in prepaid expenses and other current assets and a \$0.3 million decrease in other assets. Operating liabilities generated cash inflows of \$47.2 million due to an increase in accounts payable of \$3.8 million, an increase in accrued compensation of \$3.0 million, an increase in deferred revenue of \$42.8 million primarily driven by prepaid sales-based royalties and performance obligations not yet delivered to Qiagen, as well as undelivered storage services from our Evercord business, offset by decreases in other accrued liabilities of \$1.8 million and deferred rent of \$0.7 million.

Cash used in operating activities for the year ended December 31, 2017 was \$97.8 million. A net loss of \$137.6 million included \$20.2 million in non-cash benefits resulting from \$11.4 million of stock based compensation expense, \$7.1 million of depreciation and amortization, \$0.9 million of premium amortization and discount accretion on investment securities, \$0.6 million of asset impairment charges recorded following the final decommissioning of our previous generation of sequencing and automation equipment, \$0.6 million of interest accrued on our Credit Line and amortization of debt discount in connection with our 2017 Term Loan, \$0.5 million of inventory excess adjustments, \$0.2 million of provision of doubtful accounts and other non-cash items, and a remeasurement gain of \$1.1 million on the change in the fair value of our warrants. Operating assets generated cash inflows of \$2.3 million primarily due to a \$6.3 million decrease in accounts receivable, a \$0.6 million decrease in other assets, offset by increases in inventory and prepaid and other current assets of \$3.1 million and \$1.5 million, respectively. Operating liabilities generated cash inflows of \$17.3 million due to an increase of \$14.9 million in other accrued liabilities, which included a settlement accrued for reimbursement-related claims, an increase of \$2.3 million in deferred revenue and deferred rent, net of current portion, a \$1.3 million increase in other long-term liabilities related to the noncurrent portion of the accrued reimbursement-related claims described above, an increase in accounts payable of \$0.2 million, offset by a decrease in accrued compensation of \$1.4 million.

Cash used in operating activities for the year ended December 31, 2016 was \$74.1 million. A net loss of \$100.3 million included \$23.9 million in non-cash benefits resulting from stock compensation expense of \$10.6 million,

depreciation and amortization of \$6.2 million, an impairment charge of \$2.1 million recorded as a result of our plan to phase out certain sequencing and automation equipment significantly earlier than their previously estimated service lives, a write down on obsolete inventory of \$2.1 million, premium amortization on investment securities of \$1.4 million, provision of doubtful accounts of \$1.0 million, and other noncash items of \$0.5 million. Operating assets generated cash outflows of \$9.3 million primarily due to increases in accounts receivable of \$4.0 million, other assets of \$2.8 million, prepaid expenses and other current assets of \$2.1 million and inventory of \$0.4 million. Operating liabilities generated cash inflows of \$11.6, which was the result of an increase in accounts payable of \$1.3 million, an increase in accrued compensation of \$2.5 million, increases in deferred revenue and deferred rent of \$8.2 million, offset by other accrued liabilities of \$0.4 million.

### ***Cash (Used in) Provided by Investing Activities***

Cash used in investing activities for the year ended December 31, 2018 totaled \$5.2 million, which was comprised of \$169.0 million in proceeds resulting from sales and maturities of investments, offset by purchases of investments of \$170.3 million and acquisitions of property and equipment of \$3.9 million. Acquisitions of property and equipment were primarily related to the build-out of our Tukwila, Washington storage facility for our Evercord business, development of software for our patient portal and our Evercord business, and leasehold improvements made to secure additional laboratory space at our San Carlos, California headquarters.

Cash provided by investing activities for the year ended December 31, 2017 totaled \$13.8 million, which was comprised of \$296.5 million in proceeds resulting from sales and maturities of investments, offset by \$272.8 million of purchases of investments, and \$9.9 million in purchases of property and equipment primarily related to the transition to our next generation sequencing and automation technology, purchases of computer equipment, and costs capitalized for the development of our patient portal.

Cash provided by investing activities for the year ended December 31, 2016 totaled \$47.0 million, which was comprised of \$123.7 million in proceeds resulting from sales and maturities of investments, offset by \$53.5 million of purchases of investments, and acquisitions of property and equipment of \$23.2 million. Acquisitions of property and equipment were primarily related to the build-out of our Austin, Texas facility, leasehold improvements completed for the expansion of our headquarters in San Carlos, California, and purchases of computer hardware and software.

### ***Cash Provided by Financing Activities***

Cash provided by financing activities for the year ended December 31, 2018 totaled \$113.7 million, of which \$96.8 million was related to funds raised from the equity offering to sell shares of our common stock in July 2018, net of issuance costs. The remaining \$16.9 million was proceeds from exercise of stock options and shares purchased from the employee stock purchase plan.

Cash provided by financing activities for the year ended December 31, 2017 totaled \$80.4 million, which consisted of \$75.0 million in borrowings from our 2017 Term Loan we entered into in August 2017, along with payment of debt issuance cost of \$0.3 million, and \$5.7 million of proceeds from exercise of stock options and employee stock purchase plan.

Cash provided by financing activities for the year ended December 31, 2016 totaled \$13.2 million consisting of a net \$7.0 million in short term borrowings under our Credit Line and \$6.2 million of proceeds from exercise of stock options and employee stock purchase plan.

### **Contractual Obligations and Other Commitments**

See “Liquidity and Capital Resources” for a description of our contractual obligations under the Credit Line and the 2017 Term Loan.

The following table summarizes our contractual obligations as of December 31, 2018:

		Payments Due by Period			
	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years
		(In thousands)			
Operating leases . . . . .	\$ 50,631	\$ 8,588	\$ 17,892	\$ 17,021	\$ 7,130
Short-term debt <sup>(1)</sup> . . . . .	49,000	49,000	—	—	—
Long-term debt facility <sup>(2)</sup> . . . . .	75,000	—	—	—	75,000
Interest accrued on debt <sup>(3)</sup> . . . . .	3,274	3,274	—	—	—
Inventory purchase and other contractual obligations <sup>(4)</sup> . .	18,736	17,981	755	—	—
Total . . . . .	\$ 196,641	\$ 78,843	\$ 18,647	\$ 17,021	\$ 82,130

(1) Represents proceeds drawn from our Credit Line.

(2) Represents proceeds from our 2017 Term Loan, which will mature in August 2024.

(3) Represents interest accrued on our Credit Line of \$1.2 million and 2017 Term Loan of \$2.1 million. The interest accrued for the 2017 Term Loan was paid in January 2019.

(4) Represents material open inventory purchase orders in the aggregate with suppliers, including non-cancelable commitments with Illumina, Inc. for \$8.9 million for inventory material used in the laboratory testing process within the next 12 month. Also included were \$2.1 million of minimum committed fees relating to a non-cancelable application service agreement with a vendor for gene sequencing data analysis through March 2020, \$0.5 million of non-cancelable contractual commitments with a vendor for biological sample processing and storage within the next 12 months, and \$2.0 million of non-cancelable minimum purchase commitments with a supplier of diagnostic reagents through February 2020.

### ***Operating Lease Obligations***

As of December 31, 2018, we lease office facilities under non-cancelable operating lease agreements. We currently occupy approximately 136,000 square feet of laboratory and office space at our San Carlos, California corporate headquarters pursuant to a lease that we directly entered into with our landlord in October 2016. This lease covers two office spaces (the “First Space” and the “Second Space”). The First Space covers approximately 88,000 square feet at a base rent of \$319,095. The Second Space covers approximately 48,000 square feet at a base rent of \$190,424 per month. The term of this lease is approximately 84 months and expires in October 2023.

In March 2018, we entered into a lease for our 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 at \$11,900 per month, subject to an annual increase of approximately 3%. The lease term is 62 months and expires in July 2023.

In September 2015, our 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 rent payments beginning in December 2016 and increasing from \$0.1 million to \$0.2 million. Pursuant to the terms of the lease, our subsidiary paid a security deposit of \$0.4 million, and the landlord allotted the subsidiary a refundable allowance for leasehold improvements of up to \$7.8 million. We were reimbursed by the landlord the full amount of the allowance in 2017.

### **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 7A: 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 approximately \$1.3 million based on our \$127.3 million debt outstanding, including principal and accrued interest as of December 31, 2018.

Our investment portfolio is also 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 \$1.1 million annually in relation to amounts we would expect to earn, based on our short-term investments as of December 31, 2018.

### ***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 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

### **NATERA, INC.**

#### **INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of Natera, Inc.

### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Natera, Inc. (the Company) as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

### **Adoption of ASU No. 2014-09**

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for revenue in each period presented due to the adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers, as amended.

### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2012

San Francisco, California

March 15, 2019



# **PART I – FINANCIAL INFORMATION**

## **ITEM 1. FINANCIAL STATEMENTS**

### **Natera, Inc.**

#### **Consolidated Balance Sheets**

*(In thousands, except par value per share amount)*

	<u>December 31, 2018</u>	<u>December 31, 2017</u> (As Revised)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 46,407	\$ 12,620
Restricted cash, current portion . . . . .	4,597	59
Short-term investments . . . . .	107,461	106,247
Accounts receivable, net of allowance of \$1,788 in 2018 and \$2,000 in 2017 . . . . .	62,223	44,089
Inventory . . . . .	13,633	8,998
Prepaid expenses and other current assets . . . . .	6,197	8,612
Total current assets . . . . .	<u>240,518</u>	<u>180,625</u>
Property and equipment, net . . . . .	24,336	29,667
Restricted cash, long-term portion . . . . .	—	342
Other assets . . . . .	3,317	3,979
Total assets . . . . .	<u>\$ 268,171</u>	<u>\$ 214,613</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable . . . . .	\$ 14,587	\$ 8,529
Accrued compensation . . . . .	12,668	9,599
Other accrued liabilities . . . . .	32,442	33,257
Deferred revenue, current portion . . . . .	4,131	1,420
Short-term debt financing . . . . .	50,153	50,112
Warrants . . . . .	—	2,644
Total current liabilities . . . . .	<u>113,981</u>	<u>105,561</u>
Long-term debt financing . . . . .	73,357	73,065
Deferred rent, net of current portion . . . . .	8,613	9,241
Deferred revenue, long-term portion . . . . .	40,058	—
Other long-term liabilities . . . . .	—	1,329
Total liabilities . . . . .	<u>236,009</u>	<u>189,196</u>
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value: 50,000 shares authorized; no shares issued and outstanding at December 31, 2018 and 2017, respectively . . . . .	—	—
Common stock, \$0.0001 par value: 750,000 shares authorized at December 31, 2018 and 2017, respectively; 62,083 and 54,040 shares issued and outstanding at December 31, 2018 and 2017, respectively . . . . .	7	6
Additional paid in capital . . . . .	607,236	472,552
Accumulated deficit . . . . .	(574,529)	(446,375)
Accumulated other comprehensive loss . . . . .	(552)	(766)
Total stockholders' equity . . . . .	<u>32,162</u>	<u>25,417</u>
Total liabilities and stockholders' equity . . . . .	<u>\$ 268,171</u>	<u>\$ 214,613</u>

See accompanying notes.

**Natera, Inc.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
*(In thousands, except per share data)*

	Year ended December 31,		
	2018	2017	2016
		(As Revised)	(As Revised)
<b>Revenues</b>			
Product revenues .....	\$ 240,366	\$ 203,777	\$ 209,406
Licensing and other revenues .....	17,288	5,848	3,106
Total revenues .....	257,654	209,625	212,512
<b>Cost and expenses</b>			
Cost of product revenues .....	158,081	135,508	134,494
Cost of licensing and other revenues .....	7,974	4,088	1,080
Research and development .....	51,355	50,064	41,862
Selling, general and administrative .....	154,872	155,306	136,126
Total cost and expenses .....	372,282	344,966	313,562
<b>Loss income from operations</b> .....	(114,628)	(135,341)	(101,050)
Interest expense .....	(10,476)	(4,213)	(533)
Interest and other (expense) income, net .....	(2,729)	2,380	1,398
Loss before income taxes .....	(127,833)	(137,174)	(100,185)
Income tax expense .....	(321)	(454)	(142)
Net loss .....	<u>\$ (128,154)</u>	<u>\$ (137,628)</u>	<u>\$ (100,327)</u>
Unrealized gain (loss) on available-for-sale securities, net of tax .....	214	(41)	691
Comprehensive loss .....	<u>\$ (127,940)</u>	<u>\$ (137,669)</u>	<u>\$ (99,636)</u>
 Net loss per share (Note 13):			
Basic .....	<u>\$ (2.22)</u>	<u>\$ (2.58)</u>	<u>\$ (1.95)</u>
Diluted .....	<u>\$ (2.22)</u>	<u>\$ (2.59)</u>	<u>\$ (1.95)</u>
 Weighted-average number of shares used in computing basic and diluted net loss per share:			
Basic .....	<u>57,848</u>	<u>53,312</u>	<u>51,576</u>
Diluted .....	<u>57,848</u>	<u>53,604</u>	<u>51,576</u>

See accompanying notes.

**Natera, Inc.**  
**Consolidated Statements of Stockholders' Equity**  
*(In thousands)*

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit (As Revised)(1)	Total Stockholders' Equity (As Revised)(1)
	Shares	Amount				
<b>(in thousands)</b>						
<b>Balance as of December 31, 2015</b>	<b>50,346</b>	<b>\$ 5</b>	<b>\$ 436,259</b>	<b>\$ (1,416)</b>	<b>\$ (208,420)</b>	<b>\$ 226,428</b>
Issuance of common stock upon exercise of stock options	1,913	—	3,595	—	—	3,595
Issuance of common stock under employee stock purchase plan	341	—	2,589	—	—	2,589
Vesting of restricted stock units	65	—	—	—	—	—
Stock-based compensation	—	—	10,601	—	—	10,601
Unrealized gain on available-for sale securities	—	—	—	691	—	691
Net loss (as revised)	—	—	—	—	(100,327)	(100,327)
<b>Balance as of December 31, 2016</b>	<b>52,665</b>	<b>5</b>	<b>453,044</b>	<b>(725)</b>	<b>(308,747)</b>	<b>143,577</b>
Issuance of common stock upon exercise of stock options	565	1	2,314	—	—	2,315
Issuance of common stock under employee stock purchase plan	446	—	3,344	—	—	3,344
Issuance of common stock in exchange for commitment to provide debt financing	300	—	2,448	—	—	2,448
Vesting of restricted stock	64	—	—	—	—	—
Stock-based compensation	—	—	11,402	—	—	11,402
Unrealized loss on available-for sale securities	—	—	—	(41)	—	(41)
Net loss (as revised)	—	—	—	—	(137,628)	(137,628)
<b>Balance as of December 31, 2017</b>	<b>54,040</b>	<b>6</b>	<b>472,552</b>	<b>(766)</b>	<b>(446,375)</b>	<b>25,417</b>
Issuance of common stock upon exercise of stock options	1,967	—	13,331	—	—	13,331
Issuance of common stock under employee stock purchase plan	391	—	3,617	—	—	3,617
Issuance of common stock upon exercise of warrants	333	—	6,762	—	—	6,762
Sale of common stock through equity offering, net of issuance costs	5,175	1	96,776	—	—	96,777
Vesting of restricted stock	177	—	—	—	—	—
Stock-based compensation	—	—	14,198	—	—	14,198
Unrealized gain on available-for sale securities	—	—	—	214	—	214
Net loss	—	—	—	—	(128,154)	(128,154)
<b>Balance as of December 31, 2018</b>	<b>62,083</b>	<b>7</b>	<b>\$ 607,236</b>	<b>\$ (552)</b>	<b>\$ (574,529)</b>	<b>\$ 32,162</b>

(1) See Note 2 for a summary of adjustments. The cumulative-effect adjustment to Accumulated Deficit resulting from the adoption of Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09") as of December 31, 2015 was \$41.7 million.

See accompanying notes.

**Natera, Inc.**  
**Consolidated Statements of Cash Flows**  
*(In thousands)*

	<b>Year Ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
		<b>(As Revised)</b>	<b>(As Revised)</b>
<b>Operating activities:</b>			
Net loss	\$ (128,154)	\$ (137,628)	\$ (100,327)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	7,501	7,143	6,176
Impairment of assets	1,544	576	2,138
Stock-based compensation	14,198	11,402	10,601
Inventory excess adjustments	265	502	2,110
Provision for doubtful accounts	(41)	143	984
Premium amortization and discount accretion on investment securities	238	857	1,445
Loss (gain) realized on investment securities	43	64	(191)
(Gain) loss on sales of property and equipment	(12)	12	—
Loss (gain) from changes in fair value of warrants	4,118	(1,148)	143
Interest accrued for borrowings and claims related settlement	2,172	488	533
Amortization of debt discount	391	154	—
Changes in operating assets and liabilities:			
Accounts receivable	(18,093)	6,315	(3,956)
Inventory	(4,900)	(3,086)	(431)
Prepaid expenses and other current assets	2,643	(1,515)	(2,077)
Other assets	335	600	(2,812)
Accounts payable	3,781	217	1,256
Accrued compensation	3,069	(1,467)	2,515
Other accrued liabilities	(1,820)	14,919	(378)
Deferred revenue	42,769	846	430
Deferred rent, net of current portion	(628)	1,452	7,789
Other long-term liabilities	—	1,329	—
Net cash used in operating activities	<u>(70,581)</u>	<u>(97,825)</u>	<u>(74,052)</u>
<b>Investing activities:</b>			
Purchases of investments	(170,268)	(272,819)	(53,522)
Proceeds from sale of investments	37,387	65,270	59,185
Proceeds from maturity of investments	131,600	231,200	64,500
Purchases of property and equipment, net	(3,880)	(9,867)	(23,136)
Net cash (used in) provided by investing activities	<u>(5,161)</u>	<u>13,784</u>	<u>47,027</u>
<b>Financing activities:</b>			
Proceeds from exercise of stock options	13,331	2,315	3,595
Proceeds from issuance of common stock under employee stock purchase plan	3,617	3,344	2,589
Proceeds from equity offering, net of issuance costs	96,777	—	—
Borrowings under long-term debt facility	—	75,000	—
Payment for debt issuance costs on long-term debt facility	—	(287)	—
Borrowings under credit facility	—	—	8,000
Repayment under credit facility	—	—	(1,000)
Net cash provided by financing activities	<u>113,725</u>	<u>80,372</u>	<u>13,184</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	37,983	(3,669)	(13,841)
Cash, cash equivalents and restricted cash, beginning of period	13,021	16,690	30,531
Cash, cash equivalents and restricted cash, end of period	<u>\$ 51,004</u>	<u>\$ 13,021</u>	<u>\$ 16,690</u>
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for income taxes	\$ 332	\$ 177	\$ —
Cash paid for interest	\$ 7,914	\$ 3,568	\$ —
<b>Non-cash investing and financing activities:</b>			
Purchases of property and equipment in accounts payable and accruals	\$ 268	\$ 447	\$ 5,204
Issuance of common stock for exercise of warrants	\$ 6,762	\$ —	\$ —
Issuance of common stock for lender's commitment to debt financing	\$ —	\$ 2,448	\$ —

See accompanying notes.

**Natera, Inc.**  
**Notes to 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 operating 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; 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, and the Company also offers its Panorama test to customers 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, for research use only by oncology researchers and biopharmaceutical companies. 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 consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP").

***Liquidity Matters***

The Company has incurred net losses since its inception and anticipates net losses and negative operating cash flows for the near future. For the year ended December 31, 2018, the Company had a net loss of \$128.2 million, which increased the accumulated deficit to \$574.6 million from \$446.4 million at December 31, 2017 following the full retrospective adoption of ASU 2014-09, which required a cumulative-effect adjustment to be recorded to accumulated deficit as of the earliest period presented in the consolidated financial statements. At December 31, 2018, the Company had \$46.4 million in cash and cash equivalents, \$107.5 million in marketable securities, \$50.2 million of outstanding balance of the Credit Line (as defined in Note 9) including accrued interest, and \$73.4 million of net carrying amount of the 2017 Term Loan (as defined in Note 9). 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 financing under the 2017 Term Loan with an option to borrow an additional \$50.0 million.

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 require 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, commercialization and marketing of its products and significantly scale back its business and operations.

In July 2018, the Company completed an equity offering to sell 4,500,000 shares of its common stock to the public at a price of \$20 per share, along with the sale of 675,000 additional shares of its common stock to the underwriters upon their exercise of the option to purchase those shares. Upon the closing of the equity offering, the Company received proceeds of \$97.3 million before offering expenses, which totaled approximately \$0.5 million.

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 March 15, 2019.

### ***Principles of Consolidation***

The accompanying 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, 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.

For the year ended December 31, 2018, the Company revised the estimate of its expected consideration for certain genetic test services as the amounts collected from its payers were different than what was initially assessed. The revision of the estimate was treated as a change in accounting estimate. See Note 3 for more detail on this accounting change and its resulting impact 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***

As of December 31, 2018, the Company had restricted cash primarily consisting of \$4.2 million in cash deposits held to secure a letter of credit associated with a settlement agreement in connection with reimbursement related claims (as described in Note 7 under *Legal Proceedings*) and \$0.3 million of deposit per credit card terms.

The Company adopted Accounting Standard Update No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* (“ASU 2016-18”), effective January 1, 2018, which required the change in restricted cash to be included as part of the total cash and cash equivalents. While restricted cash is still presented as a separate line item in the Company’s balance sheet, it is no longer presented as a separate item in the statements of cash flows. ASU 2016-18 also required a restatement of the statements of cash flows in the prior period presented to report this change. 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:

	December 31, 2018	December 31, 2017	December 31, 2016	December 31, 2015
			(in thousands)	
Cash and cash equivalents in balance sheet. . . . .	\$ 46,407	\$ 12,620	\$ 15,256	\$ 28,947
Restricted cash, current portion in balance sheet . . . . .	4,597	59	1,092	901
Restricted cash in other assets in balance sheet . . . . .	—	342	342	683
Total cash, cash equivalents and restricted cash in statements of cash flows . . . . .	<u>\$ 51,004</u>	<u>\$ 13,021</u>	<u>\$ 16,690</u>	<u>\$ 30,531</u>

## ***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 reevaluates 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***

The Company has various financial instruments that are potentially subjected to credit risk, and they 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 clinics and laboratory partners and generally does not require collateral to support credit sales. In 2018, 2017 and 2016, there were no customers exceeding 10% of total revenues on an individual basis. As of December 31, 2018 and 2017, there were no customers with an outstanding balance exceeding 10% of net accounts receivable.

### ***Allowance for Doubtful Accounts***

Trade accounts receivable are recorded at the amount billed to the laboratory partners and clinics. Reducing this amount is an allowance for doubtful accounts for estimated losses resulting from the inability of its customers to make the contracted payments. Management analyzes accounts receivable and historical bad debt experience, customer creditworthiness, current economic trends, and changes in customer payment history when evaluating the adequacy of the allowance for doubtful accounts. Accounts receivable are written off against the allowance when there is substantive evidence that the account will not be paid.

### ***Revenue Recognition***

The Company adopted the new revenue recognition guidance, ASC 606, beginning January 1, 2018 on a full retrospective basis. 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 record, order and delivery systems, shipping charges to transport samples, third-party test processing 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 by the research and development team 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.

### ***Research and Development***

The Company records research and development costs in the period incurred. Research and development costs consist of personnel costs, contract services, cost of materials utilized in performing tests, costs of clinical trials and allocated facilities and related overhead expenses.

### ***Advertising Costs***

The Company expenses advertising costs as incurred. The Company incurred advertising costs of \$0.2 million, \$0.5 million and \$0.4 million for the years ended December 31, 2018, 2017 and 2016, respectively.



### ***Product Shipment Costs***

The Company expenses product shipment costs in cost of product revenues in the accompanying statements of operations. Shipping and handling costs for the years ended December 31, 2018, 2017 and 2016 were \$12.4 million, \$9.5 million and \$8.2 million, respectively.

### ***Income Taxes***

Income taxes are recorded in accordance with Financial Accounting Standards Board ASC *Topic 740, Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Tax benefits are recognized when it is more likely than not that a tax position will be sustained during an audit. Deferred tax assets are reduced by a valuation allowance if current evidence indicates that it is considered more likely than not that these benefits will not be realized.

### ***Stock-Based Compensation***

Stock-based compensation related to stock options and restricted stock units ("RSUs") granted to the Company's employees 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. No compensation cost is recognized when the requisite service has not been met and the awards are therefore forfeited.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options issued to employees and non-employees. The measurement of stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest, and the resulting change in value, if any, is recognized in the Company's statements of operations and comprehensive loss during the period that the related services are rendered.

The Black-Scholes option-pricing 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. The expected term was based on the simplified method and the volatility rate was based on that of publicly traded companies in the DNA sequencing, diagnostics, or personalized medicine industries. When selecting the public companies in these industries to be used in the volatility calculation, companies were selected with comparable characteristics to the Company, including enterprise value and financial leverage. Companies were also selected with historical share price volatility sufficient to meet the expected term of the Company's stock options. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the Company's stock options. The expected term of the non-employee option grants was based on their remaining contractual life at the measurement date. The risk-free interest rate assumption was based on U.S. Treasury instruments with maturities that were consistent with the option's expected term.

Starting January 1, 2016, the Company began using a different approach to estimate the expected term of its stock option awards, which involves calculating the average of—(1) its employees' historical stock option exercise behavior, and (2) the weighted-average of the time-to-vesting and the total contractual life of the options. The Company applied this change in methodology prospectively and accounted for it as a change in accounting estimate.

### ***Warrants***

The Company accounts for warrants to purchase shares of its common stock as a liability at fair value on the balance sheet date because the Company may be obligated to redeem these warrants at some point in the future. The warrants are subject to remeasurement at each balance sheet date, with changes in fair value recognized as a gain or loss from the changes in fair value of the warrants 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, which includes successful validation and approval from management. 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. Refer to *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 \$1.7 million and \$2.6 million as of December 31, 2018 and 2017, respectively. Amortized expense for amounts previously capitalized for the years ended December 31, 2018, 2017 and 2016 was \$1.3 million, \$1.0 million and \$0.6 million, respectively.

### ***Accumulated Other Comprehensive 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. As of December 31, 2018, and 2017, accumulated other comprehensive loss consisted of \$0.6 million and \$0.8 million of unrealized losses on available-for-sale marketable securities. See Note 5 for additional disclosures related to change in net unrealized losses and reclassifications out of accumulated other comprehensive loss upon the sale of available-for-sale marketable securities.

### ***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. The Company periodically reviews the depreciable lives assigned to property and equipment placed in service and change the estimates of useful lives to reflect the results of such reviews.

### ***Impairment of Long-lived Assets***

The Company periodically evaluates 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 amounts of the 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 about assets impairment.

### ***Inventory***

Inventory is valued at the lower of the standard cost, which approximates actual cost, or market. Cost is determined using the first-in, first-out ("FIFO") method. Inventory consists entirely of supplies, which are consumed when providing its test reports, and therefore does not maintain any finished goods inventory. The Company enters into inventory purchases and commitments so that it can meet future delivery schedules based on forecasted demand for its tests.

The Company recorded inventory obsolescence charges totaling \$0.3 million, \$0.5 million, and \$2.1 million in the years ended December 31, 2018, 2017, and 2016, respectively.

## ***Recent Accounting Pronouncements***

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the “FASB”) under its accounting standard codifications (“ASC”) 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 recently issued standards 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***

In May 2014, the FASB issued ASU 2014-09, which amends the existing accounting standards for revenue recognition. ASU 2014-09, which defines the core principles of Accounting Standards Codification Topic 606 (“ASC 606”), establishes principles for recognizing revenue upon the transfer of promised goods or services to customers, in an amount that reflects the expected consideration received in exchange for those goods or services. ASC 606 also impacts the accounting for costs incurred in obtaining a contract with a customer, provided that such costs are considered incremental and recoverable by the Company.

Effective January 1, 2018, the Company adopted ASC 606 using the full retrospective approach. The Company revised the financial results in its statements of operations and comprehensive loss for the years ended December 31, 2017 and 2016, respectively, and balance sheet as of December 31, 2017, as if ASC 606 had been effective for those periods. The adoption of ASC 606 resulted in a cumulative-effect adjustment of approximately \$41.7 million recorded retroactively to accumulated deficit as of December 31, 2015. The impact of adopting the new guidance on total revenues for the years ended December 31, 2017 and 2016 was a decrease of \$1.3 million and \$4.6 million, respectively. For financial statement disclosure purposes, the Company elected one of the practical expedients under ASC 606 to forego disclosures related to the allocation of consideration to the remaining performance obligations and the timing in which revenues will be recognized from such performance obligations.

Upon the adoption of ASC 606, the Company revised the following selected amounts in its consolidated balance sheet from amounts previously reported:

	December 31, 2017		
	As Previously Reported	Adoption of ASC 606 (in thousands)	As Revised
Accounts receivable, net of allowance. . . . .	\$ 8,252	\$ 35,837	\$ 44,089
Other accrued liabilities . . . . .	33,207	50	33,257
Accumulated deficit . . . . .	\$ (482,162)	\$ 35,787	\$ (446,375)

Upon the adoption of ASC 606, the Company restated the following selected amounts in its consolidated statements of operations and comprehensive loss from amounts previously reported:

	Year ended December 31, 2017		
	As Previously Reported	Adoption of ASC 606 (in thousands)	As Revised
Product revenues . . . . .	\$ 205,489	\$ (1,712)	\$ 203,777
Licensing and other revenues . . . . .	5,450	398	5,848
Total revenues . . . . .	210,939	(1,314)	209,625
Loss from operations . . . . .	(134,027)	(1,314)	(135,341)
Net loss . . . . .	(136,314)	(1,314)	(137,628)
<b>Net loss per share:</b>			
Basic . . . . .	\$ (2.56)	\$ (0.02)	\$ (2.58)
Diluted . . . . .	\$ (2.56)	\$ (0.03)	\$ (2.59)

	Year ended December 31, 2016		
	As Previously Reported	Adoption of ASC 606 (in thousands)	As Revised
Product revenues . . . . .	\$ 213,968	\$ (4,562)	\$ 209,406
Licensing and other revenues . . . . .	3,106	—	3,106
Total revenues . . . . .	217,074	(4,562)	212,512
Loss from operations . . . . .	(96,488)	(4,562)	(101,050)
Net loss . . . . .	(95,765)	(4,562)	(100,327)
<b>Net loss per share:</b>			
Basic . . . . .	\$ (1.86)	\$ (0.09)	\$ (1.95)
Diluted . . . . .	\$ (1.86)	\$ (0.09)	\$ (1.95)

The Company restated the following selected amounts in its consolidated statements of cash flows from amounts previously reported as a result of the adoption of ASC 606, as well as the adoption of ASU 2016-18 regarding the new financial statement presentation requirements for restricted cash:

	Year ended December 31, 2017			
	As Previously Reported	Adoption of ASU 2016-18	Adoption of ASC 606 (in thousands)	As Revised
<b>Operating activities:</b>				
Net loss . . . . .	\$ (136,314)	\$ —	\$ (1,314)	\$ (137,628)
Changes in operating assets and liabilities:				
Accounts receivable . . . . .	5,001	—	1,314	6,315
Net cash used in operating activities . . . . .	(96,792)	(1,033)	—	(97,825)
Cash, cash equivalents and restricted cash, beginning of period . . . .	15,256	1,434	—	16,690
Cash, cash equivalents and restricted cash, end of period . . . . .	\$ 12,620	\$ 401	\$ —	\$ 13,021

	Year ended December 31, 2016			
	As Previously Reported	Adoption of ASU 2016-18	Adoption of ASC 606	As Revised
		(in thousands)		
<b>Operating activities:</b>				
Net loss . . . . .	\$ (95,765)	\$ —	\$ (4,562)	\$ (100,327)
Changes in operating assets and liabilities:				
Accounts receivable . . . . .	(8,518)	—	4,562	(3,956)
Net cash used in operating activities . . . . .	(73,902)	(150)	—	(74,052)
Cash, cash equivalents and restricted cash, beginning of period . . .	28,947	1,584	—	30,531
Cash, cash equivalents and restricted cash, end of period . . . . .	\$ 15,256	\$ 1,434	\$ —	\$ 16,690

In November 2016, the FASB issued Accounting Standards Update No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* (“ASU 2016-18”). The new guidance requires restricted cash to be combined with cash and cash equivalents when reconciling the beginning and ending balances of cash on the statement of cash flows. Further, the new guidance requires the nature of the restrictions to be disclosed, as well as a reconciliation between the balance sheet and the statement of cash flows on how restricted and unrestricted cash are segregated. The Company adopted this new guidance beginning January 1, 2018 and retroactively adjusted the statements of cash flows for the years ended December 31, 2017 and 2016 to show the combined result of cash and cash equivalents and restricted cash.

In August 2016, the FASB issued Accounting Standards Update No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (A Consensus of the Emerging Issues Task Force)* (“ASU 2016-15”). The purpose of ASU 2016-15 is to limit diversity in the classification of certain transactions in the statement of cash flows. Such transactions include (1) debt prepayment or debt extinguishment costs, (2) settlement of zero-coupon bonds, (3) contingent consideration payments made after a business combination, (4) proceeds from insurance claims settlement, (5) proceeds from settlement of life insurance policies, and (6) distributions of equity method investments. The Company adopted this new guidance beginning January 1, 2018, which did not result in a material impact on its financial statements as none of the transactions described above occurred during the year ended December 31, 2018.

In May 2017, the FASB issued Accounting Standards Update No. 2017-09 (“ASU 2017-09”), *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*. The purpose of this ASU is to clarify when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The Company adopted this new guidance beginning January 1, 2018, and the impact on its financial statements was not material upon adoption.

#### *New Accounting Pronouncements Not Yet Adopted*

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases* (“ASU 2016-02”). ASU 2016-02 is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. In July 2018, the FASB also issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides an alternative by allowing a cumulative-effect adjustment to be recorded in the opening retained earnings balance as of January 1, 2019 instead of the earliest period presented, and can be adopted concurrently with ASU 2016-02. These two accounting standard updates are collectively known as ASC 842. In preparation for a proper transition to ASC 842, the Company has designated a project implementation team to assess the scope of the accounting and explore opportunities to reduce the extent and complexity of such work by utilizing certain practical expedients under the new guidance. Upon the election of such practical expedients, the Company will be allowed to forego reassessment of the lease classification of an expired or existing lease agreement, whether an expired or existing agreement contains a lease, exclude any lease agreement with a term less than 12 months from the transition, and record a cumulative-effect adjustment as of the effective date of January 1, 2019 instead of the earliest period presented in the financial statements.

The Company is in the process of finalizing its analysis and expects the amounts to be recorded for its right-of-use assets and corresponding lease liabilities to be material upon the adoption of ASC 842 using the modified retrospective approach.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13, *Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”). ASU 2016-13 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. ASU 2016-13 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 ASU 2016-13 on its financial statements.

In February 2018, the FASB issued Accounting Standards Update No. 2018-02, *Income Statement—Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* (“ASU 2018-02”). This new guidance was established as a result of the Tax Cuts and Jobs Act passed in December 2017, which provides 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. The new guidance will be effective in the first quarter of 2019, and interim periods within that year, with early adoption permitted. The Company will have the option to apply this new guidance using either the full retrospective approach or to record the reclassifications as of the beginning date in the period of adoption. The Company does not expect the impact of adopting ASU 2018-02 to be material to its financial statements given that the deferred tax assets are fully reserved by a valuation allowance as of December 31, 2018.

In June 2018, the FASB issued Accounting Standards Update No. 2018-07, *Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (“ASU 2018-07”). ASU 2018-07 is intended to reduce the cost and complexity and to improve financial reporting for nonemployee share-based payments. ASU 2018-07 expands the scope of *Topic 718, Compensation—Stock Compensation* (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU 2018-07 supersedes *Subtopic 505-50, Equity-Based Payments to Non-Employees*. ASU 2018-07 is effective for the Company for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year and early adoption is permitted. The Company does not expect the impact of adopting this new guidance to be material to its financial statements.

In August 2018, the FASB issued Accounting Standards Update No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* (“ASU 2018-13”). 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 August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, *Disclosure Update and Simplification*. These amendments eliminate, modify, or integrate into other SEC requirements certain disclosure rules. Among the amendments is the requirement to present an analysis of changes in stockholders’ equity in the interim financial statements included in quarterly reports on Form 10-Q. The analysis, which can be presented as a footnote or separate statement, is required for the current and comparative quarter and year-to-date interim periods. The amendments are effective for all filings made on or after November 5, 2018. In light of the anticipated timing of effectiveness of the amendments and expected proximity of effectiveness to the filing date for most filers’ quarterly reports, the SEC’s Division of Corporate Finance issued a Compliance and Disclosure Interpretation related to Exchange Act Forms, or CDI – Question 105.09, that provides transition guidance related to this disclosure requirement. CDI – Question 105.09 states that the SEC would not object if the filer’s first presentation of the changes in shareholders’

equity is included in its Form 10-Q for the quarter that begins after the effective date of the amendments. As such, the Company adopted these SEC amendments on November 5, 2018 and will present the analysis of changes in stockholders' equity in its interim financial statements in its March 31, 2019 Form 10-Q. The Company does not anticipate that the adoption of these SEC amendments will have a material effect on the Company's financial position, results of operations, cash flows or shareholders' equity.

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 expects to collect in exchange for the Company's 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, the Company uses a portfolio of relevant historical data to estimate variable consideration and total collections for the Company's products. 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 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 that equals 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 years ended December 31, 2018 and 2017, \$3.3 million and \$4.9 million, respectively, were released from amounts previously held in reserves in other accrued liabilities and recognized as product revenue. There were no amounts released from the reserves during the year ended December 31, 2016.

### ***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 and expiration of their right of return.

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 estimated standalone selling prices based on transaction price and observable prices 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 estimated 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. 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 achievement of certain volume, regulatory and commercial milestones, and tiered royalties. 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 test 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 estimated to be \$15.0 million based on the most likely amount approach, which was comprised of the upfront non-refundable fee and a payment associated with the initial milestone under the agreement. The remaining milestone and prepaid royalty amounts were not included in the transaction price due to the uncertainties of research and development and the potential for prepaid royalty refund, as it is not currently probable that the associated revenue, if recognized, would not be reversed later. Royalties, including prepaid royalties, will generally not be recognized until earned. 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 is 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 year ended December 31, 2018, the Company recognized revenue of approximately \$5.8 million related to support services provided and the delivery of its technology license to Qiagen.

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.

### **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:

	Year Ended December 31,		
	2018	2017 (As Revised)	2016 (As Revised)
<b>(Amounts in thousands)</b>			
<b>Sales of genetic tests</b>			
Panorama NIPT .....	\$ 140,932	\$ 128,896	\$ 140,582
HCS .....	87,171	63,467	56,417
Other genetic tests .....	12,263	11,414	12,407
Product revenues .....	240,366	203,777	209,406
<b>Licensing and other</b>			
Constellation .....	4,844	4,229	3,106
Qiagen .....	5,794	—	—
Other .....	6,650	1,619	—
Licensing and other revenues .....	17,288	5,848	3,106
<b>Total revenues</b> .....	<u>\$ 257,654</u>	<u>\$ 209,625</u>	<u>\$ 212,512</u>

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:

	Year Ended December 31,		
	2018	2017 (As Revised)	2016 (As Revised)
<b>(Amounts in thousands)</b>			
Insurance carriers .....	\$ 193,895	\$ 163,861	\$ 157,570
Laboratory partners .....	44,062	36,001	46,129
Patients .....	19,697	9,763	8,813
<b>Total revenues</b> .....	<u>\$ 257,654</u>	<u>\$ 209,625</u>	<u>\$ 212,512</u>

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

	Year ended December 31,		
	2018	2017 (As Revised)	2016 (As Revised)
<b>(Amounts in thousands)</b>			
United States .....	\$ 225,931	\$ 185,533	\$ 188,492
Americas, excluding U.S. ....	3,472	3,028	2,562
Europe, Middle East, India, Africa .....	20,866	13,998	14,256
Other .....	7,385	7,066	7,202
<b>Total</b> .....	<u>\$ 257,654</u>	<u>\$ 209,625</u>	<u>\$ 212,512</u>

The Company recognizes revenue from billings to insurance carriers and patients based on estimates of the amount that will ultimately be realized (“expected consideration”). The expected consideration estimated for genetic test services is based on many factors such as length of payer relationship, historical collection trends, changes in contract provisions and insurance reimbursement policies. Cash collections for certain tests delivered may differ from the expected consideration originally estimated. During the year ended December 31, 2018, the Company’s collections substantially improved. As a result of this, the Company updated its estimate of the amounts to be recognized for previously delivered tests which resulted in an additional \$10.2 million of revenue for the year ended December 31, 2018. These changes in estimates decreased the Company’s loss from operations by \$10.2 million and decreased basic and diluted net loss per share by approximately \$0.18 for the year ended December 31, 2018.

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

(Amounts in thousands)	Balance at December 31, 2018	Balance at December 31, 2017 (As Revised)
<b>Assets:</b>		
Accounts receivable . . . . .	\$ 62,223	\$ 44,089
<b>Liabilities:</b>		
Deferred revenue, current portion . . . . .	\$ 4,131	\$ 1,420
Deferred revenue, long-term portion . . . . .	40,058	—
Total deferred revenues . . . . .	<u>\$ 44,189</u>	<u>\$ 1,420</u>

Accounts receivable 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 \$3.9 million, of which \$3.4 million was included in accounts receivable and \$0.5 million was related to financing over the period greater than 12 month. As of December 31, 2018, accounts receivable totaled \$62.2 million. The Company reclassified \$0.5 million to other noncurrent assets in its consolidated balance sheet as of December 31, 2018.

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

	Deferred Revenues (in thousands)
Balance at December 31, 2017 . . . . .	\$ 1,420
Increase in deferred revenues . . . . .	43,481
Revenue recognized during the period that was included in deferred revenues at the beginning of the period . . . . .	(712)
Balance at December 31, 2018 . . . . .	<u>\$ 44,189</u>

During the year ended December 31, 2018, revenue recognized that was included in the deferred revenue balance at the beginning of the period totaled \$0.7 million, of which \$0.6 million was related to genetic testing services and the provision of IVD kits and \$0.1 million pertained to undelivered Evercord storage services over the remaining contractual life of such services.

As of December 31, 2018, total deferred revenues were \$44.2 million, which were comprised of the current and long-term portions of \$4.1 million and \$40.1 million, respectively. The current portion was comprised of \$2.1 million relating to the provision of IVD kits, genetic testing services and Evercord storage services that will be fulfilled within the

next 12 months, and \$2.0 million of unsatisfied performance obligations from the Qiagen Agreement. The long-term portion included \$2.9 million of Evercord storage services to be delivered by the Company over the remaining contractual life of such services, and \$37.2 million resulting from the remaining performance obligations from the Qiagen Agreement. Such remaining performance obligations were comprised of development services and market development support, for which revenue will be recognized over time based on the value of services; and the option for Qiagen to expand its commercialization to another country, with revenue recognized at a point in time when such option is exercised or expires. The Company expects to recognize \$9.2 million of the amounts reported as long-term deferred revenue as each remaining performance obligation is satisfied.

#### 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, and a liability for common stock warrants.

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. There were no transfers between Level I, Level II and Level III during the periods presented.

#### *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:

	December 31, 2018				December 31, 2017			
	Level I	Level II	Level III	Total	Level I	Level II	Level III	Total
	(in thousands)							
Financial Assets:								
Money market deposits. .	\$ 26,539	\$ —	\$ —	\$ 26,539	\$ 3,477	\$ —	\$ —	\$ 3,477
U.S. Treasury securities .	75,685	—	—	75,685	67,026	—	—	67,026
U.S. agency securities. . .	—	12,891	—	12,891	—	27,072	—	27,072
Municipal securities . . . .	—	18,885	—	18,885	—	12,149	—	12,149
Total financial assets. . . .	<u>\$ 102,224</u>	<u>\$ 31,776</u>	<u>\$ —</u>	<u>\$ 134,000</u>	<u>\$ 70,503</u>	<u>\$ 39,221</u>	<u>\$ —</u>	<u>\$ 109,724</u>
Current Liabilities:								
Warrants . . . . .	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 2,644	\$ 2,644
Total financial liabilities . .	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,644</u>	<u>\$ 2,644</u>

The Company's warrants to purchase common stock are valued using Level III inputs; the Company used inputs from a Black-Scholes model with market volatility that is determined for comparable companies in the same business sector. The carrying amounts of cash, accounts receivable, and accounts payable approximate their fair value and are excluded from the table above.

In April 2013, the Company entered into a senior secured term loan with a third-party lender, which consisted of a credit agreement, royalty agreement, warrants and loan commitment. Based upon the Company's evaluation, the senior secured term loan constituted a liability with embedded derivative features that was accounted for separately as mark-to-market instruments. In addition, adjustments to the embedded royalty feature were recorded as interest expense as they occurred, offset to the carrying amount of the debt (with the eventually cash outlay to settle such amounts recorded against the carrying amount of the debt). Based on the Company's evaluation, it was determined that the warrants granted are detachable and therefore are a stand-alone component of the senior secured term loan to be fair valued using Level III inputs as a separate derivative. In October 2015, the Company repaid the entire borrowings under the senior secured term loan.

The fair value of both the senior secured term loan and warrants was remeasured at the end of each reporting period, with the change in fair value for the term loan recorded as interest benefit from changes in the fair value of long-term debt and the remeasurement gain or loss on the warrants recorded within interest and other income (expense), net in the statements of operations and comprehensive loss.

The following table provides a roll forward of the fair value, as determined by Level III inputs, of the warrants for the years ended December 31, 2018 and 2017:

	Warrants	
	2018	2017
	(in thousands)	
Beginning balance . . . . .	\$ 2,644	\$ 3,792
Warrants exercised . . . . .	(6,762)	—
Change in fair value . . . . .	4,118	(1,148)
Ending balance . . . . .	<u>\$ —</u>	<u>\$ 2,644</u>

#### *Warrants*

The significant unobservable inputs used in the fair value of warrants are derived from the Company's common stock valuation that is based on inputs from a Black-Scholes option-pricing model. Since all of the warrants were exercised on June 26, 2018, the fair value of the warrant liability was remeasured up to that date, with valuation assumptions such as the expected term, risk-free interest rate, and market volatility based on comparable companies in the same business sector determined at the point of the exercise of warrants. The inherent risk in the market volatility is the selection of companies with similar business attributes to the Company.

Determining the fair value of warrants requires the application of judgment on the associated valuation assumptions described above. The assumptions used in calculating the fair value of warrants represent the Company's estimates, but these estimates involve inherent uncertainties. As a result, if factors change and the Company uses different assumptions, the fair value of warrants could be significantly different in the future.

## 5. Financial Instruments

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

	December 31, 2018				December 31, 2017			
	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. . . . .	\$ 26,539	\$ —	\$ —	\$ 26,539	\$ 3,477	\$ —	\$ —	\$ 3,477
U.S. Treasury securities. . . . .	76,061	29	(405)	75,685	67,480	10	(464)	67,026
U.S. agency securities. . . . .	13,017	—	(126)	12,891	27,293	—	(221)	27,072
Municipal securities. . . . .	18,935	7	(57)	18,885	12,240	—	(91)	12,149
Total . . . . .	<u>\$ 134,552</u>	<u>\$ 36</u>	<u>\$ (588)</u>	<u>\$ 134,000</u>	<u>\$ 110,490</u>	<u>\$ 10</u>	<u>\$ (776)</u>	<u>\$ 109,724</u>
Classified as:								
Cash equivalents. . . . .				\$ 26,539				\$ 3,477
Short-term investments . . . . .				107,461				106,247
Total . . . . .				<u>\$ 134,000</u>				<u>\$ 109,724</u>

The Company invests in U.S. Treasuries, U.S. agency and high quality municipal bonds which mature at par and are all paying their coupons on schedule. Thus, the Company has determined there is currently no other than temporary impairment of its investments, and will continue to recognize unrealized losses in other comprehensive income. As of December 31, 2018, the Company has 16 investments in an unrealized loss position in its portfolio. During the years ended December 31, 2018 and 2017, the amount of gross realized gains and realized losses upon sales of investments were insignificant, and during the year ended December 31, 2016, sales of investments resulted in gross realized gains of \$0.2 million and insignificant gross realized losses. Realized gains and losses are reported in interest and other (expense) income, net in the statements of operations and comprehensive loss. The following table shows the change in the net unrealized positions of the available-for-sale securities and reclassifications from accumulated other comprehensive loss upon the sale of those securities:

	December 31,	
	2018	2017
	(in thousands)	
Balance at beginning of year . . . . .	\$ (766)	\$ (725)
Net unrealized gains (losses) on available-for-sale securities, net of tax . . . . .	171	(105)
Reclassifications of losses realized from sale of available-for-sale securities . . . . .	43	64
Increase (decrease) in other comprehensive loss . . . . .	214	(41)
Balance at end of year . . . . .	<u>\$ (552)</u>	<u>\$ (766)</u>

During the years ended December 31, 2018, 2017 and 2016, the Company earned interest income of \$1.8 million, \$1.2 million and \$1.5 million, respectively, from its investment portfolio.

The following table summarizes the Company's portfolio of available-for-sale securities by contractual maturity as of December 31, 2018:

	December 31, 2018	
	Amortized Cost	Fair Value
	(in thousands)	
Less than one year . . . . .	\$ 64,477	\$ 64,276
Greater than one year but less than five years . . . . .	43,536	43,185
Total . . . . .	<u>\$ 108,013</u>	<u>\$ 107,461</u>

## 6. Balance Sheet Components

### *Allowance for Doubtful Accounts*

The following table presents a reconciliation of the allowance for doubtful accounts:

	December 31, 2018	December 31, 2017	December 31, 2016
		(in thousands)	
Beginning balance . . . . .	\$ 2,000	\$ 1,890	\$ 971
Provision for estimated bad debts . . . . .	(41)	143	984
Write offs . . . . .	(171)	(33)	(65)
Ending balance . . . . .	<u>\$ 1,788</u>	<u>\$ 2,000</u>	<u>\$ 1,890</u>

### *Property and Equipment, net*

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

	Useful Life	December 31, 2018	December 31, 2017
		(in thousands)	
Machinery and equipment . . . . .	3-5 years	\$ 35,400	\$ 31,825
Furniture and fixtures . . . . .	3 years	1,319	1,216
Computer equipment . . . . .	3 years	2,117	1,958
Capitalized software held for internal use . . . . .	3 years	4,868	4,465
Leasehold improvements . . . . .	Life of lease	10,916	10,691
Construction-in-process . . . . .		4,013	6,497
		<u>58,633</u>	<u>56,652</u>
Less: Accumulated depreciation and amortization . . . . .		<u>(34,297)</u>	<u>(26,985)</u>
Total Property and Equipment, net . . . . .		<u>\$ 24,336</u>	<u>\$ 29,667</u>

All of the Company's long-lived assets are located in the United States.

During the year ended December 31, 2018, an asset impairment charge of \$1.5 million was recorded in research and development expenses in the statements of operations and comprehensive loss. This charge was recorded to write off certain project development costs that were previously capitalized.

During the year ended December 31, 2017, the Company recorded asset impairment charges totaling \$0.6 million as a result of fully decommissioning its previous generation of sequencing and automation equipment in January 2017. These charges were recorded in cost of product revenues in the statements of operations and comprehensive loss.

During the year ended December 31, 2016, the Company recorded asset impairment charges totaling \$2.1 million in the statements of operations and comprehensive loss, of which \$1.9 million was recorded in cost of product revenues and \$0.2 million was included in general and administrative expenses, following its impairment analysis on its previous

generation of sequencing and automation equipment whose service lives were determined to be significantly shorter than initially expected. These charges also included the write-off of \$0.3 million unamortized maintenance service contract prepayments related to the impaired equipment described above. The Company expected to phase out the equipment in the first quarter of 2017 as the Company began its transition to the next generation of sequencing and automation equipment to help streamline its production workflows.

### ***Other Assets***

In April 2016, the Company entered into a four-year agreement with an insurance carrier whereby in return for partial exclusivity and the right to pricing benefits the Company paid total consideration of \$3.2 million. The total consideration was paid in the third quarter of 2016. As of December 31, 2018 and 2017, \$1.0 million and \$1.8 million in deferred costs were included in other noncurrent assets. The deferred costs are being amortized ratably over the four-year term of the agreement. During the years ended December 31, 2018 and 2017, amortization of such costs totaling \$0.8 million was recorded for each of the two years 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 agreement with OrbiMed and issued 300,000 shares of its common stock in exchange for OrbiMed's initial and remaining funding commitments (as described in Note 9). The Company also paid legal fees totaling \$0.3 million in connection with this term loan. Total debt issuance costs of \$2.7 million is accounted for as a debt discount. For financial statement presentation purposes, the Company has classified \$2.0 million of the debt discount as a direct reduction from the outstanding debt balance, while \$0.7 million of such remains in other noncurrent assets for the unused borrowing capacity of \$50.0 million. The debt discount is being amortized on a straight-line basis over the term of the loan. For the year ended December 31, 2018, amortization of debt discount related to the unused borrowing capacity was \$0.1 million. Amortization of debt discount for the unused borrowing capacity was insignificant in the year ended December 31, 2017. As of December 31, 2018, the unamortized portion of the debt discount remained at \$0.6 million.

As of December 31, 2018, other assets also included 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 \$0.5 million.

### ***Accrued Compensation***

The Company's accrued compensation consisted of the following:

	December 31, 2018	December 31, 2017
	(in thousands)	
Accrued paid time off . . . . .	\$ 1,825	\$ 1,806
Accrued commissions . . . . .	4,492	3,558
Accrued bonuses . . . . .	3,757	2,063
Other accrued compensation . . . . .	2,594	2,172
Total accrued compensation . . . . .	<u>\$ 12,668</u>	<u>\$ 9,599</u>



## ***Other Accrued Liabilities***

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

	December 31, 2018	December 31, 2017 (As Revised)
(Amounts in thousands)		
Settlement accrued for reimbursement related claims . . . . .	\$ 1,378	\$ 10,062
Reserves for refunds to insurance carriers . . . . .	10,012	6,794
Accrued charges for outsourced testing . . . . .	5,001	6,566
Testing and laboratory materials from suppliers . . . . .	2,742	1,367
Marketing and corporate affairs . . . . .	1,306	1,456
Legal, audit and consulting fees . . . . .	1,058	206
Accrued shipping charges . . . . .	852	198
Sales tax payable . . . . .	1,255	504
Accrued specimen service fees . . . . .	1,378	683
Accrued rent . . . . .	903	856
Clinical trials and studies . . . . .	1,694	483
Other accrued expenses . . . . .	4,863	4,082
Total other accrued liabilities . . . . .	<u>\$ 32,442</u>	<u>\$ 33,257</u>

As of December 31, 2017, the Company accrued a total of \$11.4 million for amounts due under a settlement agreement related to reimbursement related claims, of which \$10.1 million was the current portion and \$1.3 million due after 12 months was recorded in other long-term liabilities. The Company made approximately \$5.3 million of settlement prepayments at the end of the first quarter of 2018, and the remaining payments were allowed to be made in subsequent quarterly installments with interest accrued as described in Note 7 under *Legal Proceedings*. Interest accrued was \$0.2 million for the year ended December 31, 2018, which has been paid together with a total of three quarterly installments amounting to \$4.2 million. Additionally, a separate payment of \$0.8 million was made in connection with the settlement. As of December 31, 2018, the last quarterly installment of \$1.4 million remained in other accrued liabilities.

Reserves for refunds to insurance carriers 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, 2017, reserves relating to payers were \$6.8 million. During the year ended December 31, 2018, the Company reserved an additional \$10.3 million, and amounts previously held in reserves relating to payers totaling \$3.3 million were released. Remaining reserves relating to payers in other accrued liabilities were \$10.0 million as of December 31, 2018.

## **7. Commitments and Contingencies**

### ***Operating Leases***

As of December 31, 2018, the Company leases office facilities under non-cancelable operating lease agreements. The Company currently occupies approximately 136,000 square feet of laboratory and office space at its San Carlos, California corporate headquarters pursuant to a lease that it directly entered into with its landlord in October 2016. This lease covers two office spaces (the "First Space and the "Second Space"). The First Space covers approximately 88,000 square feet at a base rent of \$319,095. The Second Space covers approximately 48,000 square feet at a base rent of \$190,424 per month. The Company paid a security deposit totaling \$0.7 million on this lease. The term of this lease is approximately 84 months and expires in October 2023.

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 at \$11,900 per month, subject to an annual increase of approximately 3%. The lease term is 62 months expiring in July 2023.

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, increasing from \$0.1 million to \$0.2 million. Pursuant to the terms of the lease, the subsidiary paid a security deposit of \$0.4 million, and the landlord allotted the subsidiary an allowance for leasehold improvements of up to \$7.8 million. The Company was reimbursed by the landlord the full amount of the allowance in 2017.

The future annual minimum lease payments under all non-cancelable operating leases as of December 31, 2018 are as follows:

	<u>Operating Leases</u> (in thousands)
Year ending December 31:	
2019.....	\$ 8,588
2020.....	8,825
2021.....	9,067
2022.....	9,319
2023.....	7,702
2024 and thereafter.....	7,130
Total future minimum lease payments .....	<u>\$ 50,631</u>

Rent expense for the years ended December 31, 2018, 2017 and 2016 was \$7.4 million, \$7.2 million and \$5.4 million, respectively. The Company is also required to pay its share of facility operating expenses with respect to the facilities in which it operates.

### ***Legal Proceedings***

From time to time, the Company is involved in disputes, litigation, and other legal actions. The Company is aggressively pursuing 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 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. 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, or held, 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. The San Mateo Superior Court 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. 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 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 alleging various claims relating to a discordant test result. The complaint seeks unspecified damages. 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 Medicaid, 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 remained in its other accrued liabilities as of December 31, 2018. 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. 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, and/or amounts recorded as an estimated reserve for the alleged overpayments is not material.

## ***Contractual Commitments***

As of December 31, 2018, the Company has non-cancelable contractual commitments with a supplier for approximately \$8.9 million and other material supplier commitments for approximately \$5.3 million for inventory material used in the laboratory testing process.

As of December 31, 2018, 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 \$2.1 million, which covers services through March 2020.

As of December 31, 2018, the Company has a non-cancelable contractual commitments with a vendor for biological sample processing and storage totaling approximately \$0.5 million for the next 12 months.

As of December 31, 2018, the Company has non-cancelable minimum purchase commitments with a supplier of diagnostic reagents totaling approximately \$2.0 million through February 2020.

## **8. Stock-Based Compensation**

### **Equity Plans**

#### ***2015 Equity Incentive Plan***

*General.* The Company's board of directors adopted its 2015 Equity Incentive Plan, or the 2015 Plan, in June 2015. The Company's 2015 Plan replaced all of its prior stock plans.

*Share Reserve.* The initial number of shares of the Company's common stock available for issuance under the 2015 Plan was 3,451,495 shares. As of December 31, 2018, 14,584,892 shares were reserved for future issuance under the 2015 plan, which includes unissued and forfeited shares from the 2007 plan. The number of shares reserved for issuance under the 2015 Plan will be increased automatically on the first business day of each fiscal year, commencing in 2016, by a number equal to the smallest of:

- 3,500,000 shares;
- 4% of the shares of common stock outstanding on the last business day of the prior fiscal year; or
- the number of shares determined by the Company's board of directors.

Stock options vest as determined by the compensation committee. In general, they will vest over a four-year period following the date of grant. Stock options expire at the time determined by the compensation committee but in no event more than ten years after they are granted. These awards generally expire earlier if the participant's service terminates earlier.

*Restricted Shares and Stock Units.* Restricted shares and stock units may be awarded under the 2015 Plan in return for any lawful consideration, and participant who receive restricted shares or stock units generally are not required to pay cash for their awards. In general, these awards will be subject to vesting. Vesting may be based on length of service, the attainment of performance-based milestones or a combination of both, as determined by the compensation committee.

### **2015 Employee Stock Purchase Plan**

*General.* The Company's 2015 Employee Stock Purchase Plan, or 2015 ESPP, was adopted by its board of directors in June 2015 and its stockholders approved it in June 2015. The 2015 ESPP is intended to qualify under Section 423 of the Internal Revenue Code.

*Share Reserve.* The Company has reserved 893,548 shares of its common stock for issuance under the 2015 ESPP. As of December 31, 2018, 1,285,851 shares were available for issuance under the 2015 ESPP. The number of shares reserved for issuance under the 2015 ESPP will automatically be increased on the first business day of each of the Company's fiscal years, commencing in 2016, by a number equal to the least of:

- 880,000 shares;
- 1% of the shares of common stock outstanding on the last business day of the prior fiscal year; or
- the number of shares determined by the Company's board of directors.

The number of shares reserved under the 2015 ESPP will automatically be adjusted in the event of a stock split, stock dividend or a reverse stock split (including an adjustment to the per-purchase period share limit).

*Purchase Price.* Employees may purchase each share of common stock under the 2015 ESPP 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 the six-month offering periods. An employee's payroll deductions under the ESPP are limited to 15% of the compensation, and up to a maximum of 5,000 shares may be purchased 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 exceeding \$25,000 fair market value of stock for each calendar year in which such option is outstanding at any time.

*Offering Periods.* Each offering period will last a number of months determined by the compensation committee, not to exceed 27 months. A new offering period will begin periodically, as determined by the compensation committee. Offering periods may overlap or may be consecutive. Unless otherwise determined by the compensation committee, two offering periods of six months' duration will begin in each year on May 1 and November 1.

The first offering period of 2018 started on November 1, 2017 and ended on April 30, 2018, and 206,447 shares were purchased at the end of the first offering period for total proceeds of approximately \$1.9 million. The second offering period of 2018 started on May 1, 2018 and ended on October 31, 2018, and 184,825 shares were purchased at the end of this offering period for total proceeds of approximately \$1.7 million.

## Stock Options

The following table summarizes option activity during the year ended December 31, 2018:

(in thousands, except for contractual life and exercise price)	Outstanding Options				
	Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (In years)	Aggregate Intrinsic Value
Balance at December 31, 2017.....	4,737	9,963	\$ 6.54	7.03	\$ 31,902
Additional shares authorized.....	2,161	—			
Options granted.....	(2,319)	2,319	\$ 11.77		
Options exercised.....	—	(1,967)	\$ 6.78		
Options forfeited.....	852	(852)	\$ 7.54		
Balance at December 31, 2018.....	<u>5,431</u>	<u>9,463</u>	\$ 7.69	6.91	<u>\$ 61,718</u>
Exercisable at December 31, 2018.....		<u>5,484</u>	\$ 5.25	5.57	<u>\$ 48,055</u>
Vested and expected to vest at December 31, 2018..		<u>9,224</u>	\$ 7.60	6.87	<u>\$ 60,895</u>

The total intrinsic value of stock options exercised during the years ended December 31, 2018, 2017 and 2016 was \$25.6 million, \$3.7 million and \$16.9 million, respectively. The total fair value of stock options vested during the years ended December 31, 2018, 2017 and 2016 was \$11.3 million, \$12.1 million, and \$8.5 million, respectively.

The weighted-average grant date fair value of options granted during the years ended December 31, 2018, 2017 and 2016 was \$4.85, \$5.71 and \$5.92 per share, respectively.

## Performance-based Awards

In June 2017, the Board approved a stock option grant of 425,000 shares to the Company's chief executive officer, 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 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.

For the year ended December 31, 2017, the Company did not recognize any compensation expense associated with the performance-based options since none of the milestones were achieved or were probable of being achieved. For the year ended December 31, 2018, the Company recognized stock-based compensation cost associated with the performance-based options of \$0.4 million after it evaluated that milestone (ii) described above was achieved.

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 year ended December 31, 2018, and the Company did not recognize any compensation expense associated with it.

## ***Restricted Stock Units***

The following table summarizes restricted stock unit activity for the year ended December 31, 2018:

	Number of Shares	Weighted- Average Grant Date Fair Value
Balance at December 31, 2017.....	389	\$ 10.38
Granted .....	953	\$ 11.86
Vested .....	(177)	\$ 13.84
Canceled/Forfeited.....	(81)	\$ 9.91
Balance at December 31, 2018.....	<u>1,084</u>	<u>\$ 11.72</u>

## ***Stock-Based Compensation Expense***

Employee and non-employee stock-based compensation expense was calculated based on awards ultimately expected to vest and have 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.

The following table presents the effect of employee and non-employee stock-based compensation expense on selected statements of operations line items for the years ended December 31, 2018, 2017 and 2016.

	Year ended December 31,								
	2018			2017			2016		
	Employee	Non-Employee	Total	Employee	Non-Employee	Total	Employee	Non-Employee	Total
	(in thousands)								
Cost of revenues . . . .	\$ 564	\$ 5	\$ 569	\$ 544	\$ —	\$ 544	\$ 651	\$ (10)	\$ 641
Research and development . . . . .	4,043	—	4,043	3,214	—	3,214	2,829	24	2,853
Selling, general and administrative . . . . .	9,474	112	9,586	7,644	—	7,644	6,837	270	7,107
Total . . . . .	<u>\$ 14,081</u>	<u>\$ 117</u>	<u>\$ 14,198</u>	<u>\$ 11,402</u>	<u>\$ —</u>	<u>\$ 11,402</u>	<u>\$ 10,317</u>	<u>\$ 284</u>	<u>\$ 10,601</u>

As of December 31, 2018, approximately \$24.8 million of unrecognized compensation expense related to unvested option awards and RSUs, net of estimated forfeitures. The unrecognized compensation expense will be recognized over a weighted-average period of approximately 2.45 years.

## ***Valuation of Stock Option Grants to Employees***

The Company estimates the fair value of its stock options granted to employees on the grant date using the Black-Scholes option-pricing model. The fair value of employee stock options is amortized on a straight-line basis over the requisite service period of the awards, generally the vesting period. The fair value of employee stock options was estimated using the following assumptions:

	Year ended December 31,					
	2018		2017		2016	
Expected term (years) . . . . .	5.24	— 5.62	5.14	— 5.24	5.10	— 5.20
Expected volatility . . . . .	40.28%	— 42.53%	40.75%	— 62.93%	63.06%	— 72.49%
Expected dividend rate . . . . .		0 %		0 %		0 %
Risk-free interest rate . . . . .	2.37 %	— 3.06 %	1.67 %	— 2.16 %	0.97 %	— 1.92 %

## Valuation of Stock Option Grants to Non-Employees

Total options outstanding as of December 31, 2018 include 131,865 shares of option awards that were granted to non-employees, of which 36,344 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. The fair value of the stock options granted to non-employees is calculated at each reporting date using the Black-Scholes options-pricing model with the following assumptions:

	Year ended December 31,					
	2018		2017		2016	
Expected term (years) . . . . .	2.72	— 2.76	2.67	— 2.71	2.65	— 3.16
Expected volatility . . . . .	41.36%	— 43.84%	41.22%	— 52.18%	50.90%	— 72.61%
Expected dividend rate . . . . .		0 %		0 %		0 %
Risk-free interest rate . . . . .	2.36 %	— 2.86 %	1.42 %	— 1.95 %	0.68 %	— 1.38 %

**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 by calculating the average of—(1) its employees' historical stock options exercise behavior, and (2) the weighted-average of the time-to-vesting and the total contractual life of the options. For employee stock options that are not granted "at-the-money," the Company uses the binomial lattice model to calculate the expected term. Regarding non-employee stock options, 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 within its peer group over a period approximately equal to the expected term.

**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.

## 9. 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 which can be drawn down in increments at any time. The Credit Line bears interest at 30-day LIBOR plus 1.10%, and it 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 years ended December 31, 2018, 2017 and 2016, the Company recorded interest expense of \$1.6 million, \$1.0 million and \$0.5 million, respectively. Interest payments totaling \$1.5 million and \$0.5 million had been made on the Credit Line during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, remaining accrued interest was \$1.2 million, and the total principal amount outstanding including accrued interest was \$50.2 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 will 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 additional 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.

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 December 31, 2018, 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.

On August 14, 2017, the Company paid OrbiMed a fee in consideration of providing the 2017 Term Loan by issuing 300,000 shares of its common stock. The fair value of the fee was \$2.4 million, which was determined based on the Company's stock price of \$8.16 on August 8, 2017. Additionally, the Company paid legal fees of \$0.3 million in connection with this term loan. Total debt issuance costs incurred amounted to \$2.7 million, which is accounted for as a debt discount to be amortized on a straight-line basis over the term of the loan. The Company has classified \$2.0 million of the debt discount as a direct reduction from the outstanding debt balance of \$75.0 million, while the remainder is classified as noncurrent assets (as described in Note 6).

For the years ended December 31, 2018 and 2017, interest expense totaling \$8.6 million and \$3.2 million was recorded, respectively, which also included the amortization of debt discount. Debt discount amortized as interest expense was \$0.4 million and \$0.1 million for the years ended December 31, 2018 and 2017, respectively. In addition, the Company made interest payments totaling \$6.1 million and \$3.1 million during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, interest accrued for the 2017 Term Loan was \$2.1 million, which was paid in January 2019. The Company has not made any principal payment as it is not required to repay the outstanding balance until August 2024.

The following table indicates how the Company reported its long-term debt at the end of the period:

	December 31, 2018	December 31, 2017
(Amounts in thousands)		
Debt principal balance .....	\$ 75,000	\$ 75,000
Less: unamortized debt discount.....	(1,643)	(1,935)
Net carrying amount at end of period .....	<u>\$ 73,357</u>	<u>\$ 73,065</u>

## 10. Warrants

In April 2014, the Company granted warrants to purchase 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 in connection with the Company's senior secured term loan that has since been repaid and have an expiration date of April 18, 2023. It was determined that the warrants granted are detachable and therefore are a stand-alone 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.

## 11. Stockholders' Equity

As of December 31, 2018, the Company had 50,000,000 authorized shares of its preferred stock, of which no shares were issued and outstanding; and 750,000,000 authorized shares of its common stock, at \$0.0001 par value, and there were 62,082,348 shares of common stock issued and outstanding.

In August 2017, the Company paid OrbiMed a fee in consideration of providing the 2017 Term Loan (as defined in Note 9) by issuing 300,000 shares of its common stock. The fair value of the fee was \$2.4 million, which was determined based on the Company's stock price of \$8.16 on August 8, 2017.

In June 2018, OrbiMed exercised all of its warrants, which were all converted into common stock. The exercise was a cashless transaction, and there were 332,896 of net shares issued to OrbiMed following the exercise at the fair value of \$6.8 million.

In July 2018, the Company completed an equity offering to sell 4,500,000 shares of its common stock to the public at a price of \$20 per share, along with the sale of 675,000 additional shares of its common stock to the underwriters upon their exercise of the option to purchase those shares. Upon the closing of the equity offering, the Company received proceeds of \$97.3 million before offering expenses, which totaled approximately \$0.5 million.

## 12. Income Taxes

The Company's effective tax rates for the years ended December 31, 2018, 2017 and 2016 differ from the U.S. federal statutory rate as follows:

	Year Ended December 31,					
	2018		2017		2016	
	(in thousands, except percentages)					
U.S. federal taxes (benefit) at statutory rate. . . .	\$ (26,800)	(21.00)%	\$ (46,206)	(34.00)%	\$ (32,277)	(34.00)%
State tax expense . . . . .	(4,468)	(3.50)%	(6,559)	(4.83)%	(2,842)	(2.99)%
Research and development credits . . . . .	(1,164)	(0.91)%	(1,149)	(0.85)%	(1,449)	(1.53)%
Stock-based compensation . . . . .	(3,148)	(2.47)%	(5,036)	(3.71)%	1,275	1.34 %
Change in federal tax rate . . . . .	—	0.00 %	44,701	32.89 %	—	0.00 %
Mark to market fair value adjustments. . . . .	865	0.68 %	(390)	(0.29)%	49	0.05 %
Nondeductible settlement for claims . . . . .	1	0.00 %	3,873	2.85 %	—	0.00 %
Other nondeductible items . . . . .	885	0.69 %	1,009	0.74 %	933	0.99 %
Change in valuation allowance. . . . .	34,150	26.76 %	10,211	7.51 %	34,453	36.29 %
Provision for income taxes . . . . .	\$ 321	0.25 %	\$ 454	0.31 %	\$ 142	0.15 %

During the year ended December 31, 2018, the Company recorded total income tax expense of \$0.3 million. The Company provides testing to clinics and also licenses its cloud-based software to licensees that are based in a foreign country, which contributed to a foreign income tax expense of \$0.2 million. Total income tax expense also included a state income tax expense of \$0.1 million for the year ended December 31, 2018.

During the year ended December 31, 2017, the Company recorded total income tax expense of \$0.4 million, which included foreign income tax expense of \$0.2 million and state income tax expense of \$0.2 million. During the year ended December 31, 2016, the Company did not record any income tax expense given its history of losses, with the exception of \$0.1 million of foreign withholding tax in 2016.

Deferred income taxes reflect the net tax effects of temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes as well as net operating loss and tax credit carryforwards. The components of the net deferred income tax assets are as follows:

	December 31,	
	2018	2017
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards .....	\$ 95,321	\$ 77,356
Research and development tax credit carryforwards .....	15,632	12,675
Reserves and accruals .....	7,922	3,404
Stock-based compensation .....	4,076	2,929
Total deferred tax assets before valuation allowance .....	122,951	96,364
Less: valuation allowance .....	(122,441)	(95,817)
	510	547
Deferred tax liabilities:		
Property and equipment .....	(510)	(547)
Net deferred tax assets .....	\$ —	\$ —

The Company established a full valuation allowance against its net deferred tax assets in 2018 and 2017 due to the uncertainty surrounding realization of these assets. The valuation allowance increased to \$122.4 million as of December 31, 2018 from \$95.8 million as of December 31, 2017. The valuation allowance increased during 2018 due to current year losses and credits claimed, offset by a reduction due to the adoption of ASC 606. The valuation allowance increased to \$95.8 million as of December 31, 2017 from \$85.6 million as of December 31, 2016.

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 are required.

As of December 31, 2018, the Company had federal and state net operating loss (“NOLs”) carryforwards of approximately \$394.0 million and \$201.4 million, respectively, which begin to expire in 2027 and 2028, respectively, if not utilized.

The Company 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. Realization of these deferred tax assets would require \$488.1 million in taxable income to fully utilize. Realization is dependent on generating sufficient taxable income prior to expiration of the loss and credit carryforwards.

Federal and California tax laws impose substantial restrictions on the utilization of NOLs and credit carryforwards in the event of an “ownership change” for tax purpose, as defined in Section 382 of the Internal Revenue Code. Accordingly, the Company's ability to utilize these carryforwards may be limited as the result of such ownership change. Such a limitation could result in limitation in the use of the NOLs in future years and possibly a reduction of the NOLs available.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

	Year Ended December 31,		
	2018	2017 (in thousands)	2016
Balance at beginning of year .....	\$ 5,945	\$ 4,293	\$ 2,405
Additions based on tax positions related to the current year .....	1,416	1,651	1,836
Additions for tax positions of prior years .....	1	1	52
Balance at end of year .....	<u>\$ 7,362</u>	<u>\$ 5,945</u>	<u>\$ 4,293</u>

The Company adopted the provisions of ASC 740-10-50, *Accounting for Uncertainty in Income Taxes*, on January 1, 2009. During the years ended December 31, 2018, 2017 and 2016, the amount of unrecognized tax benefits increased \$1.4 million, \$1.7 million, and \$1.9 million, respectively, due to additional research and development credits generated during the year. As of December 31, 2018, 2017 and 2016, the total amount of unrecognized tax benefits was \$7.4 million, \$5.9 million and \$4.3 million, respectively. The reversal of the uncertain tax benefits would not affect the Company's effective tax rate to the extent that it continues to maintain a full valuation allowance against its deferred tax assets.

The Company is subject to U.S. federal income taxes and to income taxes in various states in the United States. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations, and require significant judgment to apply. The Company is subject to U.S. federal, state and local tax examinations by tax authorities for all prior tax years since incorporation. The Company does not anticipate significant changes to its current uncertain tax positions through December 31, 2019.

The Company recognizes any interest and/or penalties related to income tax matters as a component of income tax expense. As of December 31, 2018, there were no accrued interest and penalties related to uncertain tax positions.

### 13. Net Loss per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period.

In periods when the Company has incurred a net loss, common stock equivalents such as outstanding common stock options, restricted stock units, unvested common shares subject to repurchase and warrants are excluded from the calculation of diluted net loss per share as they give an anti-dilutive effect.

For the year ended December 31, 2017, the Company reversed \$1.1 million of remeasurement gain on the change in the fair value of warrants from its net loss and included the incremental shares from the assumed exercise of the warrants in the computation of its weighted-average shares outstanding as they yielded a dilutive effect to the net loss per share in the period. Other potentially dilutive common stock equivalents such as outstanding common stock options, shares to be purchased under the employee stock purchase plan, and restricted stock units were excluded as their effect was anti-dilutive and the net loss per share would be reduced.

The following table provides the basic and diluted net loss per share computations for the years ended December 31, 2018, 2017 and 2016:

(in thousands, except per share data)	Year ended December 31,		
	2018	2017 (As Revised)	2016 (As Revised)
<b>Numerator:</b>			
Net loss used to compute net loss per share, basic . . . . .	\$ (128,154)	\$ (137,628)	\$ (100,327)
Less: Remeasurement gain on warrant liability . . . . .	—	(1,148)	—
Net loss used to compute net loss per share, diluted . . . . .	\$ (128,154)	\$ (138,776)	\$ (100,327)
<b>Denominator:</b>			
Weighted-average common shares outstanding . . . . .	57,848	53,312	51,667
Less: Weighted-average unvested common shares subject to repurchase . . .	—	—	(91)
Weighted-average number of shares used in computing net loss per share, basic . . . . .	57,848	53,312	51,576
Add: Incremental shares from assumed exercise of warrants . . . . .	—	292	—
Weighted-average number of shares used in computing net loss per share, diluted . . . . .	57,848	53,604	51,576
Net loss per share, basic . . . . .	\$ (2.22)	\$ (2.58)	\$ (1.95)
Net loss per share, diluted . . . . .	\$ (2.22)	\$ (2.59)	\$ (1.95)

The following table shows the potentially dilutive common stock equivalents that were excluded from the computations of diluted net loss per share as their effect would be anti-dilutive, as of December 31, 2018, 2017 and 2016:

	As of December 31,		
	2018	2017	2016
Options to purchase common stock . . . . .	9,463	9,963	9,043
Warrants to purchase common stock . . . . .	—	—	377
Restricted stock units . . . . .	1,084	389	159
Employee stock purchase plan . . . . .	42	79	90
	<u>10,589</u>	<u>10,431</u>	<u>9,669</u>

#### 14. Subsequent Events

In January 2019, the Company amended the existing agreement with one of its vendors to establish non-cancelable contractual commitments for a minimum number of genetic tests to be processed, as well as the price per test processed. The amended agreement has a remaining term of two years starting January 1, 2019. For the next 12 months, total contractual commitments are \$9.7 million. The commitments beyond 12 months will be determined at the end of 2019.

In February 2019, the Company entered into a License Agreement with BGI Genomics Co., Ltd (“BGI Genomics”) to develop and commercialize NGS-based genetic testing assays for clinical use. According to the agreement, the Company will receive a total of \$50.0 million, comprising \$35.0 million in upfront technology licensing fees and prepaid royalties, and \$15.0 million in future milestone payments. The Company is committed to pay \$6.0 million for future test services. The Company will also prepay \$4.0 million to another supplier. The License Agreement has a term of ten years and expires in February 2029. This Agreement is subject to customary closing conditions, including partner government approval.

In March 2019, the Company paid off the final quarterly installment of \$1.4 million imposed by the settlement agreement relating to reimbursement-related claims. As required by the settlement agreement, a letter of credit was secured with a financial institution until the settlement amount was entirely paid off. The letter of credit expired on March 1, 2019, and accordingly, the funds totaling \$4.2 million (see Note 2 under *Restricted Cash*) were available to the Company.

## 15. Quarterly Financial Data (unaudited)

	Three months ended			
	December 31,	September 30,	June 30,	March 31,
	(in thousands, except per share data)			
<b>2018</b>				
Operating results:				
Total revenues	\$ 66,965	\$ 65,280	\$ 63,069	\$ 62,340
Cost of product revenues	40,345	39,477	39,204	39,055
Cost of licensing and other revenues	2,444	2,202	1,791	1,537
Gross profit	24,176	23,601	22,074	21,748
Operating expenses	53,903	50,767	49,292	52,265
Interest expense and other (expense) income, net	(2,128)	(2,332)	(6,493)	(2,252)
Income tax expense	14	(118)	(113)	(104)
Net loss	<u>\$ (31,841)</u>	<u>\$ (29,616)</u>	<u>\$ (33,824)</u>	<u>\$ (32,873)</u>
Per share data:				
Net loss - basic	<u>\$ (0.51)</u>	<u>\$ (0.49)</u>	<u>\$ (0.62)</u>	<u>\$ (0.61)</u>
Net loss - diluted	<u>\$ (0.51)</u>	<u>\$ (0.49)</u>	<u>\$ (0.62)</u>	<u>\$ (0.61)</u>
<b>2017 (As Revised)</b>				
Operating results:				
Total revenues	\$ 52,050	\$ 55,910	\$ 52,283	\$ 49,382
Cost of product revenues	35,153	33,558	33,709	33,088
Cost of licensing and other revenues	1,572	1,054	850	612
Gross profit	15,325	21,298	17,724	15,682
Operating expenses	61,956	47,087	46,095	50,232
Interest expense and other (expense) income, net	(405)	(1,914)	(631)	1,117
Income tax expense	(181)	(162)	(64)	(47)
Net loss	<u>\$ (47,217)</u>	<u>\$ (27,865)</u>	<u>\$ (29,066)</u>	<u>\$ (33,480)</u>
Per share data:				
Net loss - basic	<u>\$ (0.88)</u>	<u>\$ (0.52)</u>	<u>\$ (0.55)</u>	<u>\$ (0.63)</u>
Net loss - diluted	<u>\$ (0.90)</u>	<u>\$ (0.52)</u>	<u>\$ (0.55)</u>	<u>\$ (0.65)</u>

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## ITEM 9A: 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 December 31, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-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 December 31, 2018, management has concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

### **Management's Annual Report on Internal Control over Financial Reporting**

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control over financial reporting is designed 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. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has evaluated the effectiveness of our internal control over financial reporting as of December 31, 2018 using the criteria set forth in the 2013 *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on our evaluation, management has concluded that we maintained effective internal control over financial reporting as of December 31, 2018 based on the COSO criteria.

This annual report does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

### **Changes in Internal Control over Financial Reporting**

There were no 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 three months ended December 31, 2018 that has materially affected, or is reasonably likely to material 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.

## **ITEM 9B. OTHER INFORMATION**

**None.**

### **PART III**

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with our 2019 annual meeting of stockholders (the "Proxy Statement"), which we expect to file no later than 120 days after the end of our fiscal year ended December 31, 2018, and is incorporated in this report by reference.

#### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item will be contained in the Proxy Statement, which we expect to file no later than 120 days after the end of our fiscal year ended December 31, 2018, and is incorporated in this report by reference.

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this item will be contained in the Proxy Statement, which we expect to file no later than 120 days after the end of our fiscal year ended December 31, 2018, and is incorporated in this report by reference.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this item will be contained in the Proxy Statement, which we expect to file no later than 120 days after the end of our fiscal year ended December 31, 2018, and is incorporated in this report by reference.

#### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required by this item will be contained in the Proxy Statement, which we expect to file no later than 120 days after the end of our fiscal year ended December 31, 2018, and is incorporated in this report by reference.

### **PART IV**

#### **ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements (included in Part II of this report):

- Report of Independent Registered Public Accounting Firm
- Balance Sheets
- Statement of Operations
- Statement of Stockholders' Equity
- Statement of Cash Flows
- Notes to Financial Statements

(2) Financial Statement Schedules:

All financial statement schedules are omitted because the information is inapplicable or presented



in the notes to the financial statements.

(b) The following exhibits are filed with or incorporated by reference as part of this Annual Report on Form 10-K:

### INDEX TO EXHIBITS

Exhibit No.	Description	Incorporated by Reference				
		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	
4.1	Form of Common Stock Certificate	S-1/A	333-204622	4.1	6/22/2015	
4.2	Amended and Restated Investors' Rights Agreement, dated November 20, 2014.	S-1	333-204622	4.2	6/1/2015	
10.1*	2007 Stock Plan and form of agreements thereunder.	S-1	333-204622	10.1	6/1/2015	
10.2*	2015 Equity Incentive Plan and forms of agreements thereunder.	10-K	001-37478	10.2	3/24/2016	
10.3*	2015 Employee Stock Purchase Plan.	S-1/A	333-204622	10.3	6/25/2015	
10.4	Form of Indemnification Agreement, by and between Registrant and each of its directors and executive officers.	10-K	001-37478	10.4	3/16/2017	
10.5**	Supply Agreement, dated September 18, 2014, by and between Registrant and Illumina, Inc., as amended (conformed copy).	S-1/A	333-204622	10.13	6/30/2015	
10.6**	Second Amendment to Supply Agreement, dated September 21, 2015, by and between Registrant and Illumina, Inc.	10-Q	001-37478	10.1	8/11/2016	
10.7**	Third Amendment to Supply Agreement, dated June 8, 2016, by and between Registrant and Illumina, Inc.	10-Q	001-37478	10.2	8/11/2016	
10.8***	Fourth Amendment to Supply Agreement, dated January 3, 2019, by and between Registrant and Illumina, Inc.					X
10.9**	Application Service Provider Agreement, dated September 19, 2014, by and between Registrant and DNAnexus, Inc., as amended	10-K	001-37478	10.11	3/16/2017	
10.10**	Third Amendment to Application Service Provider Agreement, dated January 1, 2018, by and between Registrant and DNAnexus, Inc.	10-Q	001-37478	10.1	11/9/2018	
10.11**	Fourth Amendment to Application Service Provider Agreement, dated July 1, 2018, by and between Registrant and DNAnexus, Inc.	10-Q	001-37478	10.2	11/9/2018	
10.12*	Amended Employment Agreement, by and between Registrant and Matthew Rabinowitz, dated June 7, 2007.	S-1/A	333-204622	10.15	6/25/2015	

Exhibit No.	Description	Incorporated by Reference				
		Form	File No.	Exhibit	Filing Date	Filed Herewith
10.13*	Amended Employment Agreement, by and between Registrant and Jonathan Sheena, dated June 7, 2007.	S-1/A	333-204622	10.16	6/25/2015	
10.14*	Amended Compensation Program for Non-Employee Directors.	10-Q	001-37478	10.1	11/12/2015	
10.15.1	UBS Credit Line Agreement, dated September 23, 2015, as amended.	10-Q	001-37478	10.2	11/12/2015	
10.15.2	Amendment to UBS Credit Line Agreement, dated July 5, 2017.	10-Q	001-37478	10.1	8/9/2017	
10.16*	Natera, Inc. Management Cash Incentive Plan.	10-Q	001-37478	10.3	11/12/2015	
10.17	Lease, dated October 26, 2015, by and between Registrant and BMR-201 Industrial Road LP.	10-K	001-37478	10.23	3/23/2016	
10.18	First Amendment to Lease, dated October 6, 2016, by and between Registrant and BMR-201 Industrial Road LP.	10-Q	001-37478	10.1	11/10/2016	
10.19**	Credit Agreement, dated as of August 8, 2017, by and between Natera, Inc. and OrbiMed Royalty Opportunities II, LP.	10-Q	001-37478	10.1	11/9/2017	
10.20***	Amendment and Waiver to Credit Agreement, dated as of December 31, 2018, by and between Natera, Inc. and OrbiMed Royalty Opportunities II, LP.					X
10.21**	Pledge & Security Agreement, dated as of August 8, 2017, by and between Natera, Inc., Natera International, Inc., NSTX, Inc. and OrbiMed Royalty Opportunities II, LP.	10-Q	001-37478	10.2	11/9/2017	
10.22	Guarantee, dated as of August 8, 2017, by and between Natera International, Inc., NSTX, Inc. and OrbiMed Royalty Opportunities II, LP.	10-Q	001-37478	10.3	11/9/2017	
10.23**	License, Development and Distribution Agreement, dated as of March 9, 2018, by and between Natera, Inc. and QIAGEN LLC	10-Q/A	001-37478	10.1	2/6/2019	
21.1	List of Subsidiaries of the Registrant.	10-K	001-37478	21.1	3/16/2017	
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (see signature page of this Annual Report on Form 10-K).					X
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

Exhibit No.	Description	Incorporated by Reference				
		Form	File No.	Exhibit	Filing Date	Filed Herewith
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
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

\* Indicates a management contract or compensatory plan.

\*\* Portions of this exhibit (indicated by asterisks) have been omitted pursuant to an order granting confidential treatment. Omitted portions have been submitted separately to the Securities and Exchange Commission (SEC).

\*\*\* Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment. Omitted portions have been submitted separately to the SEC.

† The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K 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 Annual Report on Form 10-K, regardless of any general incorporation language contained in any filing.

## ITEM 16. FORM 10-K SUMMARY

None.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Carlos, State of California, on this 15th day of March, 2019.

**Natera, Inc.**

*/ s / Michael Brophy*

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**Michael Brophy**  
**Chief Financial Officer**

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Steve Chapman and Michael Brophy as his or her true and lawful attorney-in-fact and agent with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/ s / Steve Chapman</u> Steve Chapman	Chief Executive Officer, President and Director (Principal Executive Officer)	March 15, 2019
<u>/ s / Michael Brophy</u> Michael Brophy	Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2019
<u>/ s / Jonathan Sheena</u> Jonathan Sheena	Chief Technology Officer and Director	March 15, 2019
<u>/ s / Matthew Rabinowitz</u> Matthew Rabinowitz	Executive Chairman	March 15, 2019
<u>/ s / Roy Baynes</u> Roy Baynes	Director	March 15, 2019
<u>/ s / Roelof F. Botha</u> Roelof F. Botha	Director	March 15, 2019
<u>/ s / Todd Cozzens</u> Todd Cozzens	Director	March 15, 2019
<u>/ s / Edward C. Driscoll, Jr.</u> Edward C. Driscoll, Jr.	Director	March 15, 2019
<u>/ s / James I. Healy</u> James I. Healy	Director	March 15, 2019
<u>/ s / Gail Marcus</u> Gail Marcus	Director	March 15, 2019
<u>/ s / Herm Rosenman</u> Herm Rosenman	Director	March 15, 2019



**Natera, Inc.**

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