



## **2016 ANNUAL REPORT**

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

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**FORM 10-K**  

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(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, 2016

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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 30, 2016, based on the closing price of \$12.06 per share as reported on the NASDAQ was approximately \$0.5 billion.

As of February 28, 2017, the number of outstanding shares of the registrant's common stock, par value \$0.0001 per share, was 52,772,984.

**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 2017. 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, 2016.

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**Natera, Inc.**

**FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2016**

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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 reliance on our partners to market and offer our tests in the United States and in international markets;
- our ability to successfully develop additional revenue opportunities and expand our product offerings to include new tests or services, including in the field of cancer diagnostics;
- the scope of protection we establish and maintain for, and developments or disputes concerning, our intellectual property or other proprietary rights;
- competition in the markets we serve;
- our ability to successfully implement and commercialize our cloud-based distribution model;
- our reliance on collaborators such as medical institutions, contract laboratories, laboratory partners, and other third parties;
- our ability to operate our laboratory facility and meet expected demand;
- 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 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;

- our ability to successfully commercialize our planned cord blood and tissue banking service offering;
- 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 rapidly growing diagnostics company with proprietary molecular and bioinformatics technology that we are deploying to change the management of genetic 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 detect 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 determine the likelihood of a wide range of genetic conditions. Our tests are used for the detection of genetic variations covering a broad set of diseases, such as Down syndrome, which can enable diagnosis and treatment. Our technology has been proven clinically and commercially in the prenatal testing space. We believe this success can be translated into the liquid biopsy space, and we are leveraging our core expertise to develop products for oncology applications. In addition to our direct sales force in the United States, we have a global network of approximately 70 laboratory and distribution partners, including many of the largest international laboratories. We are enabling even wider adoption of our technology with our global cloud-based distribution model. We have launched seven molecular diagnostic tests since 2009, and we intend to launch new products in women's health, prenatal testing and oncology in the future. In March 2013, we launched Panorama, our non-invasive prenatal test, or NIPT. Panorama represented approximately 66% of our revenues, with over 331,000 Panorama tests accessioned, during the year ended December 31, 2016. Our revenues have grown to \$217.1 million in 2016 from \$190.4 million in 2015 and \$159.3 million in 2014. Our net losses increased to \$95.8 million in 2016 from \$70.3 million in 2015 and \$5.2 million in 2014.

In both prenatal testing and oncology, the use of blood-based diagnostic 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 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 SNPs simultaneously using 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. 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*, the *American Journal of Obstetrics & Gynecology*, and *Prenatal Diagnosis*, we believe Panorama is the most accurate NIPT commercially available in the United States.

To make sense of this deep and rich set of biological data and deliver a diagnosis, 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 diagnostic 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 in oncology applications such as recurrence monitoring, therapy monitoring and early detection screening. In oncology, we have demonstrated our ability to detect both CNVs and SNVs from very low concentrations of tumor DNA circulating in a blood sample, or ctDNA. Because lung, ovarian and breast cancer are driven,

to varying degrees, by a combination of CNVs, SNVs and gene fusions, we believe that our approach is well-suited for recurrence monitoring, therapy selection and early detection for these cancers.

## Genetics Primer

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.

## Our Solution

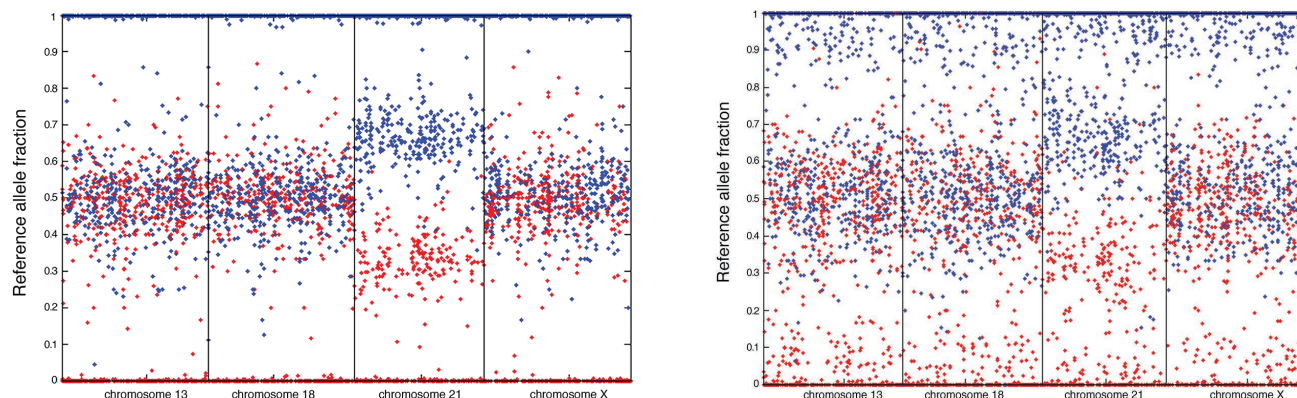
Our technologies allow us to achieve a high signal to noise ratio when detecting fragments of DNA from samples as small as a single cell, which allows us to deliver screening tests with differentiated specificity, sensitivity, and coverage. From a single blood draw, our current commercial tests assess the risk of a broad range of conditions, which we refer to as "coverage," including common fetal aneuploidies, microdeletions, triploidy, and inherited genetic conditions that could be passed on from parent to child. 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 are LDT. We perform commercial testing in our CLIA-certified laboratory.

Our proprietary innovations in both molecular biology and bioinformatics drive performance of our current prenatal genetic tests and our development pipeline. Our mmPCR technology optimizes the behavior of primers in a reaction to generate a high-resolution measurement of thousands of DNA loci in patient samples. As a result, we can capture mutations from a single DNA fragment within a large background of extraneous DNA found in a patient's blood sample. We believe our molecular technology has the potential to enable a broad range of applications in prenatal diagnostics and cancer. For example, the ability to target primers in a specific area of chromosome 22 allows our prenatal microdeletions panel to assess the risk of 22q11.2 deletion syndrome, which is caused by the deletion of a small piece of chromosome 22, with demonstrated higher sensitivity and specificity than other commercially available tests. If identified during pregnancy, 22q11.2 deletion syndrome can be treated with early intervention at the time of birth to avoid seizures and reduce cognitive impairment.

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 assay 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 and our microdeletions panel for Panorama in 2014. 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 death of the fetus. Panorama can also identify fetal sex. 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 where 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. Currently, all samples are then sent to our CLIA-certified 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 2016, we averaged approximately 99.5% 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*, *Science*, *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 confirmatory invasive procedures, lowering the total cost to the healthcare system of these procedures and limiting the resulting risk of spontaneous miscarriage associated with invasive procedures.

Panorama screens for common genetic conditions that affect both high-risk pregnancies, where maternal age is over 35 and which represent approximately 600,000 pregnancies in the United States, and average-risk pregnancies, which represent approximately 3.3 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 over 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. The American College of Medical Genetics, or ACMG, is the most recent professional society that has advocated for broader adoption of NIPT, including supporting NIPT as an optimal initial screening test for all pregnant women, regardless of age or other risk factors. 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, will be particularly important in driving 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 (Di George syndrome), 1p36 deletion, Angelman syndrome, Cri-du-chat syndrome and Prader-Willi syndrome. Microdeletions are missing sub-chromosomal pieces of DNA, which 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, or DiGeorge syndrome, doctors will know to deliver calcium to the infant to avoid seizures and permanent cognitive impairment and will know to avoid administering routine vaccinations due to the immunodeficiency frequently associated with this condition.

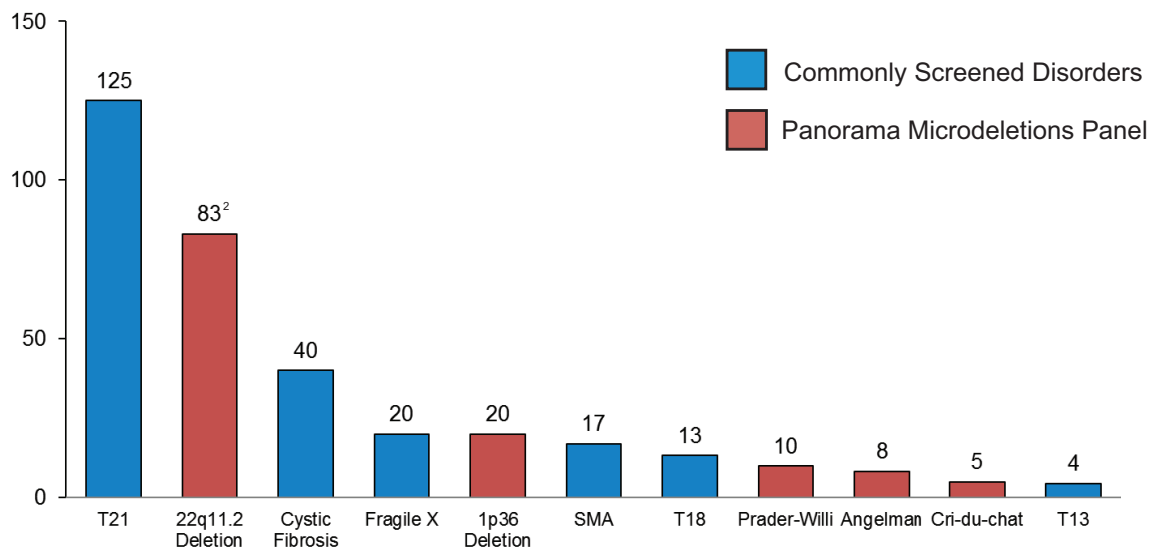
Panorama has demonstrated best-in-class performance screening for microdeletions. In validation studies, Panorama achieved sensitivity greater than 95% for deletions of approximately 2.9Mb for 22q11.2 deletion syndrome and has been validated to perform at low fetal fractions, which refers to the percentage of fetal, as opposed to maternal, DNA in a maternal plasma sample. Based on data published in the January 2016 issue of *Ultrasound in Obstetrics & Gynecology*, Panorama demonstrated a PPV of 18% and false positive rate of 0.38% for 22q11.2 deletion syndrome. We are also conducting a SNP-based Microdeletions and Aneuploidy RegisTry (SMART) 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 have enrolled more than 6,000 of the 10,000 total anticipated patients in this study. We expect to review perinatal medical records and collect postnatal DNA in order to perform genetic diagnostic testing for 22q11.2 deletion syndrome. We will also collect follow-up genetic samples from all participants found to be at high risk either through NIPT or other means. Results from the follow-up specimens will be compared to those obtained by the Panorama screening test to determine test performance, particularly PPV.

The Panorama microdeletions panel has conditional approval from the New York State Department of Health.

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.

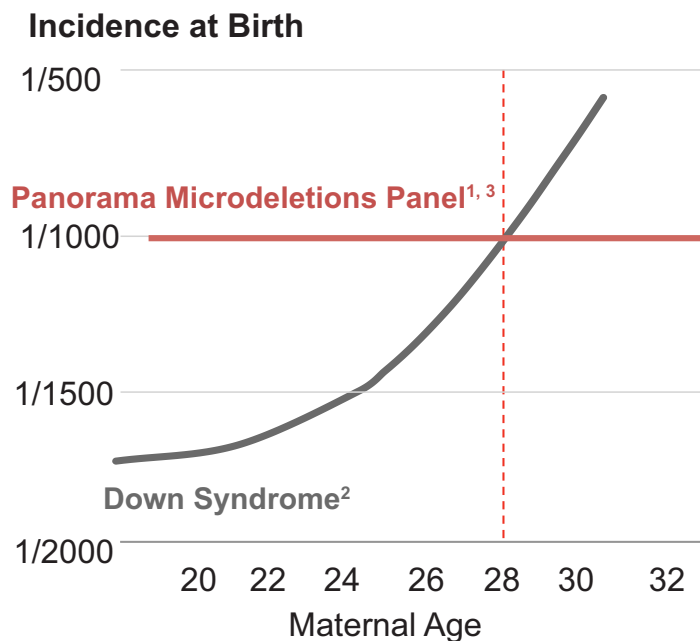
Incidence out of 100,000 Births<sup>1</sup>



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<sup>TM</sup> 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 in 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. Significantly, the AMA has recently issued a CPT code for use in billing and reimbursement for microdeletions testing, and CMS has provided a pricing benchmark for aneuploidy and microdeletions testing. See “—Reimbursement.” Since several Medicaid programs haven't yet priced aneuploidy testing, we expect the pricing of aneuploidy set by CMS will 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. While we expect that our microdeletions reimbursement will decline, at least in the near term, either due to reduced reimbursement or third-party payers declining to reimburse under the new code, 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.

Since launching Panorama, we have implemented various updates to both the molecular and computational portions of Panorama, continuing to improve performance and reduce the cost of running the test. Previous updates have significantly reduced Panorama's no-call rate, improved sensitivity at lower fetal fractions and simplified sample collection for clinics. We most recently updated Panorama in January 2017 to improve efficiency and further reduce costs by incorporating screening for 22q11.2 deletion syndrome in our base Panorama panel. 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 of over 95% for deletions of approximately 2.9Mb for 22q11.2 deletion syndrome.

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 per-indication sensitivities between 97.3% and 100%, and specificities of greater than 99.9%, for all indications. 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.

## ***Our Other Products***

The following table summarizes our other products launched to date.

<b>Product</b>	<b>Indication(s)</b>	<b>Year Launched</b>	<b>Description</b>
Constellation Software	Clinical or research applications that involve analysis of CNVs and SNVs in a DNA mixture	2015	Allows laboratory customers to gain access through the cloud to the same algorithms and bioinformatics that we use in our own laboratory, allowing for validation and commercialization of tests based on our technology, including NIPT.
Horizon Carrier Screen (CS)	Up to 274 conditions, including: Cystic fibrosis Spinal muscular atrophy Fragile X syndrome Duchenne Muscular Dystrophy	2012	CS test performed either before or during pregnancy for a large number of serious genetic disorders that could be passed on to the carrier's children.
Non-Invasive Prenatal Paternity Test	Paternity	2011	Reliably indicates paternity as early as nine weeks gestation.
Anora Products of Conception Test (POC)	Post-miscarriage testing	2010	POC test developed specifically to identify fetal chromosomal causes of miscarriages using a SNP microarray.
Spectrum Preimplantation Genetic Diagnosis (PGD) and Spectrum Pre-implantation Genetic Screening (PGS)	Inherited diseases (PGD) Extra or missing chromosomes and segmental deletions or duplications (PGS)	2010 (PGD) 2009 (PGS)	Spectrum PGD tests for specific genetic disease(s) that the couple is known to be at risk to pass on to their children. Spectrum PGS can inform clinicians and patients which IVF-created embryo samples have the correct number of chromosomes and are suitable for transfer.

## Horizon

Horizon helps couples determine if they are carriers of genetic mutations that cause specific diseases. If the mutation is passed to a child, 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. Horizon was created based on recommended screening guidelines from ACOG, ACMG, and the Victor Center for the Prevention of Jewish Genetic Diseases. Most conditions are autosomal recessive disorders, which means that both parents have to 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.

Horizon screens for up to 274 inherited diseases, including cystic fibrosis, Duchenne muscular dystrophy, spinal muscular atrophy, fragile X syndrome and other conditions. The blood sample required for Horizon can be drawn simultaneously with that required for Panorama, which makes it easier for us to offer, and for patients to take, both tests. Horizon employs next generation sequencing 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 14 business days from the day we receive the sample, depending on the number of conditions the patient has requested to be screened.

## 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, 2017, seven licensees are using our Constellation platform commercially, including six 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 continue to engage in active discussions with potential licensees in the United States and abroad to continue to grow our cloud-based distribution network, which we believe will further enhance adoption of our tests among laboratory licensees globally. We also leverage Constellation to more efficiently perform our internal commercial laboratory activities and to perform research and development of our products.

In July 2014, we achieved a CE Mark from the European Commission for our Constellation software. In May 2015, we achieved a CE Mark 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 combined CE Marks enable us to offer Constellation for Panorama NIPT 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:

- *Improve patient experience.* By eliminating the need to ship samples to our CLIA laboratory in California, patients benefit from faster turnaround times and lower costs.
- *Drive higher rates of reimbursement for our laboratory licensees.* We believe that our cloud-based distribution model allows many international laboratory licensees and their patients to achieve improved reimbursement from health insurance plans, as many state-administered and private payers in international markets require that the sample remain within national borders as a condition for reimbursement.
- *Accelerate international adoption by leveraging our licensees' existing capabilities.* Our laboratory licensees are able to offer tests under their existing laboratory certifications as required by local regulators,



leverage their local infrastructure for sample collection, and deploy local marketing capabilities to further increase test volumes.

- *Efficiently achieve scale.* The cloud-based distribution model allows us to leverage rapidly expanding sequencing capacity around the world to drive volumes faster than would be possible from the expansion of our own CLIA-certified laboratory capacity, and enables our laboratory licensees to drive volumes without significant incremental expenditures on information technology or investment in research and development.
- *Reduce costs.* As test volumes increase, the costs of shipping samples, particularly internationally, and labor costs in our CLIA-certified laboratory in California increasingly become the largest cost components. Our cloud-based distribution model eliminates these costs, expanding the margin opportunity for us and our laboratory licensees and better enabling our tests to withstand pricing pressure.
- *Efficiently deliver innovations to our laboratory licensees.* The cloud-based distribution model positions us to efficiently offer enhancements we make to our algorithms, test menu, and any new products we commercialize to the network of laboratory licensees that are already utilizing our Constellation platform.

### *Other products*

Our PGS and PGD tests, which we market under the Spectrum brand, are for couples undergoing IVF. Our PGS test screens embryos for chromosomal abnormalities prior to transfer of embryos created through IVF procedures, which have a high rate of non-viable chromosomal abnormalities. This allows IVF physicians to select and transfer embryos with normal chromosome results and, combined with single embryo transfer, greatly increases the rate of implantation and pregnancy, reduces the risks of a multiple pregnancy and may reduce the need for multiple costly IVF cycles. Our PGD test screens embryos for couples who are concerned about passing on a specific genetic defect to their child.

Anora is our POC product, which tests miscarriage tissue in women who have experienced one or more miscarriages to determine whether there was an underlying genetic reason for the miscarriage(s). The Anora product is helpful to obstetricians, gynecologists and IVF physicians in supporting their patients' reproductive goals. Anora helps couples understand their future options, the likelihood of another miscarriage 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.

### *Evercord*

We have announced our plan to commercially launch Evercord, a private cord blood and tissue banking service, in the second quarter of 2017. This offering will enable expectant parents to collect, store and potentially retrieve their newborn's cord blood and tissue for therapeutic use in transplantation and regenerative medicine applications. Cord blood, which is the blood contained in the placental blood vessels and umbilical cord, contains HPCs, which are 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. HPCs are also found in bone marrow and peripheral blood, which is blood circulating in the body; however, there is evidence suggesting that cord blood HPCs may not require as exact a match as HPCs from bone marrow or the bloodstream do, and, as a result, transplants involving compatible HPCs from cord blood may be less likely to cause adverse reactions. 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 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. Through Evercord, we offer

our customers the option to bank their child's cord blood and tissue for potential medical use by the child or related family member. We believe that our Evercord offering is a natural extension of our mission and our experience in genetic testing, as our tests currently screen for 35 of the nearly 80 diseases in which cord blood stem cell treatment has been administered.

Our Evercord service was created in partnership with Bloodworks Northwest, or Bloodworks, which currently 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 nearly 1,000 cord blood units released for transplants. Under our service agreement with Bloodworks, Bloodworks will perform processing and infectious disease testing services on blood samples submitted by Evercord customers and will cryo-preserve the cord blood and tissue samples at its Seattle, Washington-based storage facility.

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 proven effective, which includes the possible therapeutic use of cord blood stem cells. More than 300 studies are currently underway, including clinical trials focused on current and new cord blood stem cell therapies in regenerative medicine. More than 30,000 cord blood stem cell treatments have been conducted worldwide. Based on the advances in research into stem cells and regenerative medicine, it is anticipated that number may continue to grow. We believe that Evercord will be well positioned to leverage our established commercial capabilities because we already engage with potential Evercord customers through our offering of Panorama and Horizon products. Also, we believe we can establish a relationship and level of familiarity and trust through our patient portal and healthcare provider digital services through Natera Connect, which puts us at a competitive advantage over other cord blood banking providers.

#### *New NIPT Panel*

We have announced our plans to launch a NIPT panel that identifies risk for severe cardiac, neurological and other conditions that have a combined incidence of approximately 1 in 600, which is higher than that of Down syndrome, and which are often associated with cognitive disabilities or require surgical intervention. These conditions may otherwise go undetected in prenatal ultrasound findings or may not present until much later in the pregnancy, after birth or even into childhood. Screening for these conditions early on 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 intend to initially launch this NIPT on a limited basis with MFM and key opinion leaders in the field, followed by a broader launch based on usage patterns and feedback from the initial launch.

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

Through our direct sales efforts and worldwide network of approximately 70 laboratory and distribution partners, we have established a broad distribution channel. Our own direct sales force and managed care teams, which include approximately 130 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 an increasing share of Panorama orders in the future will be attributed to 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, 2016, approximately 78% of customers who ordered the basic Panorama panel directly from us also ordered screening for 22q11.2 deletion syndrome or the full microdeletions panel.

As our direct sales force has gained experience selling under the Natera name, we have developed our own strong relationships, and we have been increasing the number of our in-network contracts with payers. 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 increased to approximately 78% in 2016, from approximately 77% in 2015 and approximately 59% in 2014. 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 8% 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, we do engage in brand awareness campaigns directed at patients to highlight our products. Our marketing and medical science liaison team works 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, 2017, seven 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. 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, 2016, we and our distribution partners had in-network contracts with insurance providers that accounted for over 203 million covered lives in the United States, of which approximately 188 million were under our direct in-network contracts. We continue 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 60 countries, we currently sell predominantly through partner laboratories.

### ***Enhanced User Experience***

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

We have implemented various digital services designed to enhance 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.

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 the Horizon screening or for a microdeletion syndrome based on the Panorama screening.

## *Phlebotomy Services*

We have engaged 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.

## ***Our Development Pipeline in Oncology Diagnostics***

We believe that our ability to interrogate genes 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 circulating tumor DNA, or ctDNA. In oncology applications such as recurrence monitoring, therapy monitoring and early detection screening, many loci must be interrogated simultaneously without splitting a sample, and achieving sensitivity to tiny amounts of tumor DNA as low as a single molecule is important. We are developing a set of mmPCR panels to analyze ctDNA in plasma and identify SNVs as well as CNVs. If development is successful, we expect to work towards commercializing non-invasive oncology diagnostic products designed to measure cancer recurrence and disease load monitoring, guide therapy selection and screen for cancer in high-risk populations. We are initially focused on recurrence monitoring in lung cancer and other cancers, and are exploring various candidates for recurrence monitoring as well as reflex testing, recurrence and disease load monitoring, and early detection screening in breast cancer. To guide prognosis, predict relapse and assist in therapeutic decision-making, we may in the future develop a panel which would include known recurrent alterations that, when identified in blood at low levels, may indicate a residual presence of cancer that can remain in the patient after treatment and during remission. The panel would be used to detect variants from the initial tumor's molecular signature in low levels of ctDNA in blood prior to the appearance of clinical symptoms in order to assist in guiding earlier decisions regarding clinical management. We are working with world-renowned oncology centers, such as Stanford University, Columbia University, Vanderbilt University, UCSF/I-SPY and Cancer Research UK, on research collaborations and clinical trials to explore applications in various other cancer types and stages of diagnostic intervention for which we believe our performance in the detection of CNVs, SNVs, and gene fusions will allow us to achieve a competitive advantage.

We have demonstrated that our mmPCR platform can provide highly accurate detection of CNVs and SNVs in the plasma from patients with cancer. In a study published in the October 2015 issue of *Translational Oncology*, we demonstrated the ability of our mmPCR platform to detect CNVs in plasma with DNA concentrations of under 1%, compared to other sequencing methods which require DNA concentrations of at least 4%, for samples with a single deletion or duplication event in a given loci. We believe that our ability to simultaneously detect both CNVs and SNVs in ctDNA at very low concentrations in standard plasma samples drives our potential opportunity in the oncology diagnostics space.

Our mmPCR 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. A pilot study using blood samples collected from the first 50 patients in the TRACERx trial was published in *Annals of Oncology* in January 2016, in which we demonstrated that our multiplexed PCR technology, coupled with our proprietary algorithms, can detect both ubiquitous (clonal) and heterogeneous (subclonal) tumor mutation variants in blood samples from patients with early-stage non-small-cell lung cancer. We were able to detect subclonal mutations at concentrations as low as 0.01% fraction of cell-free DNA. Of 37 variants found in tumor tissue biopsies from four patients with Stage I and II lung cancer, our technology detected 16 variants in the blood samples, with at least two detected for each patient. Twenty-five percent of the variants we detected in the blood samples were heterogeneous, meaning that they occurred in only part of a tumor. Ninety-four percent of the variants detected in the blood samples were predicted driver mutations, meaning that they were

likely to promote tumor growth. Analysis of cell-free DNA circulating in plasma may detect variants that, due to the heterogeneous nature of tumors, may not be detected by tissue biopsy. Detection of such variants may help physicians decide which cancer therapies are most appropriate for a specific patient. We have also received preliminary results from analysis of another 50 patients in the study, adding multiple longitudinal blood samples from patients who later relapsed. With these samples, we are exploring the application of our technology to detect recurrence 4 to 6 months earlier than standard biomarkers or imaging tools.

We also have been participating in 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. This trial was launched in 2010 and is 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 will analyze blood samples at various points throughout patient treatment to evaluate the effectiveness of liquid biopsy in monitoring tumor burden, treatment response, and residual disease, as compared to traditional imaging methods.

We anticipate that we will initially commercialize our cancer tests as LDTs in our own CLIA-certified laboratory; we also plan to offer these tests as IVDs through our Constellation platform. Beyond the products we develop ourselves, in order to access the many opportunities in oncology, we plan to offer our automated mmPCR design tool as a service to researchers and CLIA-certified laboratories, allowing them to design their own oncology diagnostics assays and perform their own studies using our Constellation cloud software.

### ***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 PPV with which they are reported. We have substantial intellectual property covering the analysis of single cells, an approach we use to analyze embryos during in vitro fertilization, or IVF, for our Spectrum products. 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, which could enable us to replace invasive confirmatory procedures, such as amniocentesis, over time.

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, from tiny amounts of DNA as small as single fetal cells, 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 near full genome, 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 have developed an automated tool for assay design that meaningfully streamlines our development process. When developing new diagnostic tests, we simply specify the genomic variations and regions we are interested in investigating, and our tool generates the precise mix of necessary primer designs to obtain an accurate measurement.

We may also provide custom services for research in targeted assay design and bioinformatics interpretation, in oncology as well as in other areas. Custom panels may be designed for regions of interest 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: cancer detection in liquid, e.g. bladder cancer, forensic identity analysis in mixtures for law enforcement, organ



transplant rejection monitoring, agricultural sample screening for patented lines, prenatal relationship testing for veterinary breeding and cell line purity testing for cell repositories.

## **Key Relationships**

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 clinical use, we may no longer be entitled to discounts from Illumina. Illumina may terminate the agreement: 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.

## **Competition**

We compete with numerous companies that have developed and market NIPTs, including Sequenom, Inc., or Sequenom, which was recently acquired by Laboratory Corporation of America Holdings, or LabCorp; Illumina, through its Verinata division, Ariosa, Inc., which was acquired by F. Hoffman La-Roche Ltd in 2014; Counsyl, Inc.; Quest Diagnostics Incorporated, or Quest; Premaitha Health PLC; Beijing Genomics Institute; Berry Genomics Co., Ltd.; Progenity, Inc., or Progenity; LifeCodexx AG; Synlab International GmbH; and Multiplicom N.V., which was recently acquired by Agilent Technologies Inc. In addition, Bio-Reference, a business unit of OPKO Health, Inc., which was previously a laboratory distribution partner, is commercializing a competing NIPT. We expect additional competition as other established and emerging companies enter the prenatal testing market, including through business combinations, and new tests and technologies are introduced. These competitors could have greater technological, financial, reputational and market access resources than us.

We also compete against companies providing carrier screening tests such as LabCorp; Counsyl, Inc.; Good Start Genetics, Inc.; Progenity; Recombine Inc.; Quest; NxGen MDx LLC; and GenPath Diagnostics, which is also a business unit of OPKO Health, Inc. Each of these companies offers comprehensive CS panels.

In cord blood and tissue banking, we will compete with companies such as Cord Blood Registry, which was acquired by AMAG Pharmaceuticals, Inc. in 2015; ViaCord, a division of PerkinElmer, Inc.; Cryo-Cell International, Inc.; CorCell Companies, Inc.; and LifeBankUSA.

Our future products, such as products in the field of cancer, will face competition from various companies that offer or seek to offer competing solutions, such as Roche Molecular Systems Inc. and GRAIL, a spinoff of Illumina. In addition, Guardant Health, Inc., Personal Genome Diagnostics, Inc., Foundation Medicine, Inc. and Genomic Health Inc. have each developed and are offering liquid biopsy tests commercially in the United States, and Genomic Health Inc. has announced plans to commercialize Epic Sciences' liquid biopsy test in the United States.

We believe the principal competitive factors in our market include the following:

- test performance, as demonstrated in clinical trials;
- comprehensiveness of coverage of diseases and ability to conveniently test for multiple conditions;
- value of product offerings, including pricing and impact on other healthcare spending;
- scope of reimbursement and payer coverage;
- effectiveness of sales and marketing efforts;
- breadth of distribution of products and partnership base;
- 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 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.

## **Research and Development**

We were founded on the belief that serious unmet needs in healthcare could be addressed by combining traditional molecular diagnostics with robust statistical techniques, and this belief is the basis of our research and development efforts. We focus our research and development efforts on conceiving and delivering disruptive technologies to genetic testing. We have invested, and continue to invest, significant time and resources toward improving and expanding our core technologies and tests. Our proprietary automated tool for assay design meaningfully streamlines our development process. Research and development expenses were \$41.9 million, \$27.7 million and \$17.3 million for 2016, 2015 and 2014, respectively.

## **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, 2016, we held 18 issued U.S. and foreign patents 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 were recently engaged 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 non-invasive prenatal genetic 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. The tests for which we receive reimbursement include Panorama, Horizon, Anora and Spectrum.

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 and 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. On January 1, 2013, CMS implemented a new set of CPT codes but without a fee schedule for the particular codes specific to NIPTs. A CPT code specific to NIPT for aneuploidies came into effect in January 2015. Additionally, CMS adopted a code set for diagnosis, commonly known as ICD-10, in October 2015. The AMA recently issued a CPT code for microdeletions, and CMS provided a pricing benchmark of \$802 for aneuploidy and microdeletions testing, effective January 2017.

We currently submit for reimbursement using CPT codes that, based on the guidance of outside legal and coding experts, are determined to be the most appropriate for our testing. 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, 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.

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 recently issued updated guidelines that, among others, support NIPT as the optimal initial screening test for all pregnant women, regardless of age or other risk factors. ISPD has issued guidelines that are supportive of NIPT in average-risk pregnancies as well as high-risk pregnancies. ACOG and SMFM have each issued guidelines 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. Private payers are moving towards reimbursing for average-risk NIPT. Thirty-six commercial payers in the United States, representing over half of all commercial covered lives in the United States, have a positive coverage determination for NIPT for average-risk pregnancies.

Based on AIS 2015 publication data, as of December 31, 2016 we and our laboratory partners had in-network contracts with insurance providers that accounted for over 203 million covered lives in the United States, of which approximately 188 million were under our direct in-network contracts. 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 the 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.

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 sell products who have adopted regulations beyond CLIA. For more information on state licensing requirements, see "—California Laboratory Licensing" and "—New York Laboratory Licensing."

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, either clearance of a premarket notification, or 510(k), or premarket approval, or a PMA.

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 510(k) and PMA 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 to exercise enforcement discretion and not regulate them.

*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, 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 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. The FDA will identify "special controls" that the manufacturer must implement, which often includes labeling and other restrictions. Subsequent applicants can rely upon the de novo product as a predicate for a 510(k) clearance. The de novo route is less burdensome than the PMA process. 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 or approval 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 have been 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.

We believe that all of the tests we currently offer, including Panorama, meet the definition of LDTs, as we designed, developed, and validated them for use in our 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. The California licensure law establishes standards for the day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control

If a clinical laboratory is found to be out of compliance with California standards, the California Department of Health Services, or DHS, may suspend, restrict or revoke its license to operate the clinical laboratory, assess substantial civil money penalties, or impose specific corrective action plans.

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

Because we receive specimens from New York State, our clinical laboratory is required to be licensed under New York laws and regulations, which establish standards for the day-to-day operation of a clinical laboratory, including training and skill levels required of laboratory personnel; physical requirements of a facility; equipment; validation; and quality control.

If a laboratory is found to be out of compliance with New York statutory or regulatory standards, the New York State Department of Health, or DOH, may suspend, limit, revoke or annul the laboratory's New York license, censure the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory's operator being found guilty of a misdemeanor under New York law. Our clinical laboratory is licensed in the State of New York.

DOH also must approve each specific LDT before the test is offered in New York. We have received a permit from New York 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. We also have a permit from New York to offer our Horizon, Spectrum, Anora and non-invasive prenatal paternity tests.

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

In addition to New York and California, other states, including Florida, Maryland, Pennsylvania and Rhode Island, require licensing of out-of-state laboratories under certain circumstances. We have obtained licenses in these four 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 and the suspension or loss of various licenses, certificates and authorizations, 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.

### ***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. 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. 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 statutes 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 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, California law is applicable to our business arrangements. Both California's fee-splitting statute, Business and Professions Code Section 650, and its Medi-Cal anti-kickback statute, Welfare and Institutions Code Section 14107.2, 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 imprisonment and fines of up to \$50,000. A violation of Section 14107.2 is punishable by imprisonment and fines of up to \$10,000.

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. 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.

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 provision 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 anti-"self-referral" and other laws that are not limited to Medicare and Medicaid referrals, with which we must comply. We are subject to the California's Physician Ownership and Referral Act, or PORA. PORA generally prohibits us from billing a patient or any governmental or private payer for any diagnostic services when the physician ordering the service, or any member of such physician's immediate family, has an investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition. Further, a violation of PORA is a misdemeanor and could result in civil penalties and criminal fines.

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. A violation of this provision can lead to imprisonment and/or fines. Other states have similar anti-markup prohibitions with which we must comply. In addition, many states are so-called "direct-bill" states, 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 at a higher price.

While we have attempted to comply with the federal fraud and abuse laws, California fraud and abuse laws and similar laws of other states, 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 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, 2016, we had 852 employees, including 123 in laboratory operations and manufacturing administration, 188 in research and development and 541 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.

AMA – American Medical Association.

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.

CS test – carrier screening test.

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.

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.

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.

SMA – spinal muscular atrophy.

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.

## Financial Information about Segments and Geographic Areas

We operate in one segment. For information regarding our revenues by geographic location, please refer to Note 15 to our consolidated financial statements in this annual report on Form 10-K. All of our long-lived assets are located in the United States. For information regarding risks associated with our international operations, please refer to the section entitled “Risk Factors”.

## 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 condensed consolidated financial statements and related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. 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 year ended December 31, 2016, 2015 and 2014, 66%, 73% and 73%, respectively, of our revenues were derived from sales of our NIPT, Panorama. Although we derive some revenues from our other products, we expect to continue to derive a significant portion of our revenues from the sales of Panorama, at least in the near term. Continued and additional market acceptance of Panorama, reimbursement for the average risk population and for microdeletions, and our ability to attract new customers 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 to grow, physicians may not recommend and order Panorama, and our laboratory 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;
- 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, if we are unable to demonstrate to these constituencies that Panorama is superior to competing NIPTs;
- 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, [most third-party payers currently have negative coverage determinations for average-risk patient populations, some third-party payers do not reimburse for microdeletions screening and we expect reimbursement for microdeletions screening to continue to decrease in the near term, and most state Medicaid programs currently either reimburse at low rates or do not reimburse for our tests;
- 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 becomes available;
- we, our laboratory partners or licensees may not be able to maintain and grow effective sales and marketing capabilities, and our sales and marketing efforts may fail to effectively reach customers or effectively communicate the benefits of Panorama;
- 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;
- we may experience supply constraints, including due to the failure of our key suppliers to provide required sequencers and reagents or disputes with our key suppliers, including with respect to the required sequencers and reagents from our supplier, Illumina, Inc., which is also one of our main competitors through its Verinata division;
- we may not be successful in our efforts to reduce our cost of product, licensing and other revenues, and as a result we may experience increased cost of product, licensing and other revenues as a percentage of total revenues, as has been the case in each of the years ended December 31, 2016 and 2015 compared to the respective prior periods;
- 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;
- competitors in the NIPT market may convince laboratories, clinics, clinicians, physicians, payers or patients that their offerings are superior from a performance, reliability or pricing perspective; and a more effective and/or less expensive test that delivers comparable results for risk assessment of chromosome conditions in fetuses may be developed and commercialized
- we may fail to adequately protect our intellectual property relating to Panorama or others may claim we infringe their intellectual property rights; 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; 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, and our initial public offering. Our net loss for the years ended December 31, 2016, 2015 and 2014 was \$95.8 million, \$70.3 million and \$5.2 million, respectively. As of December 31, 2016, we had an accumulated deficit of \$345.9 million. We expect that such losses will 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 future diagnostic solutions, including in the field of cancer.

In addition, the rate of growth in our revenues has generally been low or flat in recent quarters, and this trend may continue in future periods. In particular, a significant element of our business strategy has been, and will continue to be, to increase our 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, such as Panorama for the average-risk pregnancy population or for microdeletions screening. Therefore, going in-network with third-party payers can have an adverse impact on our revenues if we are unable to increase adoption of, and favorable coverage determinations for reimbursement for, our products. Furthermore, a new CPT code for microdeletions went into effect beginning January 1, 2017. We expect that this new code will cause, at least in the near term, our microdeletions reimbursement to decline, either due to reduced reimbursement, or third-party payers declining to reimburse, under the new code, which would have an adverse effect on our revenues.

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, including future cancer products, 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, with an increasing effort to expand our platform and apply our expertise in processing and analyzing cell free DNA to the field of cancer. The development of enhanced or new tests is complex, costly and uncertain. 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, our success depends on tumors shedding mutant DNA into the bloodstream in sufficient quantities such that our technology can detect such mutations. Furthermore, enhancing or developing new tests requires us to accurately anticipate patients', clinicians' and payers' attitudes and needs and emerging technology trends. We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new tests. The research and development process in molecular diagnostics generally takes a significant amount of time from the research and design stage to commercialization. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals. For example, any tests that we may enhance or develop may not prove to be clinically effective in clinical trials

or otherwise, or we may otherwise have to abandon a test in which we have invested substantial resources. We have recently implemented updates to Panorama to reduce the costs of running the test and increase efficiency; however, we may experience unforeseen difficulties with the updated processes, which may result in increased costs and the diversion of management's attention and resources from other business matters.

The launch of any new diagnostic tests, including those in the field of cancer diagnostics, requires the completion of certain clinical development and commercialization activities and the expenditure of additional cash resources. 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 to complete clinical development for any planned diagnostic test, or we may be unable to afford or manage the large-sized clinical trials that some of our planned future products may require. We cannot assure you that we can successfully complete the clinical development of any other diagnostic test, or that we can establish or maintain the collaborative relationships that may be essential to our clinical development and commercialization efforts. Such failures could prevent or significantly delay our ability to research, develop, complete clinical development and validation, obtain FDA clearance or approval as may be necessary or desired, or launch any of our planned diagnostic tests, including those in the field of cancer diagnostics. Any failure to complete on-going clinical studies for our planned diagnostic tests could have a material adverse effect on our business, operating results or financial condition.

We cannot be certain that:

- we will be able to develop and validate any test that meets our desired target product profile and with the sensitivity and specificity necessary to address the relevant clinical need or commercial opportunity;
- we will be able to obtain necessary regulatory authorizations in a timely manner or at all;
- we will be able to develop the sales and marketing operations or enter into collaborative arrangements to achieve market awareness and demand;
- we and our laboratory partners and licensees will successfully market, or healthcare providers will order or use, or third-party payers will reimburse (and if so, to what extent), any tests that we may enhance or develop;
- any tests that we may enhance or develop, or services that we may offer, can be provided at acceptable cost and with appropriate quality;
- our current or future competitors will not introduce tests or services that have superior performance, lower prices or other characteristics that cause physicians to recommend, or consumers to choose, such competitive tests or services over ours; or
- our tests will not infringe patents held by third parties in key jurisdictions.

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

We recently announced plans to launch a new prenatal screening test, as well as our plan to launch our Evercord cord blood and cord tissue banking service in the second quarter of 2017. We cannot be certain that we will be successful in commercializing new product offerings, as further described in the risk factor entitled “*If we are unable to successfully grow revenues for products or services in addition to Panorama, our business and results of operations may be adversely affected.*”

***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 financial 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 financial results include, without limitation, those listed elsewhere in this "Risk Factors" section. In addition, our quarterly results may fluctuate due to the fact that we recognize costs as they are incurred, but there is typically a delay in the related revenue recognition as we record most revenue only upon receipt of payment. Accordingly, to the extent sales increase, we may experience increased losses unless and until the related revenues are recognized. In addition, as we continue to ramp up 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. As we continue to increase utilization of our cloud-based distribution model by additional laboratory licensees, we may experience decreased revenues or slower revenue growth as the cost per test will be lower than for our laboratory-based model. 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 may also face competitive pricing or 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 are in the molecular testing field, which is characterized by rapid technological changes, frequent new product introductions, changing customer preferences, emerging competition, evolving industry standards, intellectual property disputes, price competition, and aggressive marketing practices. Our principal competition comes from existing testing methods, technologies and products, including other NIPTs and carrier screening tests offered by our competitors, that are used by obstetricians and gynecologists, or OB/GYNs, maternal fetal medicine, or MFM, specialists or in vitro fertilization, or IVF, centers. 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, have been used for many years and are therefore difficult to displace or supplement. Moreover, many companies in our markets are offering, or may offer, products and services that compete with our tests, in some cases at a lower cost than ours. We cannot assure you that research and discoveries by other companies will not render our existing or potential tests uneconomical or result in tests superior to our existing tests and those we develop. We also cannot assure you that any of our existing tests or tests that we develop will be preferred by patients, physicians or payers to any existing or newly developed technologies or tests.

We compete with numerous companies in the genetic diagnostics space. Our competitors in NIPT include Sequenom, which was recently acquired by LabCorp; Illumina, through its Verinata division; Ariosa, Inc., which was acquired by F. Hoffman La-Roche Ltd in 2014; Counsyl, Inc.; Quest; Premaitha Health PLC; Beijing Genomics Institute; Berry Genomics Co., Ltd.; Progenity; LifeCodexx AG; Synlab International GmbH; and Multiplicom N.V., which was recently acquired by Agilent Technologies Inc. In addition, Bio-Reference, a business unit of OPKO Health, Inc., which was previously a laboratory distribution partner, is commercializing a competing NIPT. 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 competitors in carrier screening include LabCorp; Counsyl, Inc.; Good Start Genetics, Inc.; Progenity; Quest; Recombine Inc.; NxGen MDx LLC; and GenPath Diagnostics, which is also a business unit of OPKO Health, Inc. In cord blood and tissue banking, we will compete with companies such as Cord Blood Registry, which was acquired by AMAG Pharmaceuticals, Inc. in 2015; ViaCord, a division of PerkinElmer, Inc.; Cryo-Cell International, Inc.; CorCell Companies, Inc.; and LifeBankUSA. In addition, our future products, such as products in the field of cancer, will face competition from various companies that offer or seek to offer competing solutions, such as Roche Molecular Systems Inc. and GRAIL, a spinoff of Illumina. In addition, Guardant Health, Inc., Personal Genome Diagnostics, Inc., Foundation Medicine, Inc. and Genomic Health Inc. have already developed and are offering commercially in the United States so-called liquid biopsy tests, which are clinical cancer diagnostic tests that examine blood samples, rather than solid tumor biopsies, and which are the type of cancer diagnostic tests that we are seeking to develop; Genomic Health Inc. has also announced plans to commercialize Epic Sciences' liquid biopsy test in the United States. Many other companies, including much larger companies than ours, have announced that they are developing and seeking to commercialize liquid biopsy tests. Our planned cancer products are in very early stages of research and development, and we expect that the number of competitors in this space 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. Tests and services being offered or developed by these and other companies 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.

***Our cloud-based distribution model may be difficult to implement.***

We have only recently begun to deploy our bioinformatics technology for use by other laboratories by making it available through a cloud-based distribution model. This model relies on clinical laboratories in the United States and around the world taking a license from us under which the laboratory develops and runs its own NIPT based on Panorama or other molecular testing assays based on our technology in its own facilities and then accesses our proprietary algorithms through our cloud-based Constellation software for the analysis of 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 is uncertain how quickly and to what extent our cloud-based distribution model will achieve and sustain high levels of customer demand and market acceptance.

Deploying this new cloud-based distribution model involves risks, significant costs and potential liabilities and is dependent upon the skills, experience and efforts of our management and other employees and our relationship with, and efforts of, our licensees. We do not know whether we can build or support this model to scale. Among the risks to our business and results of operations are the following:

- our ability to execute the strategy in a timely or efficient manner or at all;
- our and our licensees' ability to obtain required regulatory authorizations from the FDA and international regulatory agencies;
- supply constraints, including with respect to the sequencers and reagents that are required by our licensees to implement our technology and that are supplied by Illumina, Inc., one of our main competitors through its Verinata division, and the blood collection tubes that are used for our Panorama test and that are supplied by Streck, Inc., as further described in the risk factors 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*” and “*Reimbursement and Regulatory Risks Related to Our Business—Failure to obtain necessary regulatory approvals in foreign jurisdictions may adversely affect our ability to expand our operations internationally*”;
- 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;
- disruption of our business and distraction of our employees and management;
- 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.

We do not know whether clinical laboratories will adopt this method of using our products and services in sufficient volume. As of March 1, 2017, we have active agreements with only 21 licensees under our cloud-based distribution model, and we have only been recognizing revenue under our cloud-based distribution model for NIPT for four full quarters. Only five of our licensees are using Constellation commercially to market NIPT products, and one licensee is currently using Constellation commercially to market its non-invasive prenatal paternity test in the United States and internationally. Other licensees for our cloud-based model are in earlier stages of development and implementation. The rate of adoption of our cloud-based distribution model has been 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 addition, our cloud-based software will need to be compatible with whatever next-generation sequencing, or NGS, hardware a clinical laboratory is using. Because we do not control the manufacturing and specifications of the NGS equipment, some clinical laboratories may not be able to use Constellation. 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 Verinata Health Inc., or Verinata, and may not charge a similar license fee for Verinata’s cloud-based software offering in the European Union. 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.

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, decreases in corporate spending or other challenges, we may not be able to execute our planned business model, and our results of operations may be adversely affected.

We cannot assure you that we will be able to successfully implement the cloud-based distribution model or that implementation will result in benefits or cost savings at the levels that we anticipate or at all.

***We may be unable to commercialize our cloud-based distribution model if we do not comply with ongoing FDA regulatory requirements, including if we are required to obtain FDA clearance or approval to market our software for diagnostic purposes.***

We utilize our Constellation software to aid in the calculation of test data. Laboratories utilizing our technology will have access to this software in our cloud-based distribution model. We have received a CE Mark from the European Commission for our Constellation software as well as for the key reagents that our laboratory licensees need to run their portion of the Panorama test prior to accessing our algorithms through Constellation, which enables us to offer Constellation for Panorama NIPT in the European Union and other countries that accept a CE Mark. It is possible that we will need to obtain regulatory clearance or approval in the United States and elsewhere for our Constellation software in order for it to be used by third parties in the conduct of their diagnostic tests based on our technology. We are currently 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 could be used to support our cloud-based distribution model for NIPT in the United States. The FDA has indicated to us that the CNC 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. The FDA has stated that it will not prevent us from marketing Constellation in the United States while we continue to discuss with the FDA how it will be regulated; however, it is possible that the FDA may reverse itself on the issue of our ability to continue to market Constellation during our discussions. If necessary, we intend to seek regulatory clearance or approval for our Constellation software; however, we cannot guarantee that we will obtain such clearance or approval. If clearance or approval is required 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 or approval, 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, 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 using 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, and we would not receive the anticipated revenues from that licensee.

***Implementation of our cloud-based distribution model may negatively impact our financial results and results of operations.***

Under our cloud-based distribution model, third-party laboratories perform the molecular biology analysis in their own laboratories and access our bioinformatics algorithms in the cloud through our Constellation software to analyze their results. Although we receive license fees for use of our bioinformatics technology, because we do not process these tests and perform the molecular biology analysis in our laboratory, we are not able to charge as high an amount per test as when we perform the entire test ourselves, and our revenues per test are therefore lower than the amount we receive when we perform the entire test ourselves. If the lower revenues per test performed under our cloud-based distribution model is not offset by a sufficient increase in volume of tests sold or by the reduction in costs from not performing the entire test, our overall revenues will be lower, and our results of operations may be adversely affected. Additionally, to the extent that any of our laboratory customers for whom we perform our tests entirely in our laboratory transition to our cloud-based distribution model, our revenues from such customers will decrease, which may adversely affect our results of operations.

***We may be subject to increased compliance risks as a result of our rapid growth, including our recent growth in and dependence on our direct sales force.***

The percentage of our revenues attributable to our U.S. direct sales for the years ended December 31, 2016, 2015 and 2014 was 78%, 77% and 59%, respectively. Prior to 2016, we experienced rapid growth in our U.S.-based internal sales force, and in our billing and marketing personnel, which has required us to expand our training and compliance efforts in line with the increase in new personnel in these functions. We have taken and continue to take steps to implement appropriate monitoring of our sales, billing, marketing and other personnel; however, we have in the past experienced, and may in the future experience, situations in which employees fail to strictly adhere to our policies. To the extent that there is any failure, whether actual or perceived, by our employees to follow our policies, we may incur additional training and compliance costs, or 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 the operations of our laboratory or the delivery of our cloud-based software and harm our business.***

We currently maintain a data center at our laboratory facilities in San Carlos, California. We also currently provide and will continue to provide our cloud-based Constellation software to our laboratory licensees through third-party data center hosting facilities operated by Amazon Web Services, or AWS, located in the United States. Any technical problems that may arise in connection with our on-site data center or with the AWS facilities could result in interruptions in our laboratory operations or our cloud-based services. 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. For example, AWS recently experienced an outage at one of its main storage systems in the United States, which resulted in a large portion of the system being offline and inaccessible for several hours. While our software and platforms were not materially affected by this outage, future outages that are more severe or other issues with AWS's facilities could materially impact our operations.

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 also hosted on AWS servers. These algorithms cannot currently be run other than through the DNAnexus platform, and are currently used to run our Panorama NIPT. In the event of any failure in 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 and our Constellation licensees may lose or be unable to access our proprietary algorithms and therefore be unable to process any Panorama tests. 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. 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 genetic testing results. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our test volume increases and the types of tests we offer expands. We believe that our customers are likely to be particularly sensitive to test limitations and errors, including inaccurate test results and the need on occasion to perform second blood draws on patients. As a result, if our tests do not perform as expected, our operating results, reputation, and business will suffer. We may be subject to legal claims arising from such limitations, errors, or inaccuracies.

Panorama 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 and specificity rates that are lower than we anticipate or that vary between test runs, or in a higher than anticipated number of tests which fail to produce results, or in longer than expected turnaround times, which we sometimes experience as a result of laboratory equipment issues or otherwise. In addition, we regularly evaluate and refine our testing process. These refinements may result in unanticipated issues that may reduce our sensitivity and specificity rates.

***We rely on third-party laboratories to perform some of our testing.***

We and our subsidiaries outsource the portions of testing that we do not perform in-house to third-party CLIA laboratories. For example, a significant portion of our Horizon carrier screening testing is, and we anticipate that our new NIPT panel testing will be, performed by third-party laboratories. These third-party laboratories are subject to contractual obligations to perform this testing 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 issues with delivering results to us within the time frames we expected or established in our contracts with them. In the event of any adverse developments with these third-party laboratories or their ability to perform this testing in a timely manner and in accordance with the standards that we and our customers expect, our ability to provide test results to customers may be delayed or interrupted, which could result in a loss of customers and harm to our reputation. Although we have more than one third-party laboratory performing this testing in order to avoid single sourcing, we may not have sufficient alternative backup if one or more of the third-party laboratories are unable to satisfy our demand for this testing with sufficient performance, quality and timeliness. Any natural or other disaster, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at one or more of our third-party laboratories' facilities that causes a loss of testing 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 testing could impair, delay or suspend our efforts to market and sell these tests. 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 contract 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 would suffer.

***If we are unable to successfully grow revenues for 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, and Anora, is uncertain and is subject to risks. 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; we and our laboratory partners may not be able to maintain and grow effective sales and marketing capabilities; our laboratory 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 have not yet commercially launched Evercord, a private cord blood and tissue banking service. Our success with this service offering will be subject to many of the risks affecting our business generally, as well as the inherent difficulty associated with launching a new offering, and in an industry that is new to us and that includes competitors who have been operating for close to 20 years. We may face unforeseen difficulties in a number of areas, including with Bloodworks Northwest, 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 Northwest's ability to maintain required regulatory registrations from the FDA; or disruption of our business and distraction of our employees and management. We cannot assure you that we will be successful in launching this new service or that this new service will be successful once launched.

***If the results of our clinical studies do not support the use of our tests, particularly in the average-risk pregnancy population or for microdeletions screening, or cannot be replicated in later studies required for regulatory approvals or clearances, our business, financial condition, results of operations and reputation could be adversely affected.***

As the healthcare reimbursement system in the United States evolves to place greater emphasis on comparative effectiveness and outcomes data, we cannot predict whether we will have sufficient data, or whether the data we have will be presented to the satisfaction of any payers seeking such data in the process of determining coverage for our tests, particularly in the average-risk pregnancy population and for microdeletions screening using our Panorama test, for both of which such data is expected to be of particular interest. 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, this data is new and is still being analyzed, and we cannot be certain whether or to what extent it will impact coverage or adoption of in the average-risk population. We are also enrolling patients for our SMART study to evaluate the performance of SNP-based NIPT for 22q11.2 deletion syndrome, but enrollment has proceeded at a slower pace than anticipated.

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.

The administration of clinical and economic utility studies, which are becoming more critical to commercial success of products like ours, is expensive and demands significant attention from certain members of our management team. Even if we are able to conduct such studies, the data collected from these studies may not be favorable or consistent with our existing data, or may not be statistically significant or compelling to the medical community.



In addition, 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. Limited results from earlier-stage verification studies may not predict results from studies in larger numbers of subjects drawn from more diverse populations over a longer period 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.

***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 and the testing for our new NIPT panel. Our San Carlos, California laboratory facility is situated near active earthquake fault lines. Our facilities 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, and our blood collection tubes are sole sourced. For example, Illumina is currently the sole supplier of our sequencers and related reagents for Panorama, as well as for our development activities relating to transplant and 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 are also required to use Illumina sequencers and reagents to run the tests that they develop based on our technology. Furthermore, 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 to pay an additional license fee in jurisdictions in which Illumina believes certain of the pooled intellectual property is enforceable in order to secure a supply agreement for the sequencers and reagents necessary to run NIPT under our cloud-based distribution model. 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, while our supply agreement with Illumina does not allow Illumina to charge us an additional fee, Illumina could attempt to require us to pay such a fee by, for example, bringing a patent infringement lawsuit against us. 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 a lawsuit based on this intellectual property, and the costs and distraction to management of defending against such a lawsuit would likely be significant. In addition, in early 2013, prior to our entering into our agreement with Illumina, Illumina completed its acquisition of Verinata Health Inc., or Verinata, our direct competitor in the NIPT market. We understand Illumina supplies the same or similar sequencers and consumables to Verinata, which is now a division of Illumina. Because of Illumina's acquisition of Verinata, we face increased risk and uncertainty regarding continuity of a successful working relationship with Illumina under the current supply agreement, including with respect to our ability to compete with Verinata in the marketplace based on test price and in view of economic advantages enjoyed by Verinata associated with 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 the event that it is in our



commercial or financial interest or we are forced to transition sequencing platforms, we may not be successful in selecting, acquiring on commercially reasonable terms, and implementing an alternative platform that is satisfactory for our needs or that we can employ in a commercially sustainable way.

In addition, Streck, Inc., or Streck, is the sole supplier of the blood collection tubes included in our Panorama test. All of the licensees under our cloud-based distribution model are also required to use these blood collection tubes to run the tests that they develop based on our technology. 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 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 would 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 are also required to use such sole-sourced components to run the tests they develop based on our technology, and our laboratory distribution partners are required to 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.

Our failure to maintain a continued supply of components, or a supply that meets quality control requirements, particularly in the case of sole suppliers such as Streck and Illumina, would materially and adversely harm our business, financial condition, and results of operations. Changes to or termination of our agreements or inability to renew our agreements with these parties or enter into new agreements with other suppliers could result in the loss of access to important components of our tests and could impair, delay or suspend our commercialization efforts, including efforts to market and commercialize Panorama. In the event of any adverse developments with our sole suppliers, our ability to supply our products may be interrupted, and obtaining substitute components could be difficult or require us to re-design our products or, for any products for which we may obtain approval from the FDA, obtain approval from the FDA to use a new supplier. In addition, if we obtain a premarket approval, or PMA, for Panorama, such issues with suppliers or the components that we source from suppliers could affect our commercialization efforts, 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.”* Transitioning to a new supplier from any of our sole suppliers could be time consuming and expensive, may result in interruptions in our ability to supply our products to the market, could affect the performance specifications 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.

Because we rely on third-party manufacturers, we do not control the manufacture of these components, including whether such components will meet quality control requirements. If the supply of components we receive do not meet quality control standards, we may not be able to use the components, or if we use them not knowing that they are of inadequate quality, which has in the past occurred with respect to certain reagents, our tests may not work properly or at all. Because we cannot ensure the actual production or manufacture of such critical equipment and materials, or the quality of such components, or the ability of our suppliers to comply with applicable legal and regulatory requirements, 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 causes a loss of manufacturing capacity would heighten the risks that we face.

***If our laboratory partners do not effectively market or sell, or decide to stop selling, our products, or our relationships with our laboratory partners are otherwise terminated, and we are not able to offset the resulting impact to our gross profit 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 partners to sell Panorama and our other products, both in the United States and internationally. 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. 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.

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 and may choose to promote such tests in addition to or in lieu of our tests. For example, we terminated our licensing and distribution agreement with Bio-Reference in January 2017, and Bio-Reference is currently 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.

***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 will rely on courier services to transport cord blood and tissue samples to Bloodworks' facility in which the samples will be processed and stored. Disruptions in delivery service, whether due to 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 health information, such as Panorama results, 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. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and

infrastructure, and that of our third-party billing and collections provider and other technology partners, may be vulnerable to cyber-attacks by hackers or viruses or breached 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, 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. 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, educate patients and clinicians about our service, 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. We have contractually obligated our partners to not send personally-identifiable information to our cloud servers, and we have an agreement with the vendor that hosts our software in the cloud to comply with data privacy laws, such as HIPAA. However, we cannot be certain that our partners will comply with these requirements or that our cloud vendor will comply with the terms of our agreement.

In addition, the interpretation and application of health-related, privacy and data protection laws in the United States, Europe, and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business and our reputation. Complying with these laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

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

Our Evercord cord blood and tissue banking service, which we plan to launch in the second quarter of 2017, will be subject to FDA regulatory oversight. Pursuant to FDA regulations, an individual or entity that performs any of the manufacturing steps in banking stem cells from peripheral and cord blood (recovery, processing, donor screening, donor testing, storage, labeling, packaging, or distribution) must register with the FDA unless an exception applies. Based on our direct activities, we would be subject to FDA requirements and we may be subject to FDA inspection. We are in the process of registering 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 HCPs. As a registered establishment, we may contract with another FDA registered establishment to perform any other manufacturing steps in the process on our behalf, but as the contractor establishment, we will remain responsible for ensuring that our subcontractors perform each manufacturing step in compliance with applicable requirements. We 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, and to have policies and procedures in place to ensure that the subcontractor remains compliant throughout the term of the arrangement. 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.

Pursuant to our agreement with Bloodworks, Bloodworks has made representations and warranties that it is registered with the FDA as an establishment engaged in donor evaluation, processing samples, and storage of the cord blood and tissue samples.

We are also required to comply with good tissue practice regulations, or GTPs, that establish a comprehensive regulatory program for human cellular and tissue-based products. We believe that we currently comply with GTP standards. 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 certain states, manufacturing steps in banking stem cells from cord blood and tissue is subject to state licensure or registration and compliance with state requirements. Based on our review of applicable state laws by outside counsel, we, and our subcontractors engaged in specific manufacturing steps, may be required to obtain licensure or register in the states that regulate private cord blood and/or tissue banking activities, which include California, Delaware, Illinois, Maryland, New Jersey, New York, Oregon and Washington.

***If the facility at which our customers' cord blood samples are processed and stored is damaged or destroyed, our cord blood business and prospects could be negatively affected.***

The cord blood and tissue samples that we collect will be processed and stored by Bloodworks at its facility in Seattle, Washington. If this facility or the equipment in the facility were to be significantly damaged or destroyed, we could suffer a loss of some or all of the stored cord blood and tissue units. If we encounter problems during transportation, including while our customers' samples are in the possession of third party commercial carriers used to transport the samples, some or all of the transported units could be damaged. Depending on the extent of these losses, such an event could impact our ability to process and store the cord blood and tissue samples, expose us to significant liability from our customers and affect our ability to continue to provide cord blood preservation services.

***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, 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 failure to provide such information, 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. If the resulting baby is born with the condition, the family may file a lawsuit against us claiming product or professional liability. We are currently involved in a lawsuit by a patient alleging that we failed to perform a test that was ordered. See Item 3—Legal Proceedings. 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.

***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 will be extremely important to the commercial success of our Evercord service offering. This is due in significant part to the nature of the service we will 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 premium cord blood preservation service among our competitors. However, we cannot guarantee that we will not experience unforeseen issues, such as the risk of loss or damage to a sample during transit, during the preservation process or while in storage. Any such problems, particularly if publicized in the media or

otherwise, could negatively impact our reputation, which could adversely affect our business and business prospects, including beyond Evercord to our core genetic testing business.

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 or damage to the units would be loss 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 by an owner or donor as a result of harm 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, which 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.

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

As our test volumes and product offerings grow, we will need to continue to ramp up our testing capacity, implement increases in scale and related processing, office space, customer service, billing and systems process improvements and expand our internal quality assurance program and technology platform. We will also need additional equipment, laboratory space and certified laboratory personnel to process higher volumes of our tests. As additional tests are developed, we may need to bring new equipment on-line, implement new systems, technology, controls and procedures, and hire personnel with different qualifications. The value of Panorama and our other products depends, in part, on our ability to perform the tests on a timely basis and at an exceptionally high standard of quality, and on our reputation for such timeliness and quality. Failure to implement necessary procedures, transition to new 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. For example, we recently experienced a delay in our claims submissions and processing as a result of transitioning most of our insurance billing operations from our headquarters to our facility in Austin, Texas, which resulted in our delayed receipt of approximately \$1.5 million of insurance payments and impacted our revenue for that quarter. 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 testing operations.

In particular, 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 and technical personnel and especially in the San Francisco Bay Area where our headquarters and laboratory facility is located, and the turnover rate 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 experienced 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, resulting in a diversion of our time and resources. 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. If the perceived value of our equity awards declines, it may adversely affect our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects could be adversely affected.

In addition, our growth may place a significant strain on our management, operating and financial systems and our sales, marketing and administrative resources. As a result of our growth, our operating costs may escalate even faster than planned, 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.



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

As we expand our international operations and offer our tests in other countries, we will be 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 these 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 could result in a material adverse effect on our business, prospects, financial condition, or results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures.

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 prohibitions on the import into the United States of tissue necessary for us to perform our tests or restrictions on the export of tissue or genetic data imposed by countries outside of the United States, or restrictions on importation and circulation of blood collection tubes or other equipment or supplies by countries outside the United States, may limit our ability to offer our tests internationally in the future. We may also face competition from companies located in the countries in which we or our partners 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 the United States we enlist local and regional laboratories, contract employees and other service providers to assist with blood draw, engineering, sales, marketing 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 will be necessary to effectively market and sell our tests outside 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 that are locally acceptable may not comply with relevant standards required under United States laws that apply to us, which could create additional compliance risk. Our training and compliance program and our other internal control



policies and procedures may not always protect us from acts committed by our employees, contractors or agents. Non-compliance by us or our employees, contractors or agents of these or any other 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. If our sales and marketing efforts are not successful outside the United States, we may not achieve market acceptance for our tests outside 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 Chief Executive Officer 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 Chief Executive Officer, Matthew Rabinowitz, is critical to our vision, strategic direction, culture, products and technology. Although Dr. Rabinowitz spends significant time with us and is highly active in our management, he has the ability to spend up to one business day per week on other commitments pursuant to his employment agreement. In addition, we do not maintain key-man insurance for Dr. Rabinowitz or any other member of our senior management team. The loss of our founder and 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 success of our research, development, and commercialization efforts for potential new products, including in the field of cancer;
- 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 our accounts receivable;
- the costs and success of further expansion of our sales and marketing activities and research and development activities;
- 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. 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, 2016 and 2015, we had approximately \$49.6 million and \$42.1 million, respectively, of debt outstanding. Except for operating leases, we do not have any off-balance sheet financing arrangements in place or available.

Our ability to make principal and interest payments on our indebtedness will depend on our ability to generate cash in the future. 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 as well as the other risks associated with indebtedness. In addition, our debt agreements have in the past, and may in the future, contain various restrictive covenants and may be secured by some or 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.

***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 and our other products and that we expect to conduct in the field of cancer, 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. Similarly, these concerns may lead patients to refuse to use genetic tests even if permissible. 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.***

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 its equity ownership over a three-year period), the

corporation's ability to use its pre-change net operating loss, or NOL, carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. As a result of our most recent private placements of equity securities and other transactions that have occurred over the past three years, or upon our recent initial public offering, we may have experienced an "ownership change." 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 in our control). As of December 31, 2016, we had federal and state NOL carryforwards of approximately \$ 205.3 million and \$109.6 million, respectively, which begin to expire in 2027 and 2017, respectively, if not utilized. We also had federal research and development credit carryforwards of approximately \$8.5 million, which begin to expire in 2027, and state research and development credit carryforwards of approximately \$5.8 million, which can be carried forward indefinitely. Our ability to use these carryforwards could be limited if we experience "ownership changes."

## **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 be our most significant source of payments going forward. In particular, we believe that 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, CMS, and state reimbursement programs for Panorama, will be necessary to continue to achieve commercial success. If we are unable to obtain or maintain adequate reimbursement coverage from, or achieve in-network status with, third-party payers for our existing tests or future tests, our ability to generate revenues would 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. ACMG has recently 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 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. ISPD has issued guidelines that are supportive of performing NIPT in average-risk pregnancies, as well as high-risk pregnancies. However, ACOG and SMFM have 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 that, based on the ACMG, ACOG and SMFM guidelines, more average-risk women will be informed of NIPT and may request it, it is uncertain whether third-party payers will reimburse for NIPT for these average-risk patients. Currently, a number of third-party payers have negative coverage determinations for average-risk patient populations, meaning that their policy is not to reimburse for NIPT for patients in the average-risk population. The ACOG and 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 recently 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, in which enrollment has proceeded at a slower pace than we anticipated, 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.

The reimbursement environment, particularly for molecular diagnostics, is 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 with 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, such as carrier screen tests, like Horizon, that screen for multiple conditions, or our Panorama test and the separate Panorama screen for microdeletions, into a single payment rate. 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. For example, one third-party payer has recently alleged that it has overpaid us and has demanded recoupment of the alleged overpayments. We disagree with its contentions. See “Commitments and Contingencies—Third-Party Payer Reimbursement Audits” in Note 6 to our Consolidated Financial Statements. We have dealt 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. 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 testing was in breach of contract or otherwise contrary to law, they may recoup payment, which amounts could be significant, and we might be required to restate our financials from a prior period, which would likely cause our stock price to decline.

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, which would adversely affect our revenues, and we may be subject to claims for recoupment, which could require the time and attention of our management, and may be a distraction from development of our business.

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. Further, 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 and our obligations to these payers. 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 seeking 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. Furthermore, if a third-party payer were to be successful in proving such reimbursement was in breach of contract or otherwise contrary to law, we could be required to make a repayment, which could be significant, 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 some 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 or if we are unable to successfully obtain reimbursement from state Medicaid programs.***

Our revenues from Medicare are currently very small, given the population that Medicare covers, and we do not expect those revenues to increase materially with regard to NIPT. However, Medicare reimbursement can affect Medicaid reimbursement. For example, 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 look to the amounts that Medicare pays for testing services and set their payment rates at a percentage of those amounts. Reimbursement amounts for laboratory tests furnished to Medicare beneficiaries are typically based on the Clinical Laboratory Fee Schedule, or CLFS, set by CMS pursuant to a statutory formula established by the U.S. Congress. 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 national coverage certainty afforded by a formal coverage determination by CMS. Thus, CMS could issue an adverse coverage determination as to Panorama which could influence other third-party payers, including Medicaid, which could have an adverse effect on our revenues.

Approximately 40% of all births in the United States are to state Medicaid program recipients. Under Medicaid regulations, in order for us to be reimbursed by a state's Medicaid program, we must be recognized as a Medicaid provider by the state in which the Medicaid recipient receiving the services resides. As of February 1, 2017, we are recognized by 41 states as a Medicaid provider. We may not be able to be recognized as a provider by additional Medicaid programs, because some states require that a provider maintain a 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. In addition, we have faced challenges in obtaining reimbursement even when we are recognized as a state Medicaid provider, and as a result our testing is not reimbursed by Medicaid programs in many of the states in which we are recognized as a Medicaid provider. 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 some cases, a state Medicaid program's reimbursement rate for our testing might be zero dollars. In addition, 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. Low or zero dollar Medicaid reimbursement rates for our tests could have an adverse effect on our business and revenues.

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. 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 be recognized as a Medicaid provider in that state. Thus, not being able to participate in one or more managed Medicaid plans in a given state could have an adverse effect on our 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.***

Some third-party payers from whom we have received reimbursement to date have not entered into agreements with us that govern approval or payment terms. Therefore, such third-party payers could withdraw such coverage and reimbursement for our tests in the future, at any time and 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, and 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.

Further, even if we are under contract with a third-party payer, the contract does not guarantee reimbursement for all testing we perform. For example, many third-party payers with whom we have written agreements typically have policies that state they will not reimburse for use of NIPTs in the average-risk pregnancy population 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 us to seek prior authorization from the third-party payer, require a physician or qualified practitioner's signature on test requisitions, or put in place other controls and procedures prior to conducting a test. To the extent we or the physicians ordering our tests do not follow these 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, which has occurred in some cases, and which may have an adverse impact on our revenues.

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 for the clinical laboratory industry. Because of these cost-containment trends, governmental and commercial third-party payers that currently provide reimbursement for, or may in the future cover, our tests may reduce, suspend, revoke or discontinue payments or coverage at any time. 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; and
- incorrect or missing billing information, which is required to be provided by the ordering health care 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 customers must use to bill and receive reimbursement for our diagnostic tests. Once the CPT code is established, CMS establishes payment levels and coverage rules under Medicare while private payers establish rates and coverage rules independently. A CPT code specific to NIPT for aneuploidies came into effect in January 2015. Additionally, CMS adopted a new code set for diagnosis, commonly known as ICD-10, in October 2015. The AMA issued a CPT code for microdeletions in March 2016, and CMS has provided a pricing benchmark for aneuploidy and microdeletions testing, effective January 2017. However, we expect that our microdeletions reimbursement will decline because third-party payers are declining to reimburse under this new 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. 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 that, based on the guidance of outside legal and coding experts, are determined to be the most appropriate for our testing, but there is a risk that these codes 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. We accordingly cannot guarantee that our current or any future tests will have a CPT code assigned. 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 currently anticipate initially commercializing our planned cancer tests 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 Federal Food, Drug, and Cosmetic Act, or 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. On October 3, 2014, the FDA issued draft guidances outlining its plan to actively regulate LDTs using a risk-based approach. The draft guidances have been the subject of considerable controversy, and it is unclear whether or when the FDA will seek to regulate LDTs. In November 2016, the FDA announced that it no longer plans to finalize the 2014 draft guidances, and that it intends to work with the new administration and Congress, as well as stakeholders, to update the LDT framework. 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.

In the meantime, the FDA could require us to seek clearance or approval to offer our tests for clinical use even before it finalizes any future guidance. If FDA premarket review or approval is required, or if we voluntarily pursue FDA review or approval, 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 or approval. Our business would be adversely affected while such review is ongoing and if we are ultimately unable to obtain premarket clearance or approval. For example, the regulatory 510(k) clearance or PMA process may involve, among other things, successfully completing analytical, pre-clinical and/or clinical studies beyond the studies we have already performed for each of our products and would involve submitting a premarket notification or filing a PMA application with the FDA. Performance achieved in published studies may not be repeated in later studies that would be required to obtain either FDA premarket clearance or approval. Limited results from earlier-stage verification studies, beyond the validation and other studies we have already performed for each of our products, may not accurately predict results from studies of larger numbers of subjects drawn from more diverse populations over a longer period of time. Unfavorable results from ongoing preclinical and clinical studies could result in delays, modifications or abandonment of ongoing or future clinical studies, or abandonment of a product development program or may delay, limit or prevent regulatory approvals or commercialization. In addition, we may require cooperation in our filings for FDA approval 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 desired regulatory clearances or approvals, or may be delayed or be required to expend additional costs and other resources in doing so. We may face difficulty obtaining cooperation from our main sequencer and sequencing reagent supplier, Illumina, if we seek to achieve regulatory clearance or approval for Panorama, because Illumina is the parent company of Verinata, Inc., a direct competitor of ours in the NIPT field. Furthermore, if FDA premarket review or approval is required, our cash flows may be adversely affected, 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 have informed the FDA of our intent to pursue a PMA for Panorama. We cannot assure you that Panorama or any of our other tests for which we pursue or are required to obtain premarket review by the FDA will be cleared or approved on a timely basis, if at all. In addition, if a test has been approved through a PMA, 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 approved 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 may object to the materials and methods we use to promote the use of our current prenatal tests or other LDTs we may develop in the future, 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.

***Failure to obtain necessary regulatory approvals in foreign jurisdictions may adversely affect our ability to expand our operations internationally.***

An important part of our business strategy is to expand and offer our tests internationally, either directly or through our licensees. As we do so, we will become increasingly subject to or impacted by the regulatory requirements of foreign jurisdictions, which are varied and complex. For example, our tests may be subject to the regulatory approval requirements for each foreign country in which they are sold by us or a laboratory partner or licensee 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. 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.

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. We or our partners or licensees may not be able to obtain foreign 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 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, which increases 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 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 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 required 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 of payments made to physicians, which are governed by laws and regulations including the Stark law. 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, 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, and 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. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical laboratory.

We are also required to maintain certain state licenses to conduct testing in our laboratories. California law establishes standards for the day-to-day operation of our clinical laboratory in San Carlos, California, including the training and skills required of personnel and quality control matters. We maintain a license in good standing with the California Department of Health Services, or DHS. In addition, we have obtained a license for our San Carlos laboratory from the New York Department of Health, or DOH, which mandates proficiency testing regardless of whether such laboratories are located in New York. If we are found to be out of compliance with either California or New York requirements, DHS or DOH may, among others, suspend, restrict or revoke our license for that state, assess substantial civil monetary penalties, or impose specific corrective action plans. Any such actions could materially and adversely affect our business.

Moreover, some states require that we hold licenses to test samples from patients in those states. We have obtained licenses from states that we believe require us to do so, and we intend to comply with similar requirements that we may become aware of for any other states. However, we cannot assure you that the regulators in each of the states 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, censure, or civil monetary penalties, and would result in our inability to test samples from patients in that state.

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 were to lose our CLIA certification or any required state license, or if any sanction were imposed upon us under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or any failure by us to renew a CLIA certificate, a state license or accreditation, we would not be able to operate our clinical laboratory and offer our testing services, in some or all states or countries, which would materially and adversely impact our business and results of operations.

***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, we expect, will continue to be a topic of extensive legislative and executive activity in the U.S. federal 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 of these or other 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 Health Care and Education Reconciliation Act of 2010, or collectively, the PPACA, was signed into law in March 2010 and significantly impacts the U.S. pharmaceutical and medical device industries, including the diagnostics sector, in a number of ways. Among other things, the PPACA expands current health care fraud and abuse laws such as the False Claims Act and the Anti-Kickback Statute, including required disclosures of financial arrangements with physician customers, lower thresholds for violations, new government investigative powers, and enhanced penalties for such violations. The PPACA

also created a new system of health insurance "exchanges," designed to make health insurance policies 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 cannot predict at this time 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. There have been a number of proposed legislative initiatives with respect to the PPACA, including possible repeal of the PPACA; and although the Supreme Court has upheld the constitutionality of certain provisions of the PPACA that have been challenged, the newly-elected United States President and Congress have indicated a desire to make changes to or eliminate the entirety of the PPACA. Because it is unclear whether or not, or how, the PPACA may change, and whether and to what extent NIPT 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, introduces a multi-year pricing program for services paid under the CLFS that is designed to bring Medicare allowable amounts in line with the amounts paid by private payers. CMS, which is responsible for implementing PAMA, recently released a final rule for implementation of PAMA. Under the rule, certain laboratories will be required to report third-party payer rates and test volumes; laboratories with low Medicare revenues, such as Natera, are excluded from reporting. Beginning in January 2018, the Medicare payment rate for these tests will be equal to the weighted median private payer rate reported to CMS; as a result, there may be a decline in CLFS payment rates due to the often lower negotiated private payer rates applicable to large commercial laboratories that were required to report to CMS. In addition, federal budgetary limitations and changes in healthcare policy, such as the creation of broad limits for our tests or 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 sale, or inhibit the utilization, of our tests in the future, 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 payers for our current and future tests, may adversely affect the volumes of services and tests that we provide and may therefore adversely affect our business, financial condition, results of operations, and cash flows.

***If we or our laboratory 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. The laws that may affect our ability to operate include:

- 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 consents for genetic testing and the use of genetic material;
- 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, persons from knowingly and willfully soliciting, receiving, offering or paying 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 physician self-referral law, which 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, unless the financial relationship falls within an applicable exception to the prohibition, as well as state law equivalents of the Stark law;
- the federal Civil Monetary Penalties Law, which 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, unless an exception applies;
- 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 anti-kickback 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.

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 on any person or entity that, among other things, knowingly presents, or causes 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 Item 3—Legal Proceedings, we have received a civil investigative demand from the United States Department of Justice in connection with what we understand to be a qui tam action brought by a former employee and have produced documents in response. An adverse ruling in this proceeding could require us to pay treble damages, civil penalties, and attorneys' fees, costs and expenses, which could materially and adversely affect our business, financial condition and results of operations.

Many of these laws and regulations have not been fully interpreted by the 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, health care providers, and health care 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:

- the circumstances under which the use and disclosure of protected health information are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payments for our services, and health care operations activities;
- a patient's right to access, amend and receive an accounting of certain disclosures of protected health information;
- the content of notices of privacy practices for protected health information;
- administrative, technical and physical safeguards required of entities that use or receive protected health information;
- the protection of computing systems and personal devices (such as cell phones and tablets) that maintain protected health information; and
- analysis of security incidents and breach notification requirements.

We have implemented policies and procedures related to compliance with the HIPAA privacy and security regulations as required by law. The privacy and security regulations establish minimum requirements, and do not supersede state laws that are more stringent. Therefore, we are required to comply with both federal privacy and security laws and regulations and various state privacy and security laws and regulations. The federal privacy regulations restrict our ability to use or disclose patient identifiable laboratory data, without patient authorization, for purposes other than payment, treatment or health care operations (as defined by HIPAA), except for disclosures for various public policy purposes and other specified permitted purposes. 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 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.

In addition, laws and regulations of the European Union, as well as other countries, protect the use and disclosure of personal information. In particular, the data protection laws in the European Union are generally more stringent and apply to a broader range of personal data than those in the United States, and impose various requirements on U.S.-based companies, such as ours, relating to collecting, receiving, processing and storing personal data from the European Union. As we continue to expand and grow our business, compliance with these laws and regulations may result in increased costs, and failure to comply may result in significant fines, penalties and damage to 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 prenatal testing, as well as the instruments and other capital equipment that enable the testing, are offered for sale as analyte specific reagents, or ASRs, or for research use only, or RUO. ASRs consist of single reagents or primer pairs, which are intended for use in a diagnostic application for the identification and quantification of an individual chemical substance in biological specimens. As medical devices, ASRs must comply with the QSR provisions and other device requirements, but most are



exempt from the 510(k) and PMA premarket review processes. Products that are intended for research use only and are labeled as RUO are exempt from compliance with the FDA requirements, including the approval or clearance and other product quality requirements for medical devices. A product labeled RUO but 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 it will consider the totality of the circumstances surrounding distribution and use of an RUO product, including how the product is marketed and to whom, when determining its intended use. 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, including requiring the supplier to seek clearance or approval for the products. The supplier may cease selling the 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 or approval for the sale of Illumina's sequencers and if Illumina does not obtain such clearance or approval, we would have to find an alternative sequencing platform for Panorama. We currently have not validated an alternative sequencing platform that would work for Panorama 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 could be adversely affected. Similarly, a decision by the FDA to require clearance or approval 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. Furthermore, if and to the extent that we begin to supply customers with products that are RUO, we would also be subject to the regulatory risks described above.

***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 or forced to stop performing such tests, 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 on them 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 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. 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. For example, we are presently aware of at least one instance in which a competitor has asserted to us and to third parties that it has an issued patent that covers one or more of our tests in the United States; while this competitor has not filed any patent infringement action based on this assertion, such an action could be brought at any time. 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.

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. We have in the past and may also in the future be involved with intellectual property litigation or patent office actions. For example, we were recently engaged in patent 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. For more information on our current legal and regulatory proceedings, see Item 3—Legal Proceedings.

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 or 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. 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 or patent applications are 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. 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 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. 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 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;
- 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 recognize revenue;
- 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 further in Item 3—Legal Proceedings, purported securities class action lawsuits have been filed against Natera, 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 Item 3 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 expect 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 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, 2016, as indicated in our Management Report on Internal Control over Financial Reporting included in this annual report on Form 10-K, 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, 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 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. 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.

Certain holders of shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could adversely affect the trading 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, 2016, our directors and executive officers and their affiliates beneficially own, in the aggregate, approximately 45.2% 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 merger, 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 sublease office facilities under non-cancelable operating lease agreements. We currently occupy approximately 88,000 square feet of laboratory and office space at 201 Industrial Road in San Carlos pursuant to two separate subleases, one sublease for approximately 61,000 square feet (the "First Space"), and the other sublease for approximately 27,000 square feet (the "Second Space").

In October 2016, we amended our lease agreement that we directly entered into with the landlord of our First Space and Second Space (as described above) to include a sublease of additional office space to accommodate our growth

and consolidate our operations in California at one location. The additional sublease covers approximately 48,000 square feet of office space and consists of two phases. The first phase began in October 2016 and covered approximately 16,000 square feet of office space. The second phase began in January 2017, which covered approximately 32,000 square feet of office space. The term of this sublease will expire in October 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.

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, against Natera, our directors and certain of our officers and 5% stockholders and their affiliates, and each of the underwriters of our 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 our IPO contained materially false or misleading statements, and/or omitted material information that was required to be disclosed, about our business and prospects. Among other relief, the complaints seek class certification, unspecified compensatory damages, rescission, attorneys' fees, and costs. We 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. We have appealed the remand and moved to stay, or put a hold on, discovery pending the appeal. We have also filed a demurrer, or a request for dismissal as a matter of law, in the Superior Court, which has not yet been heard. We intend to defend the matter vigorously, but we cannot provide any assurance as to the ultimate outcome or that an adverse resolution would not have a material adverse effect on our financial condition and results of operations. In light of, among other things, the early stage of these actions, we are unable to predict the outcome and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

On March 4, 2016, a lawsuit was filed against us in the Superior Court of the State of California for the County of San Diego, by a patient alleging that Natera failed to perform a test that was ordered. The complaint seeks compensatory damages. This matter is in the discovery stage. We intend to vigorously defend against the claims in this lawsuit, and assert any counterclaims that may be available to us. We cannot provide any assurance as to the ultimate outcome or that an adverse resolution of this lawsuit would not have a material adverse effect on our financial condition and results of operations. In light of, among other things, the early stage of the litigation, we are unable to predict the outcome and are 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, we received a civil investigative demand from the United States Department of Justice in connection with what we understand to be a qui tam action related to the billing of some of our testing, brought by a former employee. We have produced documents in response to the demand. An adverse ruling in this proceeding could require us to pay treble damages, civil penalties, and attorneys' fees, costs and expenses, which could materially and adversely affect our business, financial condition and results of operations. We have only received a civil investigative demand and have not been served with a complaint; accordingly, we are unable to predict the outcome and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

On December 9, 2016, we filed a lawsuit against Bio-Reference Laboratories, Inc. ("Bio-Reference") in the U.S. District Court for the Southern District of New York alleging that Bio-Reference breached a licensing and joint development agreement (the "Licensing Agreement") between Bio-Reference and Natera, misappropriated trade secrets, and converted confidential information. We also filed a motion for a temporary restraining order and preliminary

injunction enjoining Bio-Reference from launching a nationwide marketing campaign of its product in violation of the Licensing Agreement. On December 10, 2016, our motion for a temporary restraining order was denied, and the Court ordered both parties to submit proposed hearing dates with respect to our motion for a preliminary injunction. We and Bio-Reference have resolved the matter as of February 2017.

**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 has been traded on The Nasdaq Global Select Market under the symbol "NTRA" since July 2, 2015, the date of our initial public offering. Prior to that date, there was no public trading market for our common stock.

The following table sets forth on a per share basis, for the periods indicated, the low and high closing sales prices of our common stock as reported by The Nasdaq Global Select Market.

	<u>High</u>	<u>Low</u>
Year Ended December 31, 2015		
Third quarter (from July 2, 2015) .....	\$ 24.36	\$ 10.25
Fourth quarter .....	\$ 12.14	\$ 7.74
Year Ended December 31, 2016		
First quarter .....	\$ 10.46	\$ 6.61
Second quarter .....	\$ 13.79	\$ 9.37
Third quarter .....	\$ 13.28	\$ 9.53
Fourth quarter .....	\$ 12.86	\$ 8.02

#### *Holders*

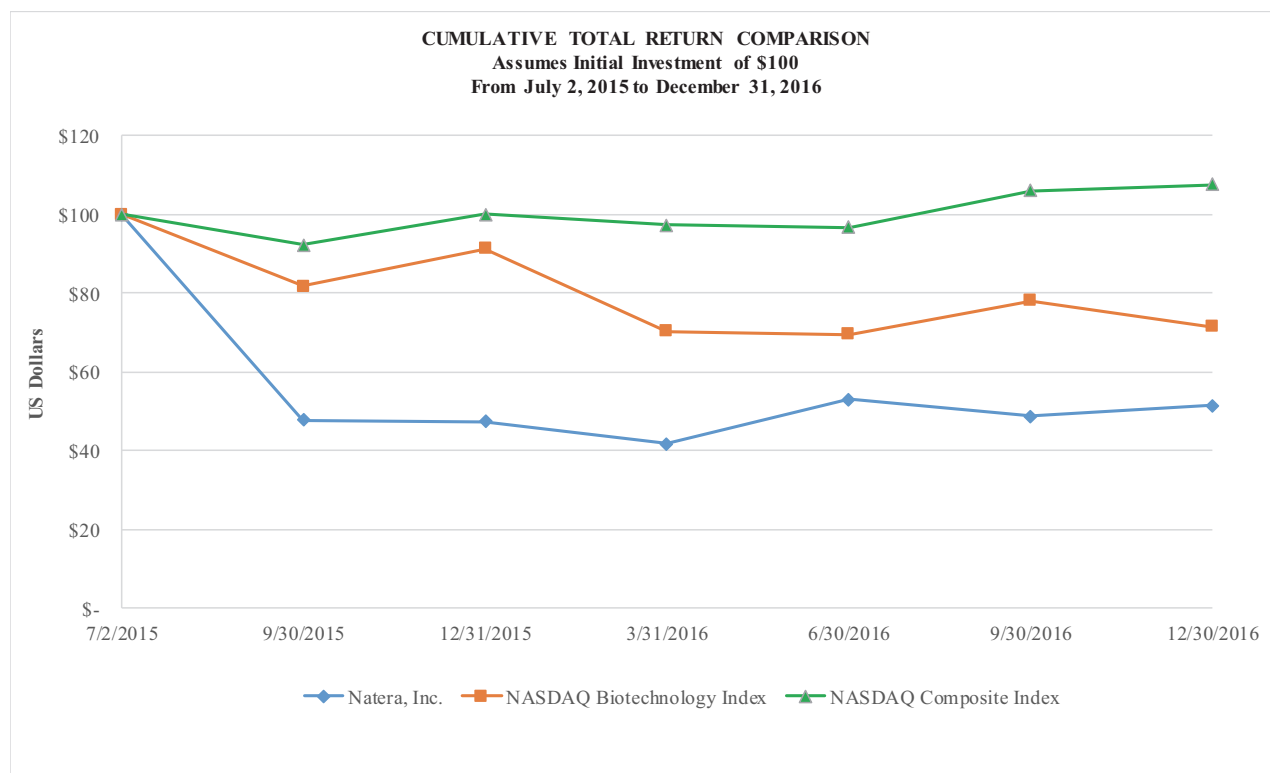
As of December 31, 2016, we had 32 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders 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.

## 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 July 2, 2015 and December 31, 2016 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.



Company/Index	Base Period 7/2/15	9/30/2015	12/31/2015	3/31/2016	6/30/2016	9/30/2016	12/31/2016
Natera, Inc. . . . .	100.00	47.71	47.49	41.86	53.06	48.86	51.50
NASDAQ Biotechnology Index . .	100.00	81.76	91.34	70.35	69.49	78.10	71.53
NASDAQ Composite Index . . . .	100.00	92.23	99.96	97.22	96.68	106.04	107.46

## Recent Sales of Unregistered Securities

None.

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

None.

## Use of Proceeds from Initial Public Offering

In July 2015, we completed an initial public offering (“IPO”), and subsequently in August 2015, we completed the sale of additional shares upon exercise of the underwriters’ over-allotment option. In connection with the IPO, we sold 10,900,000 shares of common stock at \$18.00 per share, which raised \$178.5 million in proceeds, net of underwriting discounts, commissions, and offering expenses. The offer and sale of all of the shares in the IPO were registered under the

Securities Act pursuant to a registration statement on Form S-1 (File No. 333-204622), which was declared effective by the SEC on July 1, 2015. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus dated July 1, 2015 and filed with the SEC on July 2, 2015 pursuant to Rule 424(b)(4) of the Securities Act.

## ITEM 6. SELECTED FINANCIAL DATA

The following table presents our selected historical condensed consolidated financial data. The consolidated statements of operations data for the three fiscal years ended December 31, 2016, 2015 and 2014 and the consolidated balance sheet data as of December 31, 2016 and 2015 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 year ended December 31, 2013, and the balance sheet data as of December 31, 2014 and 2013 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,			
	2016	2015	2014	2013
<b>Selected Statement of Operations Data:</b>				
Total revenues . . . . .	\$ 217,074	\$ 190,355	\$ 159,289	\$ 55,171
Total cost and expenses . . . . .	313,562	250,193	158,624	80,439
Interest expense and other income (expense), net. . . . .	865	(10,437)	(5,817)	(11,842)
Income tax expense . . . . .	(142)	—	—	—
Net loss. . . . .	\$ (95,765)	\$ (70,275)	\$ (5,152)	\$ (37,110)
Net loss per common share, basic and diluted . . . . .	\$ (1.86)	\$ (2.68)	\$ (1.07)	\$ (9.66)
<b>Selected Balance Sheet Data:</b>				
	As of December 31,			
	2016	2015	2014	2013
Cash, cash equivalents and restricted cash . . . . .	\$ 16,690	\$ 30,531	\$ 88,487	\$ 31,392
Short-term investments . . . . .	130,860	201,586	—	—
Inventory . . . . .	6,414	8,093	11,542	10,652
Property and equipment, net. . . . .	32,289	12,710	14,574	9,791
Total assets. . . . .	210,680	265,240	123,623	59,723
Debt . . . . .	49,624	42,090	26,814	24,307
Total liabilities. . . . .	104,204	80,475	54,346	46,033
Convertible preferred stock . . . . .	—	—	240,612	185,199
Total stockholders' equity (deficit). . . . .	106,476	184,765	(171,335)	(171,509)

## 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 unaudited condensed 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 rapidly growing diagnostics company with proprietary molecular and bioinformatics technology that we are deploying to change the management of genetic 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 detect a wide range of serious conditions with best in class accuracy and coverage. In addition to our direct sales force in the United States, which we are continuing to expand, we have a global network of approximately 70 laboratory and distribution partners, including many of the largest international laboratories. We are enabling even wider adoption of our technology with our global cloud-based distribution model. We have launched seven molecular diagnostic tests since 2009, and we intend to launch new products in prenatal testing and oncology in the future. We generate revenues primarily from the sale of Panorama, our non-invasive prenatal test, or NIPT, which we commercially launched in March 2013. We also launched our Constellation software platform in May 2015. During the year ended December 31, 2016, we processed greater than 447,000 tests, comprised of approximately 430,000 tests accessioned in our laboratory and 17,000 tests processed through our Constellation software platform, or Constellation units. Over 331,000 Panorama tests were accessioned during the year ended December 31, 2016, which represents an increase of approximately 30% over 2015 and approximately 79% increase over 2014. Our revenues for the year ended December 31, 2016 have grown to \$217.1 million from \$190.4 million and \$159.3 million for the years ended December 31, 2015 and 2014, respectively.

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

In the year ended December 31, 2016, 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 significant portion of our Horizon Carrier Screening testing is performed by third-party laboratories. Our customers include independent laboratories, national and regional reference laboratories, medical centers and physician practices. We market and sell our tests both through our direct sales force and those of our laboratory partners. We bill clinics, laboratory partners, patients and insurance payers for the tests we perform. In cases where we bill laboratory partners, our partners in turn bill clinics, patients and insurance payers. Insurers 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 payers with positive NIPT coverage determinations include UnitedHealthcare, AETNA, Anthem, Humana and CIGNA. As of December 31, 2016, we and our laboratory partners had in-network contracts with insurance providers that accounted for over 203 million covered lives in the United States, of which approximately 188 million were under our direct in-network contracts. 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 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 both our direct sales force and laboratory partners, and 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, the relevant information about the test is entered into our computer system and the test sample is routed into the appropriate sample flow. During the year ended December 31, 2016, we processed over 447,000 tests, comprised of 430,000 tests accessioned and over 17,000 Constellation units, compared to over 317,000 tests processed, including over 310,000 tests accessioned and over 7,000 Constellation units, for the year ended December 31, 2015, and over 215,000 tests accessioned for the year ended December 31, 2014, respectively. This increase in volume is primarily due to the commercial growth of our Panorama test and tests processed through our Constellation software platform that was launched in May 2015. We significantly increased the number of our domestic sales representatives in the third quarter of 2014 through the second quarter of 2015 in an effort to increase the number of tests distributed through our direct sales force. The percent of our revenues attributable to our U.S. direct sales force for the year ended December 31, 2016 was 78%, up from 77% and 59% for the years ended December 31, 2015 and 2014, respectively. The percent of our revenues attributable to U.S. laboratory partners for the year ended December 31, 2016 was 12%, up from 10% and 26% for the years ended December 31, 2015 and 2014, respectively. 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 year ended December 31, 2016 was 11%, down from 13% and 14% for the years ended December 31, 2015 and 2014, respectively.

In addition to distributing molecular diagnostic tests, we seek to establish licensing arrangements with laboratories under our cloud-based distribution model, whereby our laboratory licensees run the molecular workflows themselves and then access 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. We have recognized \$3.1 million, \$2.2 million and \$1.1 million in revenues from our licensing arrangements during the years ended December 31, 2016, 2015 and 2014, respectively. The DDC arrangement commenced in the second quarter of 2014 and our other arrangements commenced during the fourth quarter of 2015.

Our revenues increased to \$217.1 million in the year ended December 31, 2016 from \$190.4 million and \$159.3 million in the years ended December 31, 2015 and 2014, respectively. Panorama revenues accounted for \$143.1 million, or 66%, of our revenues for the year ended December 31, 2016; \$139.6 million, or 73%, of our revenues for the year ended December 31, 2015; and \$116.1 million, or 73%, of our revenues for the year ended December 31, 2014. For the years ended December 31, 2016 and 2015, there were no customers exceeding 10% of the total revenue on an individual basis. Bio-Reference represented 8% and 5% of our revenues for the years ended December 31, 2016 and 2015, respectively. We terminated our licensing and distribution agreement with Bio-Reference in January 2017, and their outstanding balance owed to us as of December 31, 2016 has been fully paid. Sales to Quest Diagnostics Incorporated, Progenity Inc., and Bio-Reference Laboratory, Inc. represented 10%, 5%, and 6%, respectively, of our revenues for the year ended December 31, 2014. Both Quest Diagnostics Incorporated and Progenity Inc., which were our two largest laboratory partners in 2013, terminated their agreements with us in 2014. Revenues from customers outside the United States were \$24.0 million, \$25.4 million and \$22.8 million, representing approximately 11%, 13% and 14%, respectively, of our revenues, for the years ended December 31, 2016, 2015 and 2014, respectively. Most of our revenues have been denominated in U.S. dollars, but we began to generate revenue in foreign currency in 2015, primarily denominated in Euros.

Our net losses for the years ended December 31, 2016, 2015 and 2014 were \$95.8 million, \$70.3 million and \$5.2 million, respectively. This included non-cash stock compensation expense of \$10.6 million, \$7.3 million and \$5.2 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of \$345.9 million.



## Components of the Results of Operations

### *Revenues*

We generate revenues from the sale of our genetic tests, primarily from the sale of our NIPT, Panorama. We assess whether the fee is fixed or determinable based on the nature of the fee charged for the services delivered and existing contractual arrangements. For tests performed where an agreed upon reimbursement rate or fixed fee and a predictable history or likelihood of collections exists, we recognize revenues upon delivery of a report to the prescribing physician or clinic based on the established billing rate less contractual and other adjustments, such as an allowance for doubtful accounts, to arrive at the amount that we expect to collect. In all other situations, as we do not have a fixed or determinable price, a sufficient history of collection or we are not able to determine the price for our test, we recognize revenue when cash is received.

Our two primary distribution channels are our: direct sales force and our laboratory and distribution partners. We have also recently implemented a cloud-based distribution model, from which we begin recognizing revenue in the fourth quarter of 2015. 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. We do not maintain an account receivable balance in our financial statements for outstanding billing to the insurance payers because we cannot determine the collectable portion of the billings until cash is received.

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.

The fixed fees identified in contracts with laboratory partners change only if a pricing amendment is agreed upon between both parties. In contracts whereby we have a fixed fee agreement, revenue is recognized when collection is reasonably assured and all other revenue recognition criteria is met. For cases in which there is no fixed price established with a laboratory partner, we then recognize revenues from partner distributed tests on a cash basis. For tests sold through a limited number of our laboratory partners, we bill directly to a patient, clinic or insurance carrier, or a combination of the insurance carrier and patient for the fees. We receive licensing revenue through the licensing and the provisioning of services to support the use of our proprietary technology with our customer. Licensing revenues are recognized when earned under the terms of the related agreements and are presented as Licensing and Other Revenues in the statements of operations and comprehensive loss.

Revenue recognized on a cash basis represented 82%, 85% and 67% of our revenues for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had 21 licensing and service arrangements with laboratories under our cloud-based distribution model. For the year ended December 31, 2016, we recognized revenue from only seven such arrangements.

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, offer 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, and we believe that more third-party payers will do so in the future. 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,”* because there is currently limited published data on the performance of microdeletions screening tests. A new current procedure terminology, or CPT, code for microdeletions began to go into effect on January 1, 2017. We anticipate that this new code will, in the near term, cause our microdeletions reimbursement to decline, either due to reduced reimbursement, or third-party payers declining to reimburse, under the new code. Any such decline in reimbursement would decrease our revenues. 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 will decrease. 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 will 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 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 product, licensing and other revenues for the Constellation software platform is relatively low, and therefore we expect its associated gross margin to be higher.

### ***Cost of Product, Licensing and Other Revenues***

The components of our cost of product, licensing and other revenues are materials and service costs, 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 fees, and allocated overhead including rent, information technology costs, equipment depreciation and utilities. Costs associated with performing tests are recorded when the test is processed regardless of whether and when revenues are recognized with respect to that test. As a result, our cost of product, licensing and other revenues as a percentage of revenues may vary significantly from period to period because we do not recognize all revenues in the period in which the associated costs are incurred. We expect cost of product, licensing and other 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 have 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 sensitivity 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. In addition, we are continuing to grow our cloud-based distribution network. This model reduces sample shipping, labor, and material costs at our CLIA-certified laboratory in California. Four of our laboratory licensees have begun running tests developed under license from us in their own laboratories, leaving us to provide only the algorithmic data analysis in the cloud through our Constellation software and its maintenance. We have agreements with various other laboratories, and are in active discussions with many other potential licensees, to implement this distribution model.

### ***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, 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 will increase in absolute dollars in future periods as we continue to invest in research and development activities related to developing additional products. In the near term we will continue to grow research and development expenses in support of Panorama and other new products and programs, including the application of our proprietary technologies for cancer and other disease detection.

### ***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, education seminars, payer outreach programs and allocated overhead, including rent, information technology, equipment depreciation, and utilities. In the near term, we expect selling, general and administrative expenses will increase driven by the costs of hiring

additional sales personnel associated with further penetrating the domestic and international market, and marketing and education expenses to drive market penetration and reimbursement. We also expect selling, general and administrative expenses to increase as a result of becoming a public company. These expenses are 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. We also expect our selling, general and administrative expenses will increase in absolute dollars as we expand our billing and client services functions.

### ***Interest Expense***

Interest expense is attributable to borrowing under our senior secured term loan and our equipment financing facility prior to repayment and our line of credit. We also recognized revenue-based royalties to the lender associated with our senior secured term loan prior to prepayment during 2015 as part of interest expense.

### ***Interest Benefit from Changes in the Fair Value of Long-Term Debt***

Interest benefit also arises from changes in the fair value associated with our senior secured term loan prior to repayment during 2015.

### ***Interest Income and Other Income (Expense), Net***

Interest income and other income (expense), net is from interest earned on our cash, settlement over contract dispute, debt extinguishment of our secured term loan, realized gains on investments, foreign currency re-measurement gains and other expense relates to the changes in the fair value of our warrants.

### **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 reflect the more significant estimates and assumptions used in the preparation of our financial statements.

### **Revenue Recognition**

We consider our services rendered when we deliver reports of our test results. When we have contracted a fixed or determinable price for our services and when collectability of revenues is reasonably assured, we recognize revenues upon delivery of test reports which include contractual and other adjustments, such as an allowance for doubtful accounts, to arrive at the amount that we expect to collect. The fixed fees identified in contracts change only if a pricing amendment is agreed upon between the parties. For cases in which there is no price established, we recognize revenues on a cash basis. In all other situations, as we do not have a sufficient history of collection and are not able to determine a predictable pattern of payment, we recognize revenues when cash is received. For tests sold through a limited number of our laboratory partners, we bill directly to a patient, clinic or insurance carrier, or a combination of the insurance carrier and patient for the fees. We receive licensing revenue through the licensing and the provisioning of services to support the use of our proprietary technology with our customer. Licensing revenues are recognized when earned under the terms of the related agreements and are presented as Licensing and Other Revenues in the statements of operations and comprehensive loss.

We may not get reimbursed for tests completed if the tests are not covered under the insurance carrier's reimbursement policies or we are not a qualified provider to the insurance carrier. From time to time, we receive requests for refunds of payments previously made by insurance carriers. We have established an accrued liability for potential refund requests based on our experience, which is accounted for as reductions in revenues in the statement of operations and comprehensive loss.

Certain of our arrangements include multiple deliverables. For revenue arrangements with multiple deliverables, we evaluate each deliverable to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has "stand-alone value" to the customer and whether a general right of return exists. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. We use judgment in identifying the deliverables in our arrangements, assessing whether each deliverable is a separate unit of accounting, and in determining the best estimate of selling price for certain deliverables. We also use judgment in determining the period over which the deliverables are recognized in certain of our arrangements. Any amounts received that do not meet the criteria for revenue recognition are recorded as deferred revenue until such criteria are met.

As of December 31, 2016, we had 21 licensing and service arrangements with laboratories under our cloud-based distribution model. For the year ended December 31, 2016, we recognized revenue from only seven such arrangements. Royalty revenues from these licensing and service agreements are recognized when earned and are included in other revenues in the statement of operations.

## **Income Taxes**

We file U.S. federal income tax returns and tax returns in various states. To date, we have not been audited by the Internal Revenue Service or any state income tax authority. Due to our history of operating losses, we have not recorded any U.S. federal income tax expense for the year ended December 31, 2016, with the exception of a foreign withholding tax of \$142,000. For the years ended December 31, 2015 and 2014, we did not record any U.S. federal income tax expense.

As of December 31, 2016, our net deferred tax assets before valuation allowance were \$86.1 million, for which we established a full valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses, or NOLs, and tax credit carryforwards. As of December 31, 2016, we had federal and state NOLs carryforwards of approximately \$205.3 million and \$109.6 million, respectively, which begin to expire in 2027 and 2017, respectively, if not utilized. The deferred tax assets related to NOLs do not include excess tax benefits from employee stock option exercises. We also had federal research and development credit carryforwards of approximately \$8.5 million, which begin to expire in 2027, and state research and development credit carryforwards of approximately \$5.8 million, which can be carried forward indefinitely.

We are required to reduce our deferred tax assets by a valuation allowance if it is more likely than not that some or all of our deferred tax assets will not be realized. We must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of our valuation allowance, if any, we assess the likelihood that we will be able to recover our deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses and, based on all available evidence, we believe it is more likely than not that our recorded net deferred tax assets will not be realized. Accordingly, we recorded a valuation allowance against all of our net deferred tax assets as of December 31, 2016. We will continue to maintain a full valuation allowance on our deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this allowance.

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, our ability to utilize these carryforwards may be limited as the result of such ownership change. Such a limitation could restrict the use of the NOLs in future years and possibly a reduction of the NOLs available.

We are 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. We are no longer subject to U.S. federal, state, and local tax examinations by tax authorities for tax years before 2010. We are subject to U.S. federal, state and local tax examinations by tax authorities for all prior tax years since incorporation.

As of December 31, 2016, the balance of gross uncertain tax benefits was \$4.3 million. In 2016, the balance of gross uncertain tax benefits increased \$1.9 million related to current year research credits claimed. The reversal of the uncertain tax benefits will not affect our effective tax rate to the extent that we continue to maintain a full valuation allowance against our deferred tax assets. We do not anticipate significant changes to our current uncertain tax positions through December 31, 2017. We recognize any interest and/or penalties related to income tax matters as a component of income tax expense. As of December 31, 2016, there were no accrued interest and penalties related to uncertain tax positions.

## **Fair Value Measurements**

Our financial assets and liabilities carried at fair value comprise investments in money market funds and liabilities for preferred stock warrants and our senior secured term loan. The fair value accounting guidance requires that assets and liabilities carried at fair value be classified in one of the following three categories:

- Level I: Quoted prices in active markets for identical assets and liabilities that we have 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; or
- Level III: Inputs that are unobservable data points that are not corroborated by market data.

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

### *Fair Value—Senior Secured Term Loan*

We elected to account for our senior secured term loan at fair value prior to its repayment during 2015. The fair value of this liability represented a term loan, royalty interest, and a delayed draw loan that was based upon the achievement of certain revenues targets over the life of the contract. The fair value of the liability was determined using Level III inputs such as discounted cash-flow methodology, a Monte Carlo Simulation model for projected revenues, and the Longstaff-Schwartz model for royalty payments with significant inputs that included discount rate, projected revenues, projected royalty payments and percentage probability of occurrence for projected revenues and royalty payments. A significantly different fair value measurement could result from the following: a significant change in projected revenues in isolation, a significant change in the timing of the delayed draw loan, a significant change in the discount rate in isolation, or changes in the probability of occurrence between the outcomes in isolation. In October 2015, we repaid the entire borrowings under the secured term loan. We made a payment comprising in principal, prepayment penalty and royalty payment applied toward the royalty obligation. This payment released us from all future loan payments, royalty payments and all associated liens securing the loan.

### *Fair Value—Warrants*

Our common stock warrants are valued using Level III inputs; we use inputs from a Black-Scholes model with market volatility that is determined for comparable companies in the same business sector. Significant judgement is employed in determining the Level III inputs such as volatility and the term. Changes to our assumptions could have a material impact on our results of operations in any given period and actual results may differ from estimates. For example, significant lower estimates of volatility would result in material lower fair value measurement while higher volatilities



would result in higher fair value measurements, carrying amounts of cash, accounts receivable, and accounts payable approximate their fair value.

## 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,								
	2016			2015			2014		
	Employee	Non-Employee	Total	Employee	Non-Employee	Total	Employee	Non-Employee	Total
	(in thousands)								
Cost of revenues . . .	\$ 651	\$ (10)	\$ 641	\$ 351	\$ 241	\$ 592	\$ 262	\$ 29	\$ 291
Research and development . . . . .	2,829	24	2,853	1,566	9	1,575	1,563	30	1,593
Selling, general and administrative . . . . .	6,837	270	7,107	4,993	166	5,159	3,180	93	3,273
Total . . . . .	<u>\$ 10,317</u>	<u>\$ 284</u>	<u>\$ 10,601</u>	<u>\$ 6,910</u>	<u>\$ 416</u>	<u>\$ 7,326</u>	<u>\$ 5,005</u>	<u>\$ 152</u>	<u>\$ 5,157</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. 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. We use the Black-Scholes option-pricing model to estimate the fair value of our stock options. We account for stock options issued to non-employees based on the estimated fair value of the awards using the Black-Scholes option-pricing model. 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 during the period that the related services are rendered.

Effective in the year ended December 31, 2015, pursuant to agreements with our option holders, we changed the estimated expiration of our repurchase right for 1.3 million exercised and unvested shares outstanding that are subject to repurchase right held by us through the 210 days after the date of the prospectus filed in connection with our initial public offering. Accordingly, the unrecognized compensation expense is being accelerated over a shorter performance period through January 2016. As a result of this acceleration, we recorded an additional \$1.3 million in stock-based compensation expense during the year ended December 31, 2015.

We estimate the fair value of our 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,					
	2016		2015		2014	
Expected term . . . . .	5.1	— 5.2	5.6	— 10.0	4.9	— 7.1
Expected volatility . . . . .	62.2%	— 72.5%	69.7%	— 78.8%	73.4%	— 87.0%
Expected dividend rate . . . . .		0 %		0 %		0 %
Risk-free interest rate . . . . .	0.97%	— 1.92%	1.56%	— 2.32%	1.65%	— 2.04%

*Expected Term:* The expected term of options represents the period of time that options are expected to be outstanding. For granted "at-the-money" stock options, we estimated the expected term by using the simplified method up until December 31, 2015, which involved calculating the average of the time-to-vesting and the total contractual life of the options. Starting January 1, 2016, we use a different approach by calculating the average of—(1) our 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 stock options that are not granted "at-the-money," we use the binomial lattice model to calculate the expected

term. The binomial lattice model is a model for determining the expected term by utilizing a range of possible future outcomes.

*Expected Volatility:* We derived the expected volatility from the average historical volatilities of comparable publicly traded companies within our peer group over a period approximately equal to the expected term.

*Expected Dividend Rate:* We have not paid and do not anticipate paying any dividends in the near future.

*Risk-Free Interest Rate:* The risk-free interest rate assumption is based on the 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.

### ***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 years ended December 31, 2016 and 2015, 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 initially expected by us. We recorded an asset impairment charge of \$2.1 million and \$1.6 million during the years ended December 31, 2016 and 2015, respectively.

## **Results of operations**

### ***Comparison of the years ended December 31, 2016, 2015 and 2014***

	Year Ended December 31,			Changes	
	2016	2015	2014	2016 - 2015	2015 - 2014
	(in thousands)				
Revenues:					
Product revenues .....	\$ 213,968	\$ 188,168	\$ 157,308	\$ 25,800	\$ 30,860
Licensing and other revenues .....	3,106	2,187	1,981	919	206
Total revenues .....	217,074	190,355	159,289	26,719	31,066
Cost and expenses:					
Cost of product, licensing and other revenues .....	135,574	112,845	78,396	22,729	34,449
Research and development .....	41,862	27,711	17,292	14,151	10,419
Selling, general and administrative .....	136,126	109,637	62,936	26,489	46,701
Total cost and expenses .....	313,562	250,193	158,624	63,369	91,569
(Loss) income from operations .....	(96,488)	(59,838)	665	(36,650)	(60,503)
Interest expense .....	(533)	(3,505)	(4,219)	2,972	714
Interest benefit from changes in the fair value of long-term debt .....	—	964	118	(964)	846
Interest and other income (expense), net .....	1,398	(7,896)	(1,716)	9,294	(6,180)
Loss before income taxes .....	(95,623)	(70,275)	(5,152)	(25,348)	(65,123)
Income tax expense .....	(142)	—	—	(142)	—
Net loss .....	<u>\$ (95,765)</u>	<u>\$ (70,275)</u>	<u>\$ (5,152)</u>	<u>\$ (25,490)</u>	<u>\$ (65,123)</u>

## *Revenues*

Revenues increased \$26.7 million, or 14%, in the year ended December 31, 2016 from the year ended December 31, 2015. This was primarily due to the increase in volume of tests performed during the year. Approximately 77% of our revenues during the year ended December 31, 2016 were derived from test volumes accessioned in the year ended December 31, 2016; the balance of our revenues was derived from tests accessioned in prior years. Revenue from Horizon carrier screening test increased \$25.8 million as the number of tests accessioned increased 92% during the year ended December 31, 2016, compared to the same period of the prior year. Panorama revenue increased \$3.5 million due to increased testing volumes, and licensing revenue increased \$0.9 million during the year ended December 31, 2016 compared to the same period of the prior year. However, our revenue growth was offset by lower average selling price per test paid by insurance carriers that transitioned from out-of-network to in-network.

Revenues increased \$31.1 million, or 19.5%, in the year ended December 31, 2015 from the year ended December 31, 2014. This was primarily due to the increase in volume of tests performed during the year. Approximately 84% of our revenues during the year ended December 31, 2015 were derived from test volumes accessioned in the year ended December 31, 2015; the balance of our revenues was derived from tests accessioned in prior years. Panorama revenue increased \$23.5 million during the year ended December 31, 2015 compared to the year ended December 31, 2014 due to increased Panorama volumes, and revenues from non-Panorama products increased \$7.6 million during the year ended December 31, 2015 compared to the year ended December 31, 2014.

During the year ended December 31, 2016, we processed over 447,000 tests, including over 331,000 Panorama tests accessioned, over 80,000 Horizon carrier screening tests accessioned, and over 17,000 Constellation units. We recognized revenue on greater than 220,000 tests accessioned, including greater than 180,000 Panorama tests and greater than 32,000 Horizon carrier screening tests, in the year ended December 31, 2016. Eighty-three percent of the 220,000 tests, including 84% of the 180,000 Panorama tests and 81% of the 32,000 Horizon career screening tests were accessioned in the year ended December 31, 2016 and the remainder were accessioned in prior years. During the year ended December 31, 2015, we accessioned greater than 310,000 tests, including greater than 254,000 Panorama tests and greater than 42,000 Horizon carrier screening tests. We recognized revenue on greater than 138,000 tests, including greater than 118,000 Panorama tests and greater than 12,600 Horizon carrier screening tests, in the year ended December 31, 2015. Eighty-four percent of the 138,000 tests, including 85% of the 118,000 Panorama tests and 75% of the 12,600 Horizon carrier screening tests, were accessioned in the year ended December 31, 2015, and the remainder were accessioned in prior years. During the year ended December 31, 2014, we accessioned greater than 215,000 tests, including greater than 185,000 Panorama tests and greater than 16,300 Horizon carrier screening tests. We recognized revenue on greater than 138,000 tests, including greater than 121,000 Panorama tests and greater than 7,600 Horizon carrier screening tests, in the year ended December 31, 2014. Ninety-three percent of the 138,000 tests, including 94% of the 121,000 Panorama tests and 86% of the 7,600 Horizon carrier screening tests, were accessioned in the year ended December 31, 2014, and the remainder were accessioned in prior years.

The number of tests we accession in a given period differs from the number of tests on which we recognize revenue in that period because we recognize revenue for certain tests upon cash receipt, which may occur a number of months after the test is accessioned; and in some cases, we do not ultimately receive reimbursement or payment for tests we accession. The vast majority of tests distributed through our direct sales force are billed to insurance payers and revenue is predominantly recognized on a cash basis as price is not fixed and determinable and collection is not reasonably assured. The percentage of tests that was both accessioned and recognized as revenue within the same year in the year ended December 31, 2016 was flat when compared to the same period of the prior year. The percentage of tests that were both accessioned and recognized as revenue during the year ended December 31, 2015 decreased when compared to the year ended December 31, 2014 due to the increasing percentage of tests distributed through our direct sales force in each year. We also saw an increase in the percentage of revenue recognized in the three months ended December 31, 2016 from tests accessioned in that period, compared to the three months ended September 30, 2016. Approximately 58% of revenue recognized in the three months ended December 31, 2016 was derived from test volumes accessioned in that quarter, compared to approximately 51% of revenue recognized from tests accessioned in the quarter ended September 30, 2016. This increase is primarily attributable to the transition of Bio-Reference from a cash basis payer to an accrual basis payer, which resulted in revenue being recognized at the time this payer was billed.

Revenues from customers outside the United States were \$24.0 million, \$25.4 million and \$22.8 million for the year ended December 31, 2016, 2015 and 2014, respectively.

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

Cost of product, licensing and other revenues increased \$22.7 million, or 20%, in the year ended December 31, 2016 compared to the year ended December 31, 2015 primarily due to an increase in the volume of tests performed in the year, combined with an increase in material and other related costs of \$10.0 million, which are directly related to the continuing growth in Panorama and HCS tests performed and additional costs incurred by outsourcing HCS test processing to laboratories in the year ended December 31, 2016. The increase is also attributed to higher payroll and related expenses of \$1.3 million, outside service costs of \$1.0 million, cost to operate our laboratory and testing of \$0.8 million, as well as facility related expenses and overhead of \$5.0 million. As a percentage of total revenues, cost of product, licensing and other revenues were 63% for the year ended December 31, 2016 compared to 59% for the year ended December 31, 2015 as a result of innovations that allowed us to streamline our laboratory workflows and other laboratory-related efficiencies. The percentage of our revenues attributable to cost of product, licensing and other revenues is impacted because we continued to derive Panorama volume growth in the average risk population, which is not yet broadly reimbursed.

The increase in cost of product, licensing and other revenues in the year ended December 31, 2016 also included total asset impairment charge of \$1.9 million following our impairment analysis on certain sequencing and automation equipment whose service lives were determined to be significantly shorter than initially expected. Additionally, we wrote off the remaining maintenance service contract associated with the equipment described above. Those equipment were phased out in January 2017 as we began our transition to the next generation of sequencing and automation equipment to streamline our production workflows. Further, we recorded a \$2.1 million write down of inventory that we determined as obsolete in connection with our impairment analysis of the associated automation and sequencing equipment described above.

Cost of product, licensing and other revenues increased \$34.4 million, or 43.9%, in the year ended December 31, 2015 compared to the year ended December 31, 2014 primarily due to an increase in the volume of tests performed in the year combined with an increase in material and personnel costs, which are directly related to the growth in Panorama tests performed in the year ended December 31, 2015. As a percentage of total revenues, cost of product, licensing and other revenues were 59.3% for the year ended December 31, 2015 compared to 49.2% for the year ended December 31, 2014 in part due to increased cost per test related to expenses associated with our microdeletions panel, impairment of assets expected to be sold and increased proportion of Horizon carrier screening, which has a higher cost per test than Panorama. Also, we continued to drive Panorama volume growth in the average risk population, which is not yet broadly reimbursed.

We recorded an asset impairment charge of \$1.0 million against a specific group of machinery and equipment during the year ended December 31, 2015. We no longer use this specific group of machinery and equipment because of outsourcing to our partners. The impairment charge was recorded to reflect reductions in the estimated realizable value of the machinery and equipment as a result of planning for its sale in the secondary market. We recorded the total impairment charge of \$1.0 million in cost of product, licensing and other revenues. We sold some of the impaired machinery and equipment during the fourth quarter of 2015 for \$0.5 million and classified the remaining impaired machinery and equipment as held for sale at the estimated realizable value of \$0.2 million.

#### *Research and development*

Research and development expenses increased \$14.2 million, or 51%, in the year ended December 31, 2016 compared to the year ended December 31, 2015. The increase was primarily the result of higher salaries and related expenses of \$8.7 million associated with headcount growth and the new 2015 Employee Stock Purchase Plan, or ESPP, offered to our employees, \$3.1 million of outside service costs related to outsourcing the processing of our Horizon carrier screening tests to other providers, \$1.9 million of facilities and other office related expenses, and \$1.3 million of expenses incurred by clinical studies and trials of our future product offerings, offset by \$1.1 million of operation costs due to reduced usage of our automation and sequencing equipment in production.

Research and development expenses increased \$10.4 million, or 60.3%, in the year ended December 31, 2015 compared to the year ended December 31, 2014. The increase in research and development expenses was primarily attributable to a \$6.5 million increase in salaries and personnel-related costs associated with an increase in research and development headcount as well as a \$1.9 million increase in outside services costs, a \$1.1 million increase in laboratory expenses, and a \$0.9 million increase in office, facilities and other expenses. We expect our research and development expenses will increase in absolute dollars in future periods as we continue to invest in research and development activities related to developing additional products. In the near term, we will continue to grow research and development expenses in support of Panorama, Constellation, and other future programs, including the application of our proprietary technologies for cancer and other disease detection.

#### *Selling, general and administrative*

Selling, general and administrative expenses increased \$26.5 million, or 24%, in the year ended December 31, 2016 compared to the year ended December 31, 2015. The increase was primarily attributable to a 21% headcount growth and infrastructure implementation since we became a public company in July 2015, resulting in a \$10.1 million higher salaries and related expenses and stock-based compensation from the new ESPP offered to our employees. Outside service costs increased in a total of \$5.7 million, of which \$3.5 million was related to consulting on continuing education and training and market research performed for our current and future product offerings, and \$2.2 million was related to contractors hired for our insurance billing and accounting functions, and legal fees paid for assistance on our corporate affairs and compliance with regulations for public companies. Marketing and travel expenses increased \$2.9 million due to increased marketing events, speaker conferences and promotions to our laboratory partners, and sales commissions increased by \$0.9 million resulting from increased product sales. Facilities and other office related expenses increased \$5.1 million primarily due to the transition of our insurance billing operation to our Austin, Texas location and facility improvements and expansions in our California locations to accommodate the continuing headcount growth. Other corporate expenses increased by \$1.6 million due to increased business insurance costs, increased bank service charges, and tax and license fees.

The increase in selling, general and administrative expenses also included an asset impairment charge of \$0.2 million for the year ended December 31, 2016. The impairment charge was recorded to write off the carrying value of an equipment that was not actively used in production based on our assessment.

Selling, general and administrative expenses increased \$46.7 million, or 74.2%, in the year ended December 31, 2015 compared to the year ended December 31, 2014. The increase in selling, general and administrative expenses was primarily attributable to a \$30.7 million increase in salaries and personnel-related costs associated with an increase in sales and marketing personnel to support our growth in our direct sales model. Selling, general and administrative expenses reflects the net addition of 142 employees and contractors from December 31, 2014 to December 31, 2015. In addition, we experienced a \$5.4 million increase in travel expenses and \$2.1 million increase in outside services costs, primary related to insurance billing and legal fees. Marketing expenses increased \$3.2 million, administrative and other expenses increased \$2.1 million, office expenses increased \$1.9 million, and facilities expenses increased \$1.3 million. As we continue to grow as a public company, we expect our selling, general and administrative expenses to continue to increase.

#### *Interest expense*

Interest expense decreased \$3.0 million, or 85%, in the year ended December 31, 2016 compared to the year ended December 31, 2015, primarily due to the repayment of the higher interest rate senior secured term loan, see “*Liquidity and Capital Resources—Senior Secured Term Loan*,” compared to the interest rate on the line of credit. See “*Liquidity and Capital Resources—Credit Line Agreement*.”

Interest expense decreased \$0.7 million, in the year ended December 31, 2015 compared to the year ended December 31, 2014 and was primarily comprised of interest expense related to the senior secured term loan and equipment financing facility.



### *Interest benefit from changes in the fair value of long-term debt*

Interest benefit from changes in the fair value of long-term debt decreased \$1.0 million in the year ended December 31, 2016 compared to the year ended December 31, 2015 due to the payment in full of the senior secured loan in October 2015.

Interest benefit from changes in the fair value of long-term debt increased \$0.8 million in the year ended December 31, 2015 compared to the year ended December 31, 2014 due to fair value measurement of the senior secured term loan for the year ended December 31, 2015. This term loan was entered into in April 2013 and repaid in October 2015.

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

Interest and other income (expense), net increased \$9.3 million, or 118%, in the year ended December 31, 2016 compared to the year ended December 31, 2015 primarily due to the elimination of \$7.3 million of debt extinguishment expenses resulting from the repayment of our senior secured term loan, a \$1.3 million favorable movement on the change in the fair value of our warrant obligation and a \$1.3 million increase in interest income earned on investments, offset by \$0.6 million increase in other expenses from the previous year.

Interest and other income (expense), net increased \$6.2 million in the year ended December 31, 2015 compared to the year ended December 31, 2014 and was primarily related to the debt extinguishment expenses from the repayment of our senior secured term loan.

### **Liquidity and Capital Resources**

We have incurred net losses each year since our inception. For the years ended December 31, 2016, 2015 and 2014, we had net losses of \$95.8 million, \$70.3 million and \$5.2 million, respectively, and we expect to incur additional losses in future years. As of December 31, 2016 and 2015, we had \$15.3 million and \$28.9 million of cash and cash equivalents, \$1.4 million and \$1.6 million of restricted cash, \$130.9 million and \$201.6 million of investments, and an accumulated deficit of \$345.9 million and \$250.1 million, respectively.

### **Initial Public Offering**

In July 2015, we completed an initial public offering (“IPO”), and subsequently in August 2015, we completed the sale of additional shares upon exercise of the underwriters’ over-allotment option. In connection with the IPO, we sold 10,900,000 shares of common stock at \$18.00 per share, which raised \$178.5 million in proceeds, net of underwriting discounts, commissions, and offering expenses.

### **Senior Secured Term Loan**

In April 2013, we entered into a senior secured term loan arrangement with ROS Acquisition, L. P., as amended June 6, 2014, which we refer to as the Secured Loan Arrangement for \$40.0 million in aggregate borrowing capacity, of which we borrowed \$20.0 million. The Secured Loan Arrangement consisted of a term loan, or Credit Agreement, a warrant to purchase 376,691 shares of common stock with an exercise price of \$2.3229 per share (which expires in April 2023) and an agreement to pay royalties on our revenues, or Royalty Agreement. In October 2015, we made a \$28.0 million payment to ROS to extinguish the amounts owed, which included the principal and royalty obligation. This terminated the term loan, royalty and all associated liens securing the Credit Agreement.

### **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. In October 2015, we borrowed \$32.0 million against the Credit Line, primarily to prepay all outstanding amounts under the Credit Agreement with ROS. The Credit Line bears interest at one-month LIBOR plus 0.65%, and equaled approximately 0.84% per annum at the time of the draw. The Credit Line 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.

In November 2015, we borrowed an additional \$10.0 million from the Credit Line to provide working capital at an interest rate of approximately 0.85% (one-month LIBOR plus 0.65%). This draw down increased the total principal amount outstanding under the Credit Line to \$42.0 million. We accrued \$0.1 million in interest on the \$42.0 million Credit Line during the year ended December 31, 2015. In June 2016, we borrowed an additional \$8.0 million from the Credit Line and repaid \$1.0 million, thereby resulting in a remaining \$0.4 million available for draw down, net of accrued interest of \$0.6 million as of December 31, 2016.

### ***Equipment Financing Facility***

In November 2011, we entered into a loan and security agreement with Comerica Bank. We amended this agreement in January 2012, May 2012, January 2013, April 2013 and December 2014, or the Fifth Amendment. The loan and security agreement, as amended, or the Equipment Financing Facility, allowed us to borrow \$5.9 million to fund equipment purchases. We paid interest on the unpaid principal at the financial institution's prime rate plus 3.10%, which equals 6.35%.

In September 2015, we repaid the remaining balance of the Equipment Financing Facility in the amount of \$4.1 million comprising principal, interest and administrative fees and settling our obligations under the Equipment Financing Facility.

### **Cash Flows**

Our primary uses of cash are to fund our operations as we continue to grow our business. We expect to continue to incur operating losses in the future as our operating expenses increase to support the growth of our business. We expect that our research and development, and selling, general and administrative expenses will continue to increase as we expand our marketing efforts and support our internal sales force to drive increased adoption of and reimbursement for Panorama, continue our research and development efforts with respect to expanding Panorama's and Horizon's capabilities and further developing our product pipeline. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

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 16, 2017. Management may elect, however, to finance operations by selling additional equity securities. If additional funding is required or desired, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all, or that we will generate sufficient cash from operations to adequately fund our operating needs or achieve or sustain profitability. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to curtail planned activities to reduce costs. Doing so will likely have an unfavorable effect on our ability to execute on our business plan. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition, and results of operations could be adversely affected.

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 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 us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our products and significantly scale back our business and operations.

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

	Year Ended December 31,		
	2016	2015	2014
	(In thousands)		
Cash (used in) provided by operating activities .	\$ (73,902)	\$ (37,832)	\$ 10,490
Cash provided by (used in) investing activities .	47,027	(210,679)	(9,942)
Cash provided by financing activities . . . . .	13,184	190,282	56,132
Net (decrease) increase in cash . . . . .	(13,691)	(58,229)	56,680
Cash at beginning of year . . . . .	28,947	87,176	30,496
Cash at end of year . . . . .	\$ 15,256	\$ 28,947	\$ 87,176

### Cash (Used in) Provided by Operating Activities

Cash used in operating activities for the year ended December 31, 2016 was \$73.9 million. The net loss of \$95.8 million was the primary use of our cash, which included a number of noncash items such as 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 before 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. The increase in net operating assets of \$13.7 million was primarily due to increases in accounts receivable of \$8.5 million, other assets of \$2.8 million, prepaid expenses and other current assets of \$2.1 million, inventory of \$0.4 million, offset by a decrease in restricted cash of \$0.1 million. Operating liabilities increased \$11.6 million, which was the result of an increase in other accrued liabilities of \$7.4 million, an increase in accrued compensation of \$2.5 million, an increase in accounts payable of \$1.3 million, and a \$0.4 million increase in deferred revenue.

Cash used in operating activities for the year ended December 31, 2015 was \$37.8 million. The net loss of \$70.3 million reflects, cash charges of \$7.3 million, non-cash charges of \$5.5 million of depreciation and amortization, \$7.3 million of stock compensation expense and a \$0.5 million charge from the change in the value of long-term debt and warrants, \$1.6 million impairment on assets, and other non-cash charges of \$0.9 million. The increase in operating assets of \$2.6 million was primarily due to an increase in prepaid assets and other current assets of \$3.8 million, an increase in accounts receivable of \$0.5 million, and an increase in other assets and restricted cash of \$1.3 million, offset by a decrease in inventory of \$2.9 million. Operating liabilities increased by \$12.0 million primarily driven by increases in accounts payable of \$1.4 million, accrued compensation of \$2.6 million, and other accrued liabilities of \$8.0 million.

Cash provided by operating activities for the year ended December 31, 2014 was \$10.5 million. The net loss of \$5.2 million reflects non-cash charges of \$5.1 million of depreciation and amortization, \$5.2 million of stock compensation, a \$1.7 million charge from the change in the value of warrants and other non-cash charges of \$0.2 million. The increase in operating assets of \$0.7 million was primarily due to a \$0.9 million increase in inventory to meet the material requirements for the sale of Panorama and an increase in prepaid assets of \$0.1 million offset by a decrease in accounts receivable of \$0.3 million. Operating liabilities increased by \$4.1 million primarily driven by increases in accrued compensation of \$3.0 million and other accrued liabilities of \$4.4 million offset by decreases in accounts payables of \$2.4 million and deferred revenue of \$0.9 million.

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

Cash provided by investing activities for the year ended December 31, 2016 totaled \$47.0 million, which was comprised of \$70.2 million in investment proceeds, net of purchases, and the acquisition of \$23.2 million of property and equipment, net of proceeds. Acquisitions of property and equipment are primarily related to the build out of our Austin, Texas diagnostic testing facility, leasehold improvements completed for the expansion of our headquarters in San Carlos, California, and purchases of computer hardware and software.



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

As of December 31, 2016, we sub-lease office facilities under non-cancelable operating lease agreements. We occupy approximately 88,000 square feet of laboratory and office space at our corporate headquarters in San Carlos, California pursuant to two separate subleases. One sublease covers approximately 61,000 square feet (the “First Space”), and the other sublease covers approximately 27,000 square feet (the “Second Space”). In connection with the sublease for the First Space in January 2013 and the Second Space in March 2014, we executed two letters of credit in favor of the lessors for \$0.8 million and \$0.3 million, respectively.

In October 2016, we amended the lease agreement that we entered into with the landlord of our First Space and Second Space (as described above) to include a sublease of additional office space to accommodate our growth and consolidate our operations in California at one location. The additional sublease covers approximately 48,000 square feet of office space and consists of two phases. The first phase began in October 2016 and covers approximately 16,000 square feet of office space at a base rent of \$60,730 per month. The second phase began in January 2017, which covers approximately 32,000 square feet of office space at a base rent of \$121,460 per month. The term of this sublease is approximately eighty-four months, with the same expiration date as the First Space and Second Space, which is in October 2023.

In April 2015, we entered into a sublease agreement for additional office space in Redwood City, California. The additional carried a base rent of \$0.1 million per month. The lease period began in June 2015 and terminated in August 2016 with no option to extend the lease. In addition, we paid a security deposit of \$0.1 million.

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 was 132 months and began in December 2015 with monthly rent payments beginning in December 2016, increasing from \$0.1 million to \$0.2 million. Pursuant to the terms of the lease, our subsidiary has paid a security deposit of \$0.4 million, and the landlord has allotted the subsidiary a refundable allowance for leasehold improvements of up to \$7.8 million. As of December 31, 2016, a total of \$5.4 million of the allowance has been reimbursed by the landlord.

In October 2015, our subsidiary entered into a one year lease agreement for temporary office space in Austin, Texas. The property carries a monthly rent of \$12,900 per month for the 12 months of the lease and \$12,900 per month on a month to month basis following the 12<sup>th</sup> month. The terms of the lease include a \$12,900 security deposit.

We amortize our leasehold improvements allowance over the entire life of the lease contract on a straight-line basis as an offset to monthly rent expense. Monthly rent expense is calculated by summing all of the rent payments over the life of the lease and calculating the monthly rent expense on a straight-line basis by dividing the sum of all payments over the life of the lease by the number of months in the lease contract. Monthly rent expense is then offset by the amortization of leasehold improvements allowance when applicable.

### ***Inventory Purchase Obligations***

As of December 31, 2016, we have non-cancelable contractual commitments with Illumina, Inc. and other material suppliers for approximately \$5.1 million and \$3.4 million respectively, for inventory material used in the laboratory testing process. This represents binding and future minimum purchase obligations within the next 12 months.

### ***Contractual Obligations***

As of December 31, 2016, we have a non-cancelable license agreement with a vendor for approximately \$3.0 million. This represents binding and remaining commitments with the vendor through December 31, 2019.

### ***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 0.65%. The LIBOR rate is variable. An incremental change in the borrowing rate of 100 basis points would increase our annual interest expense by approximately \$0.5 million based on our \$49.6 million balance under the Credit Line including principal and accrued interest as of December 31, 2016.

Our investment portfolio is exposed to market risk from changes in interest rates. This risk is mitigated as we have maintained a relatively short average maturity for our investment portfolio. If a 100 basis point change in interest rates were to occur to our investments in 2016, our interest income would change by approximately \$1.3 million annually in relation to amounts we would expect to earn, based on our cash, cash equivalents, and short-term investments as of December 31, 2016.

### ***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.

We have audited the accompanying consolidated balance sheets of Natera, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Natera, Inc. at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Redwood City, California  
March 16, 2017

# **PART I – FINANCIAL INFORMATION**

## **ITEM 1. FINANCIAL STATEMENTS**

### **Natera, Inc.** **Consolidated Balance Sheets** *(In thousands, except per share data)*

	<u>December 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 15,256	\$ 28,947
Restricted cash, current portion . . . . .	1,092	901
Short-term investments . . . . .	130,860	201,586
Accounts receivable, net of allowance of \$1,890 in 2016 and \$971 in 2015 . . . . .	13,396	5,862
Inventory . . . . .	6,414	8,093
Prepaid expenses and other current assets . . . . .	7,097	5,337
Total current assets . . . . .	<u>174,115</u>	<u>250,726</u>
Property and equipment, net. . . . .	32,289	12,710
Restricted cash, long term portion . . . . .	342	683
Other assets . . . . .	3,934	1,121
Total assets. . . . .	<u>\$ 210,680</u>	<u>\$ 265,240</u>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable. . . . .	\$ 11,479	\$ 7,332
Accrued compensation . . . . .	11,067	8,552
Other accrued liabilities. . . . .	19,879	18,708
Deferred revenue . . . . .	574	144
Short-term debt financing . . . . .	49,624	42,090
Warrants . . . . .	3,792	3,649
Total current liabilities . . . . .	<u>96,415</u>	<u>80,475</u>
Deferred rent, net of current portion. . . . .	7,789	—
Total liabilities. . . . .	<u>104,204</u>	<u>80,475</u>
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value: 50,000 shares authorized; no shares issued and outstanding at December 31, 2016 and 2015, respectively . . . . .	—	—
Common stock, \$0.0001 par value: 750,000 shares authorized at both December 31, 2016 and December 31, 2015, respectively; 52,665 and 50,346 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively . . . . .	5	5
Additional paid in capital. . . . .	453,044	436,259
Accumulated deficit . . . . .	(345,848)	(250,083)
Accumulated other comprehensive loss . . . . .	(725)	(1,416)
Total stockholders' equity . . . . .	<u>106,476</u>	<u>184,765</u>
Total liabilities and stockholders' equity. . . . .	<u>\$ 210,680</u>	<u>\$ 265,240</u>

See accompanying notes.

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

	<b>Year ended December 31,</b>		
	<b>2016</b>	<b>2015</b>	<b>2014</b>
<b>Revenues</b>			
Product revenues . . . . .	\$ 213,968	\$ 188,168	\$ 157,308
Licensing and other revenues . . . . .	<u>3,106</u>	<u>2,187</u>	<u>1,981</u>
Total revenues . . . . .	217,074	190,355	159,289
<b>Cost and expenses</b>			
Cost of product, licensing and other revenues . . . . .	135,574	112,845	78,396
Research and development . . . . .	41,862	27,711	17,292
Selling, general and administrative . . . . .	<u>136,126</u>	<u>109,637</u>	<u>62,936</u>
Total cost and expenses . . . . .	<u>313,562</u>	<u>250,193</u>	<u>158,624</u>
<b>(Loss) income from operations</b> . . . . .	(96,488)	(59,838)	665
Interest expense . . . . .	(533)	(3,505)	(4,219)
Interest benefit from changes in the fair value of long term debt . . . . .	—	964	118
Interest and other income (expense), net . . . . .	<u>1,398</u>	<u>(7,896)</u>	<u>(1,716)</u>
Loss before income taxes . . . . .	(95,623)	(70,275)	(5,152)
Income tax expense . . . . .	<u>(142)</u>	<u>—</u>	<u>—</u>
Net loss . . . . .	<u>\$ (95,765)</u>	<u>\$ (70,275)</u>	<u>\$ (5,152)</u>
Unrealized gain (loss) on available-for-sale securities, net of tax . . . . .	691	(1,416)	—
Comprehensive loss . . . . .	<u>\$ (95,074)</u>	<u>\$ (71,691)</u>	<u>\$ (5,152)</u>
 Basic and diluted net loss per share . . . . .	 <u>\$ (1.86)</u>	 <u>\$ (2.68)</u>	 <u>\$ (1.07)</u>
 Weighted-average number of shares used in computing basic and diluted net loss per share . . . . .	 <u>51,576</u>	 <u>26,204</u>	 <u>4,800</u>

See accompanying notes.



**Natera, Inc.**  
**Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
*(In thousands, except per share data)*

(in thousands)	Convertible Preferred Stock		Common Stock		Additional Paid-in	Notes Receivable	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	from Officers	Loss	Deficit	Equity (Deficit)
Balance as of December 31, 2013. . . . .	27,048	\$ 185,199	6,561	\$ 1	\$ 3,338	\$ (192)	—	\$ (174,656)	\$ (171,509)
Issuance of Series F Convertible Preferred Stock at \$12.76 per share net of issuance costs of \$86,933. . . . .	4,349	55,413	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options. . . . .	—	—	318	—	169	—	—	—	169
Stock-based compensation. . . . .	—	—	—	—	5,157	—	—	—	5,157
Net loss. . . . .	—	—	—	—	—	—	—	(5,152)	(5,152)
Balance as of December 31, 2014. . . . .	31,397	240,612	6,879	1	8,664	(192)	—	(179,808)	(171,335)
Issuance of common stock upon exercise of stock options. . . . .	—	—	1,170	—	1,258	—	—	—	1,258
Stock-based compensation. . . . .	—	—	—	—	7,326	—	—	—	7,326
Issuance costs of Series F Convertible Preferred Stock. . . . .	—	(27)	—	—	—	—	—	—	—
Officer loan receivable repayment. . . . .	—	—	—	—	—	192	—	—	192
Issuance of common stock in connection with the initial public offering. . . . .	—	—	10,900	1	182,465	—	—	—	182,466
Issuance costs of initial public offering. . . . .	—	—	—	—	(4,036)	—	—	—	(4,036)
Conversion of all Preferred Stock into Common Stock upon the completion of the initial public offering. . . . .	(31,397)	(240,585)	31,397	3	240,582	—	—	—	240,585
Unrealized (loss) on available-for-sale investments. . . . .	—	—	—	—	—	—	(1,416)	—	(1,416)
Net loss. . . . .	—	—	—	—	—	—	—	(70,275)	(70,275)
Balance as of December 31, 2015. . . . .	—	—	50,346	5	436,259	—	(1,416)	(250,083)	184,765
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 investments. . . . .	—	—	—	—	—	—	691	—	691
Net loss. . . . .	—	—	—	—	—	—	—	(95,765)	(95,765)
Balance as of December 31, 2016. . . . .	—	\$ —	52,665	\$ 5	\$ 453,044	\$ —	\$ (725)	\$ (345,848)	\$ 106,476

See accompanying notes.

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

	<b>Year Ended December 31,</b>		
	<b>2016</b>	<b>2015</b>	<b>2014</b>
<b>Operating activities</b>			
Net loss . . . . .	\$ (95,765)	\$ (70,275)	\$ (5,152)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization . . . . .	6,176	5,535	5,148
Amortization of premium on investment securities . . . . .	1,445	288	—
Gain realized on investment securities . . . . .	(191)	—	—
Impairment of assets . . . . .	2,138	1,557	—
Inventory excess adjustments . . . . .	2,110	—	—
Stock-based compensation . . . . .	10,601	7,326	5,157
Loss from changes in fair value of warrants . . . . .	143	1,481	1,664
Provision for doubtful accounts . . . . .	984	529	349
Non-cash interest accrual . . . . .	533	—	—
(Gain) loss on sales of property and equipment . . . . .	—	(2)	11
Amortization of debt discount . . . . .	—	28	—
Gain from change in fair value of long term debt . . . . .	—	(964)	(118)
Loss on debt extinguishment . . . . .	—	7,313	—
Changes in operating assets and liabilities:			
Accounts receivable . . . . .	(8,518)	(450)	341
Inventory . . . . .	(431)	2,929	(890)
Prepaid expenses and other current assets . . . . .	(2,077)	(3,797)	(137)
Restricted cash . . . . .	150	(273)	—
Other assets . . . . .	(2,812)	(1,041)	(24)
Accounts payable . . . . .	1,256	1,354	(2,430)
Income taxes payable . . . . .	—	—	(15)
Accrued compensation . . . . .	2,515	2,572	2,994
Other accrued liabilities . . . . .	7,411	8,026	4,450
Deferred revenue . . . . .	430	32	(858)
Net cash (used in) provided by operating activities . . . . .	<u>(73,902)</u>	<u>(37,832)</u>	<u>10,490</u>
<b>Investing activities</b>			
Purchases of investments . . . . .	(53,522)	(203,290)	—
Proceeds from sale of investments . . . . .	59,185	—	—
Proceeds from maturity of investments . . . . .	64,500	—	—
Proceeds from sale of property and equipment . . . . .	—	463	15
Purchases of property and equipment, net . . . . .	<u>(23,136)</u>	<u>(7,852)</u>	<u>(9,957)</u>
Net cash provided by (used in) investing activities . . . . .	<u>47,027</u>	<u>(210,679)</u>	<u>(9,942)</u>
<b>Financing activities</b>			
Proceeds from issuance of common stock, net of issuance costs . . . . .	—	180,001	170
Proceeds from exercise of stock options . . . . .	3,595	1,258	—
Proceeds from issuance of common stock under employee stock purchase plan . . . . .	2,589	—	—
Proceeds from issuance of preferred stock, net . . . . .	—	—	55,413
Borrowings under credit facility . . . . .	8,000	—	—
Repayment under credit facility . . . . .	(1,000)	—	—
Costs paid for loan . . . . .	—	(6)	—
Proceeds from short-term financing . . . . .	—	42,000	—
Proceeds from equipment financing . . . . .	—	—	5,105
Repayments of equipment financing . . . . .	—	(5,850)	(2,480)
Repayments of secured financings . . . . .	—	(20,000)	—
Proceeds from collection of officer receivable . . . . .	—	192	—
Payment to lender for debt extinguishment . . . . .	—	(7,313)	—
Change in restricted cash . . . . .	—	—	(415)
Deferred offering costs . . . . .	—	—	(1,661)
Net cash provided by financing activities . . . . .	<u>13,184</u>	<u>190,282</u>	<u>56,132</u>
Net (decrease) increase in cash . . . . .	<u>(13,691)</u>	<u>(58,229)</u>	<u>56,680</u>
Cash at beginning of period . . . . .	28,947	87,176	30,496
Cash at end of period . . . . .	<u>\$ 15,256</u>	<u>\$ 28,947</u>	<u>\$ 87,176</u>
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for interest . . . . .	\$ —	\$ 2,060	\$ 2,063
Purchases of property and equipment through accounts payable and accruals . . . . .	<u>\$ 5,204</u>	<u>\$ 765</u>	<u>\$ 3,223</u>
Conversion of convertible preferred stock to common stock . . . . .	<u>\$ —</u>	<u>\$ 240,585</u>	<u>\$ —</u>

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; Horizon Carrier Screening ("Horizon") 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 exclusively by a licensee from whom the Company receives a royalty. All testing is available principally in the United States and 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.

#### **Initial Public Offering**

In July 2015, the Company completed an initial public offering ("IPO"), and subsequently in August 2015, the Company completed the sale of additional shares upon exercise of the underwriters' over-allotment option. In connection with the IPO, including the over-allotment option, the Company sold 10,900,000 shares of common stock at \$18.00 per share, which raised \$178.5 million in proceeds, net of underwriting discounts and commissions and offering expenses.

#### **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").

##### ***Need to Raise Additional Capital***

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, 2016, the Company had a net loss of \$95.8 million, and as of December 31, 2016, it had an accumulated deficit of \$345.9 million. At December 31, 2016, the Company had \$15.3 million in cash and cash equivalents, \$130.9 million in marketable securities, and \$49.6 million of outstanding debt with accrued interest. While the Company has introduced multiple products that are generating revenues, these revenues have not been sufficient to fund all operations. Accordingly, the Company has funded the portion of operating costs that exceeds revenues through a combination of equity issuances, debt issuances, and other financings.

The Company expects 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.

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 16, 2017.

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

The accompanying condensed consolidated financial statements include all the accounts of the Company and its subsidiary. The Company established a subsidiary that operates in the state of Texas in December 2014 to support the Company's laboratory and operational functions, which became active in the second quarter of 2015. 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, accrued liability for potential refund requests, stock-based compensation, the fair value of common stock and fair value of debt accounted for under ASC 815, as well as income tax uncertainties. 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; however, actual results could differ from these estimates and could have an adverse effect on the Company's financial statements.

### ***Fair Value***

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

### ***Cash and Cash Equivalents***

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

### ***Restricted Cash***

The Company discloses both short-term and long-term restricted cash. Short-term restricted cash consists of \$1.1 million, which secured a \$0.8 million letter of credit for the sublease of the First Space (defined in Note 6) that expired in October 2016, however, the associated restriction has not been released as of December 31, 2016, and a \$0.3 million letter of credit for the sublease of the Second Space (defined in Note 6), which expired in January 2017. Long-term restricted cash consists of \$0.3 million deposit per credit card terms.

### ***Investments***

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 loss, which is a separate component of stockholders' equity.

### ***Risk and Uncertainties***

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

The Company bills third-party payers for certain tests performed. The amount that is ultimately received from the payer for the Company's claim and the timing of such payments are subject to the determination of the payer based on the nature of the test performed and their view of the Company's business practices with respect to collections of plan deductibles and co-payments from patients and other activities. This determination can impact both the amount and timing of when the Company's invoices are collected. Payers may also withhold payments and request refunds of prior payments if the Company does not perform 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. For 2016, 2015 and 2014, there were no customers exceeding 10% in total revenue. As of December 31, 2016, one customer had an outstanding balance of approximately 52% of net accounts receivable, and as of December 31, 2015, no customers had an outstanding balance greater than 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 generally bills an insurance carrier, a clinic or a patient for the test upon delivery of the test result. The Company also bills patients directly for out-of-pocket costs not covered by their insurance carriers representing co-pays and deductibles in accordance with their insurance carrier and health plans. For tests performed, where an agreed upon reimbursement rate or fixed fee and a predictable history or likelihood of collections exists, the Company recognizes revenues upon delivery of the test report to the prescribing physician based on the established billing rate less contractual and other adjustments, such as an allowance for doubtful accounts, to arrive at the amount that the Company expects to collect. In all other situations, as the Company does not have sufficient history of collection and is not able to determine collectability, the Company recognizes revenues when cash is received. The Company may not get reimbursed for tests completed if the tests are not covered under the insurance carrier's reimbursement policies or the Company is not a qualified provider to the insurance carrier. From time to time, the Company receives requests for refunds of payments previously made by insurance carriers. The Company has established an accrued liability for potential refund requests based on its experience, which is accounted for as reductions in revenues in the statement of operations and comprehensive loss.

In cases where the Company sells its tests through its laboratory partners, the majority of the laboratory partners bill the patient, clinic, or insurance carrier for the performance of the Company's tests.

For tests sold through a limited number of its laboratory partners, the Company bills directly to a patient, clinic or insurance carrier, or a combination of the insurance carrier and patient for the fees. The Company considers its services



rendered when it delivers reports of its test results to the laboratory partner, clinic or patient. When the Company has contracted fixed rates for its services and collectability of its revenues is reasonably assured, it recognizes revenues upon delivery of test reports. The fixed fees identified in contracts with laboratory partners change only if a pricing amendment is agreed upon between both parties. For cases in which there is no fixed price established with a laboratory partner, the Company then recognizes revenues from partner distributed tests on a cash basis.

Certain of the Company's arrangements include multiple deliverables. For revenue arrangements with multiple deliverables, the Company evaluates each deliverable to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has "stand-alone value" to the customer and whether a general right of return exists. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. The Company uses judgment in identifying the deliverables in its arrangements, assessing whether each deliverable is a separate unit of accounting, and in determining the best estimate of selling price for certain deliverables. The Company also uses judgment in determining the period over which the deliverables are recognized in certain of its arrangements. Any amounts received that do not meet the criteria for revenue recognition are recorded as deferred revenue until such criteria are met.

The Company receives royalty revenue through the licensing and the provisioning of services to support the use of the Company's proprietary technology with its customer. Royalty revenues are recognized when earned under the terms of the related agreements and are included in licensing and other revenues in the statements of operations and comprehensive loss.

The Company recognizes revenue from the cloud-based distribution service offering. The Company grants its customers licenses to use the Company's proprietary intellectual properties and the cloud-based Natera software, and provides the other services to support the use of the Company's proprietary technology with its customers. Natera's proprietary software is used in connection with the analysis of DNA sequence data in a manner yielding a result indicating the likely presence or absence of full or partial chromosomal abnormalities. The licensees do not have the right to possess Natera software, but rather are treated as software as a service. The revenues are recognized on an accrual basis (assuming all revenue recognition criteria are met) under the terms of the related agreements and are included in licensing and other revenues in the statements of operation and comprehensive loss.

#### ***Cost of Product, Licensing and Other Revenues***

Cost of product, licensing and other revenues includes the cost of materials, direct labor of laboratory personnel, equipment and infrastructure expenses associated with processing blood and other samples, quality control analyses, and shipping charges to transport samples and specimens from ordering physicians, clinics or individuals. Infrastructure expenses include allocated facility and related occupancy costs. Costs associated with the performance of diagnostic services are recorded as tests are processed.

#### ***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 \$0.4 million, \$1.1 million and \$1.1 million for the years ended December 31, 2016, 2015 and 2014, respectively.

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

The Company expenses product shipment costs in cost of product, licensing and other revenues in the accompanying statements of operations. Shipping and handling costs for the years ended December 31, 2016, 2015 and 2014 were \$8.2 million, \$7.0 million and \$4.5 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 on stock options for employees who do not render the requisite service and therefore forfeit their rights to the stock options. The Company uses the Black-Scholes option-pricing model to estimate the fair value of its stock options.

The Company accounts for stock options issued to non-employees based on the estimated fair value of the awards using the Black-Scholes option-pricing model. 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, a risk-free interest rate, and expected dividends. Determining these assumptions requires significant judgment. The expected term was based on the simplified method and where the Company did not qualify to use the simplified method, the Company used the lattice model, 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. The expected dividend assumption was based on the Company's history and expectation of dividend payouts.

Starting January 1, 2016, the Company uses 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. The Company will continue to adjust the liability for changes in fair value until such time that the warrants are converted or expire.

### ***Capitalized Software Held for Internal Use***

The Company capitalizes costs of software held for internal use during the application development stage of a project and amortize those costs over their estimated useful lives of three years. The net book value of capitalized software held for internal use was \$1.3 million and \$0.8 million as of December 31, 2016 and 2015, respectively. Amortized expense for amounts previously capitalized for the years ended December 31, 2016 and 2015 was \$0.6 million and \$0.2 million, respectively. There was no amortization of such capitalized costs for the year ended December 31, 2014.

### ***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, 2016, and 2015, accumulated other comprehensive loss consisted of \$0.7 million and \$1.4 million of unrealized losses on available-for-sale marketable securities. There was \$0.2 million reclassified out of accumulated other comprehensive loss during the year ended December 31, 2016, and no reclassifications were made in the years ended December 31, 2015 and 2014.

### ***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 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. During the third and fourth quarters of 2016, the Company performed an assessment on its estimated use of certain sequencing and automation equipment. As a result of the assessment, it was determined that the service lives of several of such equipment over which the remaining economic benefit was to be received from were significantly shorter than initially expected by the Company. Additionally, the Company wrote off the remaining maintenance service contract associated with the equipment described above. The Company accounted for the revision of its depreciation estimates on the sequencing and automation equipment and the write off of the unamortized prepaid maintenance as a change in accounting estimate, which increased its loss from operations and net loss by \$1.7 million, and increased its basic and diluted net loss per share by \$0.04 for the year ended December 31, 2016. During the second quarter of 2015, the Company increased the depreciable lives of certain sequencing and automation equipment from three years to five years. The effect of this change in estimate for the year ended December 31, 2015 was a decrease in loss from operations and net loss of \$1.7 million, and a decrease in basic and diluted net loss per share of \$0.07.

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

The Company 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. For the years ended December 31, 2016 and 2015, we recorded asset impairment losses of \$2.1 million and \$1.6 million, respectively. See Note 5 for more detail about the asset 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.

In December 2016, the Company determined \$2.1 million of inventory as obsolete in connection with its impairment analysis of the associated automation and sequencing equipment described above, and recorded an associated charge for these materials.

### ***Recent Accounting Pronouncements***

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or FASB 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.

In August 2014, FASB issued Accounting Standards Update No. 2014-15 (“ASU 2014-15”), *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*. ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. ASU 2014-15 is effective for the Company in the first quarter of 2017 with early adoption permitted. The Company has elected to early adopt this guidance for its annual reporting period ending December 31, 2016, and this ASU applies to all future annual and interim reporting periods. Upon adoption, the Company is required to perform assessment using detailed prospective financial information during each interim period and annually to determine whether substantial doubt exists about its ability to continue as a going concern for at least 12 months from the issuance date of the financial statements, and to provide the related disclosures. As a result of the analysis, the adoption of ASU 2014-15 did not have a material impact on the Company’s financial statements and related disclosures, although the related disclosures could be impacted in future periods.

In May 2014, FASB issued Accounting Standards Update No. 2014-09 (“ASU 2014-09”), *Revenue from Contracts with Customers* to provide guidance on revenue recognition. To date, the Company’s revenues have been derived primarily from contracts with insurance carriers, patients, clinics and licensing arrangements. Approximately 82% of the Company’s revenues are recognized on the cash basis, and based on the Company’s preliminary assessment, this portion of revenues may be recognized at an earlier date than in the period of actual cash receipt. Consideration is received from either patients, clinics, or insurance carriers and/or any combination of the three, and licensees. Each one of these arrangements, whether sell-in or sell-through, is considered unique and being evaluated individually under the five-step process prescribed by the new revenue standard. Currently, the Company continues to assess its contracts with insurance carriers. The Company has not completed its analysis, and it is evaluating whether the impact of adopting ASU 2014-09 will be material to its financial statements. ASU 2014-09 will be effective for the Company in the first quarter of 2018, with early adoption permitted starting the first quarter of 2017. Upon adoption, ASU 2014-09 can be applied retrospectively to all periods presented or using the modified retrospective approach, which requires the cumulative effect of changes reflected in the opening balance of retained earnings only in the most current period presented. The Company has not yet determined which method will be used upon adoption, and will plan on adopting the new guidance in the first quarter of 2018.

In July 2015, FASB issued Accounting Standards Update No. 2015-11 (“ASU 2015-11”), *Inventory (Topic 330): Simplifying the Measurement of Inventory* (ASU 2015-11). ASU 2015-11 simplifies the subsequent measurement of inventory by replacing today’s lower of cost or market test with a lower of cost and net realizable value test. ASU 2015-11 is effective for the Company in the fiscal year beginning after December 15, 2016, and interim periods within those fiscal years. The Company does not expect the adoption of ASU 2015-11 will have a material impact on its financial statements.

In November 2015, FASB issued Accounting Standards Update No. 2015-17 (“ASU 2015-17”), *Balance Sheet Classification of Deferred Taxes*, which simplifies the presentation of deferred taxes by requiring that deferred tax assets and liabilities be presented as noncurrent on the balance sheet. ASU 2015-17 is effective for the Company in the fiscal year beginning after December 15, 2016, and interim periods within those fiscal years. The Company currently does not have any deferred tax assets or liabilities on its balance sheet as a full valuation allowance has been reserved against them, and it does not expect the adoption of ASU 2015-17 will have a material impact on its financial statements.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02 (“ASU No. 2016-02”), *Leases*. 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. ASU 2016-02 is effective for the Company in the fiscal year beginning after December 15, 2018, and interim periods within those fiscal years with early adoption permitted. The Company plans to adopt this new guidance prospectively in the first quarter of 2019. The Company is evaluating the impact of the adoption of this guidance on its financial statements, and expects that it will increase our lease assets and correspondingly increase our lease liabilities.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09 (“ASU 2016-09”), *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 includes provisions intended to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. The new guidance requires any excess tax benefits (“windfalls”) and tax deficiencies (“shortfalls”) associated with vested or settled share-based awards to be recognized in the income statement rather than additional paid-in capital, which is to be applied prospectively. Further, windfalls will be required to be presented as an operating activity rather than as an outflow from operating activity and an inflow to financing activity, as required by the existing guidance. This new presentation guidance can be applied retrospectively or prospectively. The new guidance also eliminates the requirement to delay the recognition of windfalls until it begins to reduce current income taxes payable, and this is to be applied using the modified retrospective approach, with a cumulative effect adjustment to opening retained earnings. In addition, ASU 2016-09 allows entities to withhold an amount up to the employees’ maximum individual tax rate in the relevant jurisdiction without having to account for the award as a liability-based award, and this guidance is to be applied using the modified retrospective approach, with a cumulative effect adjustment to opening retained earnings. ASU 2016-09 also permits forfeitures to be either estimated, as required by the existing guidance, or recognized when they occur. The change in the accounting for forfeitures is required to be applied using a modified retrospective approach, with a cumulative effect adjustment to opening retained earnings. The new guidance will be effective for public entities in fiscal years beginning after December 15, 2016. The Company plans to adopt this new guidance in the first quarter of 2017 and does not expect a material impact on its financial statements given the full valuation allowance position on its deferred tax assets.

In August 2016, the FASB issued Accounting Standards Update No. 2016-15 (“ASU 2016-15”), *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (A Consensus of the Emerging Issues Task Force)*. 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. ASU 2016-15 will be effective for the Company in the fiscal year beginning after December 15, 2017, and interim periods within that fiscal year. The Company is currently evaluating the impact of adopting ASU 2016-15 on its financial statements.

In November 2016, the FASB issued Accounting Standards Update No. 2016-18 (“ASU 2016-18”), *Statement of Cash Flows (Topic 230): Restricted Cash*. The purpose of ASU 2016-18 is to eliminate the diversity in classifying and presenting changes in restricted cash in the statements of cash flows. 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, thereby no longer requiring transactions such as transfers between restricted and unrestricted cash to be treated as a cash flow activity. 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 new guidance will be effective for the Company in the fiscal year beginning after December 15, 2017, and interim periods within that fiscal year, with early adoption permitted. The Company is currently evaluating the effect the new guidance is expected to have on its financial statements.

### **3. 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, a liability for convertible preferred stock warrants and a liability for common stock



warrants. The Company's Credit Line described in Note 8, is not measured at fair value on a recurring basis and is carried at amortized cost. The Company believes that the fair value of the Credit Line approximates its carrying value or amortized costs, due to the short-term nature of this obligation and the interest rate relative to market rates.

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, 2016				December 31, 2015			
	Level I	Level II	Level III	Total	Level I	Level II	Level III	Total
	(in thousands)							
Financial Assets:								
Money market deposits . . . . .	\$ 10,777	\$ —	\$ —	\$ 10,777	\$ 5,966	\$ —	\$ —	\$ 5,966
U.S. Treasury securities . . . . .	57,442	—	—	57,442	103,813	—	—	103,813
U.S. agency securities . . . . .	—	56,114	—	56,114	—	78,853	—	78,853
Municipal securities . . . . .	—	17,304	—	17,304	—	18,920	—	18,920
Total financial assets . . . . .	<u>\$ 68,219</u>	<u>\$ 73,418</u>	<u>\$ —</u>	<u>\$ 141,637</u>	<u>\$ 109,779</u>	<u>\$ 97,773</u>	<u>\$ —</u>	<u>\$ 207,552</u>
Current Liabilities:								
Warrants . . . . .	\$ —	\$ —	\$ 3,792	\$ 3,792	\$ —	\$ —	\$ 3,649	\$ 3,649
Total financial liabilities . . . . .	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,792</u>	<u>\$ 3,792</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,649</u>	<u>\$ 3,649</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. The Company considered the guidance under ASC 825-10, *Financial Instruments*, which provides a measurement basis election for most financial instruments (i.e., either historical cost or fair value), allowing reporting entities to mitigate potential mismatches that arise under the current mixed measurement attribute model and ASC 820, *Fair Value Measurements and Disclosures* that provides for the fair value measurement of assets and liabilities, except for derivatives, for which the fair value is determined by ASC 815, *Derivatives and Hedging*.

The Company evaluated the components of the senior secured term loan and determined that they were derivatives to be evaluated under ASC 815-15-25-1. The fair value accounting for derivatives is not an option, as derivatives must be fair valued under ASC 815 following the measurement guidance under ASC 820. Therefore, the Company engaged a third



party to determine the fair value of the derivatives using the guidance of ASC 820 and recorded the senior secured term loan at fair value.

ASC 815 requires the terms and features of an instrument that are not a derivative itself to be evaluated for embedded derivatives that must be bifurcated and separately accounted for as freestanding derivatives, provided that certain criteria of ASC 815 are met. As a result of the Company's evaluation, it was indicated that the senior secured term loan constituted a liability with embedded derivative features, which were accounted for separately as mark-to-market instruments. As for the warrants that were granted with this senior secured term loan, it was determined that they were detachable and therefore a stand-alone component of the senior secured term loan which was to be fair valued using Level III inputs as a separate derivative. Determining the fair value of these instruments required significant judgment or estimation, and the Company utilized various techniques such as (i) discounted future cash flows, (ii) the income approach, using various revenue assumptions and applying a Monte-Carlo Simulation to each outcome and (iii) Black-Scholes Option Pricing Model with market volatility that was determined by comparison to comparable companies in the same business sector. The fair value of both the senior secured term loan and warrants was re-measured at the end of each reporting period with the change in fair value recorded within non-operating expense in the statements of operations and comprehensive loss. In October 2015, the Company repaid the entire borrowings under the senior secured term loan.

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, 2016 and 2015:

	<b>Warrants</b>	
	<b>2016</b>	<b>2015</b>
	<b>(in thousands)</b>	
Beginning balance .....	\$ 3,649	\$ 2,232
Warrants exercised .....	—	(240)
Change in fair value .....	143	1,657
Ending balance .....	<u>\$ 3,792</u>	<u>\$ 3,649</u>

The following table provides a roll forward of the fair value, as determined by Level III inputs, of the senior secured term loan for the years ended December 31, 2016 and 2015:

	<b>Term Loan</b>	
	<b>2016</b>	<b>2015</b>
	<b>(in thousands)</b>	
Beginning balance .....	\$ —	\$ 20,964
Change in fair value recognized in non-operating expense .....	—	(964)
Loan payment .....	—	(20,000)
Ending balance .....	<u>\$ —</u>	<u>\$ —</u>

The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurement classified in Level III of the fair value hierarchy at December 31, 2016.

	<b>Fair Value at December 31, 2016 (in thousands)</b>	<b>Valuation Methodology</b>	<b>Significant Unobservable Input</b>	<b>Weighted Average Interest on Discount Rate (range, if applicable)</b>
Warrants .....	\$ 3,792	Black-Scholes Option Pricing Model	Volatility	61.3 %

#### *Warrants*

The significant unobservable inputs used in the fair value of warrants are derived from the Company's common stock valuation that is based upon a model with inputs from a Black-Scholes model and market volatility that is determined for comparable companies in the same business sector. The inherent risk in the market volatility is the selection of

companies with similar business attributes to the Company. The Company changed the volatility assumption from a group of 15 companies that was shared with the secured debt volatility prior periods to a group of four companies that is shared with the volatility used for stock-based compensation. The Company determined this was appropriate as the secured debt was settled in October 2015 and results in consistent volatility assumptions used for both common stock warrants and stock-based compensation. This resulted in an increase of the Company's warrant valuation of \$0.1 million on December 31, 2016.

#### 4. Financial Instruments

The Company elected to invest a portion of its cash assets in conservative, income earning, liquid investments effective September 2015. Cash equivalents and investments, all of which are classified as available-for-sale securities, consisted of the following:

	December 31, 2016				December 31, 2015			
	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 .....	\$ 10,777	\$ —	\$ —	\$ 10,777	\$ 5,966	\$ —	\$ —	\$ 5,966
U.S. Treasury securities .....	57,846	—	(404)	57,442	104,537	1	(725)	103,813
U.S. agency securities .....	56,261	—	(147)	56,114	79,491	—	(638)	78,853
Municipal securities .....	17,478	—	(174)	17,304	18,974	2	(56)	18,920
Total .....	<u>\$ 142,362</u>	<u>\$ —</u>	<u>\$ (725)</u>	<u>\$ 141,637</u>	<u>\$ 208,968</u>	<u>\$ 3</u>	<u>\$ (1,419)</u>	<u>\$ 207,552</u>
Classified as:								
Cash equivalents ...				\$ 10,777				\$ 5,966
Short-term investments ...				130,860				201,586
Total .....				<u>\$ 141,637</u>				<u>\$ 207,552</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 our investments, and will continue to recognize unrealized losses and gains in other comprehensive income. For the year ended December 31, 2016, the Company had \$0.2 million in realized gains and immaterial realized losses for a total net realized gain of \$0.2 million as a result of the sale of investments. There was no sale of investments for the year ended December 31, 2015.

As of December 31, 2016, the Company has 27 investments in an unrealized loss position in its portfolio. Available-for-sale debt securities that were in a continuous loss position but were not deemed to be other than temporarily impaired were immaterial as of December 31, 2016. The Company earned interest income of \$1.5 million during the year ended December 31, 2016. The following table summarizes the Company's portfolio of available-for-sale securities by contractual maturity as of December 31, 2016:

	December 31, 2016	
	Amortized Cost	Fair Value
(in thousands)		
Less than one year .....	\$ 48,265	\$ 48,212
Greater than one year but less than five years .....	83,320	82,648
Total .....	<u>\$ 131,585</u>	<u>\$ 130,860</u>

## 5. Balance Sheet Components

### *Allowance for Doubtful Accounts*

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

	December 31, 2016	December 31, 2015
	(in thousands)	
Beginning balance . . . . .	\$ 971	\$ 527
Provision for estimated bad debts . . . . .	984	529
Write offs . . . . .	(65)	(85)
Ending balance . . . . .	<u>\$ 1,890</u>	<u>\$ 971</u>

### *Property and Equipment, net*

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

	Useful Life	December 31, 2016	December 31, 2015
		(in thousands)	
Machinery and equipment . . . . .	3-5 years	\$ 27,303	\$ 20,670
Furniture and fixtures . . . . .	3 years	1,087	217
Computer equipment . . . . .	3 years	861	911
Capitalized software held for internal use . . . . .	3 years	2,172	1,037
Leasehold improvements . . . . .	Life of lease	10,444	1,686
Construction-in-process . . . . .		9,759	1,979
		<u>51,626</u>	<u>26,500</u>
Less: Accumulated depreciation and amortization . . . . .		(19,337)	(13,790)
Total Property and equipment, net . . . . .		<u>\$ 32,289</u>	<u>\$ 12,710</u>

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

In September 2015, the Company paid off the Equipment Financing Facility, thus none of the Company's equipment is subject to pledge.

The Company periodically evaluates the carrying value of long-lived assets when events or circumstances warrant such a review. The carrying value of a long-lived asset is considered impaired when the estimated realizable value of the asset is less than the carrying value of the asset. In that event, a loss is recognized based on the amount by which the carrying value exceeds the fair value of the long-lived asset. Fair value is determined based on the estimated realizable value of the long-lived asset.

The Company recorded asset impairment charges totaling \$2.1 million in cost of product, licensing and other revenues in the statements of operations and comprehensive loss during the year ended December 31, 2016 following its impairment analysis on certain sequencing and automation equipment whose service lives were determined to be significantly shorter than initially expected. Total impairment charge of \$2.1 million also included the write-off of \$0.3 million unamortized maintenance service contract prepayments related to the impaired equipment described above. Those equipment were phased out in January 2017 as the Company began its transition to the next generation of sequencing and automation equipment to help streamline its production workflows. Another impairment charge of \$0.2 million was recorded in general and administrative expenses in the statements of operations and comprehensive loss to write off the carrying value of an equipment that was not actively used in production.

The Company recorded an asset impairment charge of \$1.0 million against a specific group of machinery and equipment during the year ended December 31, 2015. The Company no longer uses this specific group of machinery and equipment because of outsourcing to its partners. The impairment charge was recorded to reflect reductions in the estimated realizable value of the machinery and equipment as a result of planning for its sale in the secondary market. The Company recorded the total impairment charge of \$1.0 million in cost of product, licensing and other revenues. The Company sold some of the impaired machinery and equipment during the fourth quarter of 2015 for \$0.5 million and classified the remaining impaired machinery and equipment as held for sale at the estimated realizable value of \$0.2 million. The remaining impaired machinery was sold in January 2016 for \$0.2 million.

### ***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. As of December 31, 2016, \$2.6 million in deferred costs was included in other assets. The deferred costs are being amortized ratably over the four-year term of the agreement. During the year ended December 31, 2016, the Company has amortized \$0.6 million of the deferred costs, which was recorded as a reduction of product revenues in the statements of operations and comprehensive loss.

### ***Accrued Compensation***

The Company's accrued compensation consisted of the following:

	December 31, 2016	December 31, 2015
	(in thousands)	
Accrued paid time off . . . . .	\$ 1,892	\$ 2,024
Accrued commissions . . . . .	3,868	3,691
Accrued bonuses . . . . .	2,387	1,348
Other accrued compensation . . . . .	2,920	1,489
Total accrued compensation . . . . .	<u>\$ 11,067</u>	<u>\$ 8,552</u>

### ***Other Accrued Liabilities***

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

	December 31, 2016	December 31, 2015
	(in thousands)	
Overpayments from insurance carriers . . . . .	\$ 7,535	\$ 3,306
Other accrued expenses . . . . .	4,521	4,344
Testing and laboratory materials from suppliers . . . . .	3,804	7,736
Marketing and corporate affairs . . . . .	202	1,118
Leasehold improvement projects in progress . . . . .	1,659	—
Accrued specimen service fees . . . . .	469	454
Accrued shipping charges . . . . .	467	401
Sales tax payable . . . . .	459	346
Clinical trials and studies . . . . .	388	90
Accrued rent . . . . .	195	450
Legal, audit and consulting fees . . . . .	180	421
Deferred lease obligation . . . . .	—	42
Total other accrued liabilities . . . . .	<u>\$ 19,879</u>	<u>\$ 18,708</u>

## 6. Commitments and Contingencies

### *Operating Leases*

As of December 31, 2016, the Company sub-leases office facilities under non-cancelable operating lease agreements. The Company occupies approximately 88,000 square feet of laboratory and office space at our corporate headquarters in San Carlos, California pursuant to two separate subleases. One sublease covers approximately 61,000 square feet (the “First Space”), and the other sublease covers approximately 27,000 square feet (the “Second Space”). In connection with the sublease for the First Space in January 2013 and the Second Space in March 2014, the Company executed two letters of credit in favor of the lessors for \$0.8 million and \$0.3 million, respectively.

In October 2016, the Company amended the lease agreement that it directly entered into with the landlord of our First Space and Second Space (as described above) to include a sublease of additional office space to accommodate its growth and consolidate its operations in California at one location. The additional sublease covers approximately 48,000 square feet of office space and consists of two phases. The first phase began in October 2016 and covers approximately 16,000 square feet of office space at a base rent of \$60,730 per month. The second phase began in January 2017, which covers approximately 32,000 square feet of office space at a base rent of \$121,460 per month. The term of this sublease is approximately eighty-four months, with the same expiration date as the First Space and Second Space, which is in October 2023.

In April 2015, the Company entered into a sub-lease agreement for additional office space in Redwood City, California. The additional space carried a base rent of \$0.1 million per month. The lease period began in June 2015 and terminated in August 2016 with no option to extend the lease. In addition, the Company paid a security deposit of \$0.1 million.

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 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 has paid a security deposit of \$0.4 million, and the landlord has allotted the subsidiary an allowance for leasehold improvements of up to \$7.8 million. As of December 31, 2016, a total of \$5.4 million of the allowance has been reimbursed by the landlord.

The future annual minimum lease payments under all non-cancelable operating leases as of December 31, 2016 are as follows:

	<u>Operating Leases</u> <u>(in thousands)</u>
Year ending December 31:	
2017.....	\$ 6,914
2018.....	6,914
2019.....	6,413
2020.....	6,313
2021.....	6,313
2022 and thereafter.....	15,622
Total future minimum lease payments .....	<u>\$ 48,489</u>

Rent expense for the years ended December 31, 2016, 2015 and 2014 was \$5.4 million, \$2.7 million and \$1.5 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 defending its current litigation matters, and while there can be no assurances and the outcome of these matters is currently not determinable, the Company currently believes that there are no existing claims or proceedings that are

likely to have a material adverse effect on its financial position. There are many uncertainties associated with any litigation and these actions or other third-party claims against the Company may cause the Company to incur costly litigation and/or substantial settlement charges.

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

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 the Company, its directors and 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 moved to stay, or put a hold on, discovery pending the appeal. The Company has also filed a demurrer, or a request for dismissal as a matter of law, in the San Mateo Superior Court, which has not yet been heard. The Company intends 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. In light of, among other things, the early stage of the litigations, 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 March 4, 2016, a lawsuit was filed against the Company in the Superior Court of the State of California for the County of San Diego, by a patient alleging that Natera failed to perform a test that was ordered. The complaint seeks compensatory damages. This matter is in the discovery stage. The Company intends to vigorously defend against the claims in this lawsuit, and assert any counterclaims that may be available to it. The Company cannot provide any assurance as to the ultimate outcome or that an adverse resolution of this lawsuit would not have a material adverse effect on its financial condition and results of operations. In light of, among other things, the early stage of the litigation, 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 December 12, 2015, the Company received a civil investigative demand from the United States Department of Justice in connection with what the Company understands to be a qui tam action related to the billing of some of its testing, brought by a former employee. The Company has produced documents in response to the demand. An adverse ruling in this proceeding could require the Company to pay treble damages, civil penalties, and attorneys' fees, costs and expenses, which could materially and adversely affect its business, financial condition and results of operations. The Company has only received a civil investigative demand and has not been served with a complaint; accordingly, 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 an unfavorable outcome.

On December 9, 2016, the Company filed a lawsuit against Bio-Reference Laboratories, Inc. ("Bio-Reference") in the U.S. District Court for the Southern District of New York alleging that Bio-Reference breached a licensing and joint development agreement (the "Licensing Agreement") between Bio-Reference and Natera, misappropriated trade secrets, and converted confidential information. The Company also filed a motion for a temporary restraining order and preliminary injunction enjoining Bio-Reference from launching a nationwide marketing campaign of its product in violation of the Licensing Agreement. On December 10, 2016, the Company's motion for a temporary restraining order was denied, and



the Court ordered both parties to submit proposed hearing dates with respect to our motion for a preliminary injunction. The Company and Bio-Reference have resolved the matter as of February 2017.

### ***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***

In November 2014, a third-party payer sought information as part of an investigative audit of claims which it had paid for certain genetic testing. The Company complied with their request and provided responsive information. In a letter dated June 2, 2015, the third-party payer alleged that it had overpaid \$1.9 million to the Company, which it claimed was an overpayment reflecting the difference between what it paid to the Company and what it contended it should have paid based on its fee schedule and coverage determinations. In August 2015, the Company reached an agreement for a settlement payment of \$1.2 million as part of a complete settlement of this matter. This charge was recorded against revenue in the second quarter of 2015.

In March 2017, a third-party payer alleged that it had overpaid the Company, and has demanded recoupment of the alleged overpayments. The Company disagrees with the contentions.

### ***Contractual Commitments***

As of December 31, 2016, the Company has non-cancelable contractual commitments with a supplier for approximately \$5.1 million and other material supplier commitments for approximately \$3.4 million for inventory material used in the laboratory testing process.

As of December 31, 2016, the Company has a non-cancelable license agreement with a vendor for approximately \$3.0 million. This represents binding and remaining commitments with the vendor through December 31, 2019.

## **7. 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 its 2007 Stock Plan. However, awards outstanding under the 2007 Plan will continue to be governed by the terms of the 2007 plan.

*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, 2016, 13,094,869 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 of our fiscal years, 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 our 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.

### **2007 Stock Plan**

*General.* The Company's board of directors adopted its 2007 Plan in January 2007, and it was approved by the Company's stockholders. No further awards have been made under the 2007 Plan after July 1, 2015, the date of the Company's initial public offering; however, awards outstanding under our 2007 Plan will continue to be governed by their existing terms.

*Share Reserve.* As of December 31, 2016, the Company reserved 7,713,510 shares of its common stock for issuance under the 2007 Plan, all of which may be issued as incentive stock options. As of December 31, 2016, options to purchase 6,098,564 shares of common stock, at exercise prices ranging from \$0.0978 to \$12.8501 per share, or a weighted-average exercise price of \$2.71 per share, were outstanding under the 2007 Plan.

Options vest as determined by the administrator. In general, the Company granted options that vest over a four-year period following the date of grant. In most cases, options granted prior to 2011 (and prior to 2012 with respect to the Company's executive officers) were immediately exercisable, subject to the Company's right to repurchase unvested shares. Options expire at the time determined by the administrator, but in no event more than ten years after they were granted, and generally expire earlier if the optionee's service terminates earlier.

*Restricted Shares.* Restricted shares could be awarded or sold under the 2007 Plan in return for cash or cash equivalents or, as permitted by the administrator in its sole discretion, in exchange for services rendered to the Company, by delivery of a full-recourse promissory note or through any other means permitted by applicable law. Restricted shares vest as determined by the administrator.

### **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, 2016, 1,056,344 shares were available for issuance under the 2015 plan. 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 our 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).

*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 started on December 15, 2015 and ended on April 30, 2016, and 116,215 shares were purchased at the end of this offering period for a total proceeds of \$1.0 million. The second offering period started on May 1, 2016 and ended on October 31, 2016, and 224,637 shares were purchased at the end of this offering period for a total proceeds of \$1.6 million.

*Purchase Price.* The price of each share of common stock purchased under our 2015 ESPP will not be less than 85% of the lower of the fair market value per share of common stock on the first day of the applicable offering period (or, in the case of the first offering period, the price at which one share of common stock is offered to the public in this offering) or the fair market value per share of common stock on the purchase date.

#### ***Early Exercise of Employee Options***

As of December 31, 2015, the Company had approximately 1.3 million exercised and unvested shares outstanding that are subject to a repurchase right held by the Company at the original issuance price in the event that the optionee's employment is terminated, either voluntarily or involuntarily. Effective in the year ended December 31, 2015, pursuant to the agreements with the option holders, the Company changed its estimated expiration of its repurchase right for 1.3 million exercised and unvested shares outstanding that are subject to repurchase right held by it through the 210 days after the date of the prospectus filed in connection with the Company's IPO. Accordingly, the unrecognized compensation expense is being accelerated over a shorter performance period through January 2016. As a result of this acceleration, the Company recorded an additional \$1.3 million in stock-based compensation expense during the year ended December 31, 2015.

## Stock Options

The following table summarizes option activity during the year ended December 31, 2016:

(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, 2015.....	3,743	9,316	\$ 3.96	8.31	\$ 63,713
Additional shares authorized.....	2,014	—			
Options granted.....	(2,558)	2,558	\$ 10.23		
Options exercised.....	—	(1,915)	\$ 1.88		
Options forfeited.....	916	(916)	\$ 8.28		
Balance at December 31, 2016.....	<u>4,115</u>	<u>9,043</u>	\$ 5.72	7.55	<u>\$ 55,396</u>
Exercisable at December 31, 2016.....		<u>5,054</u>	\$ 3.10	6.51	<u>\$ 43,938</u>
Vested and expected to vest at December 31, 2016		<u>9,039</u>	\$ 5.72	7.55	<u>\$ 55,386</u>

The total intrinsic value of stock options exercised during the years ended December 31, 2016, 2015 and 2014 was \$16.9 million, \$6.9 million and \$1.2 million, respectively. The total fair value of stock options vested during the years ended December 31, 2016, 2015 and 2014 was \$8.5 million \$4.5 million and \$4.1 million, respectively.

The weighted-average grant date fair value of options granted during the years ended December 31, 2016, 2015 and 2014 was \$5.92, \$7.29 and \$3.28 per share, respectively.

## Restricted Stock Awards

In February 2016, the Company granted 24,540 fully vested restricted shares to a non-employee service provider.

## Restricted Stock Units

Starting April 2016, the Company began granting restricted stock units to its employees from the 2015 Plan. The following table summarizes restricted stock unit activity for the year ended December 31, 2016:

	Shares	Weighted-Average Grant Date Fair Value
Balance at December 31, 2015.....	—	\$ —
Granted.....	212	\$ 9.76
Vested.....	(40)	\$ 9.59
Canceled/forfeited.....	<u>(13)</u>	\$ 9.81
Balance at December 31, 2016.....	<u>159</u>	\$ 9.80

## 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, 2016, 2015 and 2014.

	Year ended December 31,								
	2016			2015			2014		
	Employee	Non-Employee	Total	Employee	Non-Employee	Total	Employee	Non-Employee	Total
	(in thousands)								
Cost of revenues . . .	\$ 651	\$ (10)	\$ 641	\$ 351	\$ 241	\$ 592	\$ 262	\$ 29	\$ 291
Research and development . . . .	2,829	24	2,853	1,566	9	1,575	1,563	30	1,593
Selling, general and administrative . . . .	6,837	270	7,107	4,993	166	5,159	3,180	93	3,273
Total . . . . .	<u>\$ 10,317</u>	<u>\$ 284</u>	<u>\$ 10,601</u>	<u>\$ 6,910</u>	<u>\$ 416</u>	<u>\$ 7,326</u>	<u>\$ 5,005</u>	<u>\$ 152</u>	<u>\$ 5,157</u>

As of December 31, 2016, approximately \$19.4 million of unrecognized compensation expense, adjusted for estimated forfeitures, related to unvested awards will be recognized over a weighted-average period of approximately 2.8 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,								
	2016			2015			2014		
Expected term . . . . .	5.1	—	5.2	5.6	—	10.0	4.9	—	7.1
Expected volatility . . . . .	62.2%	—	72.5%	69.7%	—	78.8 %	73.4 %	—	87.0 %
Expected dividend rate . . . . .			0 %			0 %			0 %
Risk-free interest rate . . . . .	0.97%	—	1.92%	1.56%	—	2.32 %	1.65 %	—	2.04 %

**Expected Term:** The expected term of options represents the period of time that options are expected to be outstanding. For granted "at-the-money" stock options, the Company estimated the expected term by using the simplified method up until December 31, 2015, which involved calculating the average of the time-to-vesting and the total contractual life of the options. Starting January 1, 2016, the Company uses a different approach 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 stock options that are not granted "at-the-money," the Company uses the binomial lattice model to calculate the expected term.

**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.

## Valuation of Stock Option Grants to Non-Employees

Total options outstanding as of December 31, 2016, include 141,046 shares of option awards that were granted to non-employees, of which 10,456 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,								
	2016			2015			2014		
Expected term .....	2.7	—	3.2	4.9	—	9.8	4.4	—	10.0
Expected volatility .....	50.9%	—	72.6 %	70.2%	—	75.4 %	71.9 %	—	80.2 %
Expected dividend rate .....			0 %			0 %			0 %
Risk-free interest rate .....	0.68%	—	1.38 %	1.74%	—	2.24 %	1.41 %	—	2.61 %

## 8. Debt

### Senior Secured Term Loan

In April 2013, as amended in June 2014, the Company entered into a senior secured term loan arrangement (the "Secured Loan Arrangement") with ROS Acquisition LP ("ROS"). The Secured Loan Arrangement provided for up to \$40.0 million in borrowing capacity ("Credit Agreement"), a warrant to purchase shares of Common Stock, and an agreement to pay royalties on Company revenues ("Royalty Agreement"). The Company borrowed \$20.0 million on the effective date of the Credit Agreement. The Credit Agreement provided for an interest rate equal to the greater of (a) LIBOR or (b) 1% per annum plus the applicable margin of 8% per annum or 9% floor on the outstanding balance of the term loan. The Royalty Agreement obligated the Company to make royalty payments of 1% applied to total Company fiscal year revenues of up to \$50.0 million and 1.5% applied to fiscal year incremental revenues above \$50.0 million. For the year ended December 31, 2015, the Company incurred approximately \$1.4 million and \$7.1 million in interest expenses under the Credit Agreement and royalty expenses under the Royalty Agreement, respectively. The \$7.1 million in royalty expense included \$1.8 million in royalty due and the remainder was for part of the \$28.0 million pay-off to ROS. Please refer to paragraph below for pay-off details. For the year ended December 31, 2014, the Company incurred approximately \$1.8 million and \$2.2 million in interest expenses under the Credit Agreement and royalty expenses under the Royalty Agreement, respectively. The interest on the loan is set forth in the financial statements as interest expense below loss from operations. The effective yield was approximately 20.9% and 19.8%, respectively, for the year ended December 31, 2015 and 2014, excluding royalty and interest early termination payments. Under the terms of the Secured Loan Arrangement, the Company issued ROS a warrant to purchase 376,691 shares of common stock with an exercise price of \$2.3229 per share. The Credit Agreement principal was due and payable on April 18, 2019. The Company could at its option, prepay the term loan borrowings subject to a prepayment premium equivalent to 10% of the outstanding principal. Prepayment of the amount due under the Credit Agreement did not eliminate the royalty payment obligation, which if not terminated, would have expired no later than April 18, 2023.

In October 2015, the Company made a payment of \$28.0 million to ROS to extinguish the amounts owed, which included the principal and royalty obligation. This terminated the term loan, royalty and all associated liens securing the Credit Agreement.

### Credit Line Agreement

In September 2015, the Company entered into the Credit Line with UBS providing for a \$50.0 million revolving line of credit which can be drawn down in increments at any time. In October 2015, the Company borrowed \$32.0 million against the Credit Line, primarily to prepay all outstanding amounts under the Secured Loan Arrangement with ROS. The Credit Line bears interest at 30-day LIBOR plus 0.65%, and equals approximately 0.84% per annum at the time of the draw. In November, 2015, the Company borrowed an additional \$10.0 million which bears interest at approximately 0.85% per annum. Interest of \$0.1 million was accrued during the year ended December 31, 2015. In June 2016, the Company borrowed an additional \$8.0 million from the Credit Line and repaid \$1.0 million, thereby resulting in a remaining \$0.4



million available for draw down, net of accrued interest of \$0.6 million as of December 31, 2016. The outstanding balance of the Credit Line, including accrued interest, was \$49.6 million as of December 31, 2016. The Credit Line is secured by a first priority lien and security interest in the Company's money market and marketable securities held in its managed investment account with UBS. UBS has the right to demand full or partial payment of the Credit Line Obligations and terminate the Credit Line, in its discretion and without cause, at any time.

### **Equipment Financing Facility**

In April 2013, the Company entered into an equipment financing facility (the "Equipment Financing Facility") with a financial institution pursuant to which the Company could borrow up to \$5.0 million to fund equipment purchases. The financial institution maintained a security interest in the underlying equipment until payment in full of the loan. The loan bore interest at the financial institution's prime reference rate (defined as the 30-day LIBOR rate plus 2.50%) plus 4.10%, which equaled 7.35% upon closing of the agreement. In December 2014, the Company amended the Equipment Financing Facility increasing the loan amount to \$5.9 million to fund equipment purchased. The Company paid interest on the unpaid principal at the financial institution's prime reference rate plus 3.10%, which equaled 6.35%. Under the terms of the Equipment Financing Facility, the loan would mature on May 31, 2017. Under the terms of the Equipment Financing Facility, the Company would be required to make 30 payments of principal and interest through the maturity of the loan in May 2017.

In September 2015, the Company paid off the remaining principal balance of the equipment financing facility. The Company made a payment of \$4.1 million, comprising of principal, interest and administrative fees settling all of its obligations under the loan.

## **9. Warrants**

In 2007, the Company issued warrants to purchase an aggregate of 24,538 shares of common stock at an exercise price of \$0.0978 per share to various holders. As of December 31, 2016, these warrants were fully exercised.

In 2009, the Company granted warrants to purchase 33,742 shares of Series B convertible preferred stock at an exercise price of \$1.8908 per share. The warrants were granted to a financial institution in connection with a secured equipment loan and expire on November 2, 2019. In connection with the IPO in July 2015, these warrants were converted into the right to purchase common stock at a one-to-one ratio. In December 2015, the financial institution net-exercised all 33,742 of their warrant shares at the strike price of \$1.8908 per share. Based on the Company's closing price of \$11.57 per share on the prior business day, the Company issued 28,227 shares to the financial institution.

In April 2014, the Company granted warrants to purchase approximately 376,691 warrants to purchase common stock at 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 and expire on 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. As of December 31, 2016, these warrants remained exercisable for common stock.

In connection with the Series F financing, the Series E preferred stockholders agreed to change the liquidation preference from two times to one times the liquidation value as described in the agreement. In exchange, on November 20, 2014, the Company issued common stock warrants to the Series E preferred stockholders to purchase 429,440 shares at \$0.0163 per share. The warrants are carried in Additional Paid In Capital and the issuance of the warrants was treated as a deemed dividend by the common stockholder out of Additional Paid in Capital. In connection with the IPO in July 2015, such warrants were automatically net exercised into 429,042 shares of common stock.

## **10. Convertible Preferred Stock**

At the closing of the IPO in July 2015, 31,397,221 shares of outstanding convertible preferred stock were automatically converted into common stock on a one-to-one basis. Following the IPO, there were no shares of preferred stock outstanding. In connection with the IPO, the Company amended and restated its Amended and Restated Certificate

of Incorporation to change the authorized capital stock to 750.0 million shares designated as common stock and 50.0 million shares designated as preferred stock, all with a par value of \$0.0001 per share.

As of December 31, 2014, the convertible preferred stock consisted of the following:

Series	Shares Authorized	Shares Issued and Outstanding	Liquidation Amount	Proceeds, net of Issuance Costs
		(in thousands)		
A-1 .....	5,000	3,067	\$ 20	\$ 20
A .....	8,173	5,014	4,005	3,927
B .....	5,745	3,491	6,600	6,569
C .....	8,941	5,485	12,160	58,876
D .....	6,694	4,107	20,047	80,788
E .....	9,592	5,884	35,425	35,019
F .....	7,088	4,349	55,500	55,413
	<u>51,233</u>	<u>31,397</u>	<u>\$133,757</u>	<u>\$ 240,612</u>

## 11. Common Stock

The Company's Certificate of Incorporation, as restated in connection with the closing of the IPO, authorizes the Company to issue 750.0 million shares of common stock with a par value of \$0.0001 per share. As of December 31, 2016 and December 31, 2015, the Company had 52.7 million and 50.3 million shares of common stock outstanding, respectively. Each shareholder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders.

The Company's board of directors and stockholders approved an amendment to its Certificate of Incorporation to effect a 1-for-1.63 reverse split of its capital stock, which was effected on June 19, 2015. All references to common stock, options to purchase common stock, restricted stock, share data, per share data, warrants, convertible preferred stock and related information have been retroactively adjusted where applicable in this report to reflect the reverse stock split of the Company's capital stock as if it had occurred at the beginning of the earliest period presented.

## 12. Income Taxes

The Company's effective tax rates for the years ended December 31, 2016 and 2015 differ from the U.S. federal statutory rate as follows:

	December 31,			
	2016		2015	
	(in thousands, except percentages)			
U.S. federal taxes (benefit) at statutory rate . . . . .	\$ (32,277)	(34.0)%	\$ (24,375)	(34.00)%
State tax expense . . . . .	(2,842)	(2.99)%	(2,428)	(3.39)%
Research and development credits . . . . .	(1,449)	(1.53)%	(751)	(1.05)%
Stock-based compensation . . . . .	1,275	1.34 %	1,683	2.35 %
Mark to market fair value adjustments. . . . .	49	0.05 %	504	0.70 %
Other nondeductible items . . . . .	933	0.99 %	841	1.17 %
Change in valuation allowance. . . . .	34,453	36.29 %	24,526	34.21 %
Provision for income taxes . . . . .	\$ 142	0.15 %	\$ —	— %

Due to its history of operating losses, the Company has not recorded any income tax expense for the year ended December 31, 2016, with the exception of \$142,000 of foreign withholding tax in 2016. As the provision for income taxes was not significant for and the year ended December 31, 2015, any income taxes were reclassified in other income and expenses.

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,	
	2016	2015
	(in thousands)	
Deferred tax assets		
Net operating loss carryforwards .....	\$ 68,504	\$ 41,451
Research and development tax credit carryforwards .....	8,634	4,794
Reserves and accruals .....	5,719	3,108
Stock-based compensation. ....	3,220	2,206
Total deferred tax assets before valuation allowance .....	86,077	51,559
Less: valuation allowance. ....	(85,606)	(51,153)
	471	406
Deferred tax liabilities		
Property and equipment. ....	(471)	(406)
Net deferred tax assets .....	\$ —	\$ —

The Company established a full valuation allowance against its net deferred tax assets in 2016 and 2015 due to the uncertainty surrounding realization of these assets. The valuation allowance increased by \$34.5 million, \$24.5 million and \$0.9 million during the years ended December 31, 2016, 2015 and 2014, respectively.

As of December 31, 2016, the Company had federal and state net operating loss ("NOLs") carryforwards of approximately \$205.3 million and \$109.6 million, respectively, which begin to expire in 2027 and 2017, respectively, if not utilized. The deferred tax assets related to NOLs do not include excess tax benefits from employee stock option exercises. Equity will be increased by \$7.2 million, if and when such deferred tax assets are ultimately realized. The Company uses ASC 740 ordering when determining when excess tax benefits have been realized. The Company also had federal research and development credit carryforwards of approximately \$8.5 million, which begin to expire in 2027, and state research and development credit carryforwards of approximately \$5.8 million, which can be carried forward indefinitely. Realization of these deferred tax assets would require \$226.2 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:

	December 31,	
	2016	2015
	(in thousands)	
Balance at beginning of year .....	\$ 2,405	\$ 1,360
Additions based on tax positions related to the current year .....	1,836	1,045
Additions for tax positions of prior years .....	52	—
Balance at end of year. ....	\$ 4,293	\$ 2,405

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, 2016 and 2015, the amount of unrecognized tax benefits increased \$1.9 million and \$1.0 million, respectively, due to additional research and development credits generated during the year. As of December 31, 2016 and 2015, the total amount of unrecognized tax benefits was \$4.3 million and \$2.4 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, 2017.

The Company recognizes any interest and/or penalties related to income tax matters as a component of income tax expense. As of December 31, 2016, there were no accrued interest and penalties related to uncertain tax positions.

### **13. Related-Party Transactions**

The Company entered into a full recourse promissory note with the Company's chief executive officer, in April 2012 whereby the Company loaned Dr. Rabinowitz \$154,000. This interest only loan bore interest at a rate per annum of 1.15%, compounded annually. This loan, including all accrued interest, was repaid in full by Dr. Rabinowitz in May 2015.

The Company entered into a full recourse promissory note with Jonathan Sheena, the Company's chief technology officer, in April 2012 whereby the Company loaned Mr. Sheena \$38,280. This interest only loan bore interest at a rate per annum of 1.15%, compounded annually. This loan, including all accrued interest, was repaid in full by Mr. Sheena in May 2015.

### **14. 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. Prior to the Company's IPO of its common stock, the Company's convertible preferred stock was entitled to receive dividends, prior and in preference to any declaration or payment of any dividend on common stock and thereafter participate pro rata on an as converted basis with the common stock holders on any distributions to common stockholders. The convertible preferred shares were therefore considered to be participating securities. As a result, the Company calculated the net loss per share using the two-class method. Accordingly, the net loss attributable to common stockholders is derived from the net loss for the period and, in periods in which the Company has net income attributable to common stockholders, an adjustment is made for the noncumulative dividends and allocations of earnings to participating securities based on their outstanding shareholder rights. Under the two-class method, the net loss attributable to common stockholders is not allocated to the convertible preferred stock as the convertible preferred stock did not have a contractual obligation to share in the Company's losses. The diluted net income per share attributable to common stockholders is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. In periods when the Company has incurred a net loss, convertible preferred stock, options to purchase common stock, common stock warrants and common stock subject to repurchase are considered common stock equivalents but have been excluded from the calculation of diluted net loss per share attributable to common stockholders as their effect is antidilutive.

The following table provides the basic and diluted net loss per common share computations for the years ended December 31, 2016, 2015 and 2014.

(in thousands, except per share data)	Year ended December 31,		
	2016	2015	2014
<b>Basic and diluted loss per share:</b>			
Net loss. ....	\$ (95,765)	\$ (70,275)	\$ (5,152)
Weighted-average common shares outstanding .....	51,667	27,687	6,670
Less: weighted-average unvested common shares subject to repurchase .....	(91)	(1,483)	(1,870)
Weighted-average number of shares used in computing net loss per share, basic and diluted. ....	51,576	26,204	4,800
Basic and diluted net loss per share .....	\$ (1.86)	\$ (2.68)	\$ (1.07)

Potentially dilutive shares that were not included in the diluted per share calculations because they would be antidilutive as of the years ended December 31, 2016, 2015 and 2014 were as follows:

	Year ended December 31,		
	2016	2015	2014
Options to purchase common stock .....	9,043	9,316	8,450
Warrants to purchase common stock .....	377	377	864
Restricted stock units .....	159	—	—
Employee stock purchase plan .....	90	—	—
Common stock subject to repurchase. ....	—	1,307	1,690
Convertible preferred stock .....	—	—	31,397
	<u>9,669</u>	<u>11,000</u>	<u>42,401</u>

## 15. Geographic Information

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

(in thousands)	Year ended December 31,		
	2016	2015	2014
United States. ....	\$ 193,054	\$ 164,952	\$ 136,478
Americas, excluding U.S. ....	2,562	4,552	4,883
Europe, Middle East, India, Africa .....	14,256	15,437	13,098
Other .....	7,202	5,414	4,830
Total .....	<u>\$ 217,074</u>	<u>\$ 190,355</u>	<u>\$ 159,289</u>

**16. Quarterly Financial Data (unaudited)**

	Three months ended			
	December 31,	September 30,	June 30,	March 31,
	(in thousands, except per share data)			
<b>2016</b>				
Operating results:				
Total revenues .....	\$ 49,299	\$ 53,889	\$ 51,984	\$ 61,902
Cost of product, licensing and other revenues ..	38,000	34,261	30,973	32,340
Gross profit .....	11,299	19,628	21,011	29,562
Other costs and expenses .....	49,012	46,283	43,526	39,167
Interest expense and other (expense) income, net	(155)	741	(641)	920
Income tax expense .....	(39)	(103)	—	—
Net loss .....	(37,907)	(26,017)	(23,156)	(8,685)
Per share data:				
Net loss - basic and diluted .....	\$ (0.72)	\$ (0.50)	\$ (0.46)	\$ (0.17)
<b>2015</b>				
Operating results:				
Total revenues .....	\$ 52,912	\$ 44,921	\$ 45,087	\$ 47,435
Cost of product, licensing and other revenues ..	31,814	30,456	25,732	24,843
Gross profit .....	21,098	14,465	19,355	22,592
Other costs and expenses .....	38,446	35,206	34,827	28,869
Interest expense and other (expense) income, net	(5,612)	3,111	(4,209)	(3,727)
Net loss .....	(22,960)	(17,630)	(19,681)	(10,004)
Per share data:				
Net loss - basic and diluted .....	\$ (0.47)	\$ (0.39)	\$ (3.58)	\$ (1.89)

**17. Subsequent Events**

In January 2017, the Company amended an existing agreement with one of its vendors to revise its minimum purchase commitments of gene sequencing tests in exchange for certain additional rights under the agreement. The revised minimum purchase commitments amount to \$3.6 million for 2017. For 2018, the minimum purchase commitments total \$4.5 million. If the Company fails to meet its minimum purchase commitments in 2018, there is no financial consequence, but it would lose certain exclusivity rights under the agreement.



## **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, 2016. 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, 2016, 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, 2016 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, 2016 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, 2016 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 2017 annual meeting of stockholders (the “Proxy Statement”), which we expect to file not later than 120 days after the end of our fiscal year ended December 31, 2016, 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 not later than 120 days after the end of our fiscal year ended December 31, 2016, 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 not later than 120 days after the end of our fiscal year ended December 31, 2016, 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 not later than 120 days after the end of our fiscal year ended December 31, 2016, 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 not later than 120 days after the end of our fiscal year ended December 31, 2016, 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 (Deficit)
- Statement of Cash Flows
- Notes to Financial Statements

(2) Financial Statement Schedules

All other financial statement schedules are omitted because the information is inapplicable or presented in the notes to the financial statements.

(b) Reference is made to the Exhibit Index accompanying this Annual Report on Form 10-K.

### **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 16th day of March, 2017.

**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 Matthew Rabinowitz and Herm Rosenman as his true and lawful attorney-in-fact and agent with full power of substitution, for him 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 / Matthew Rabinowitz</u> Matthew Rabinowitz	Chief Executive Officer, President and Chairman (Principal Executive Officer)	March 16, 2017
<u>/ s / Michael Brophy</u> Michael Brophy	Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2017
<u>/ s / Jonathan Sheena</u> Jonathan Sheena	Chief Technology Officer and Director	March 16, 2017
<u>/ s / Roelof F. Botha</u> Roelof F. Botha	Director	March 16, 2017
<u>/ s / Todd Cozzens</u> Todd Cozzens	Director	March 16, 2017
<u>/ s / Edward C. Driscoll, Jr.</u> Edward C. Driscoll, Jr.	Director	March 16, 2017
<u>/ s / James I. Healy</u> James I. Healy	Director	March 16, 2017
<u>/ s / Herm Rosenman</u> Herm Rosenman	Director	March 16, 2017
<u>/ s / John Steuart</u> John Steuart	Director	March 16, 2017



## 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	3/23/2016	
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.					X
10.5	Warrant, dated April 18, 2013, by and between Registrant and Royalty Opportunities S. à r.l.	S-1	333-204622	10.9	6/1/2015	
10.6	Warrant, dated November 2, 2009, by and between Registrant and Silicon Valley Bank.	S-1	333-204622	10.10	6/1/2015	
10.7	Form of Warrant to Purchase Common Stock.	S-1	333-204622	10.12	6/1/2015	
10.8**	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	
10.9**	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	
10.10**	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	
10.11***	Application Service Provider Agreement, dated September 19, 2014, by and between Registrant and DNAnexus, Inc., as amended					X
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	
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*	Offer Letter, by and between Registrant and Herm Rosenman, dated January 17, 2014.	S-1/A	333-204622	10.17	6/25/2015	
10.15*	Amended Compensation Program for Non-Employee Directors.	10-Q	001-37478	10.1	11/12/2015	

Exhibit No.	Description	Incorporated by Reference				
		Form	File No.	Exhibit	Filing Date	Filed Herewith
10.16	UBS Credit Line Agreement, dated September 23, 2015, as amended.	10-Q	001-37478	10.2	11/12/2015	
10.17*	Natera, Inc. Management Cash Incentive Plan.	10-Q	001-37478	10.3	11/12/2015	
10.18	Lease, dated October 26, 2015, by and between Registrant and BMR-201 Industrial Road LP.	10-K	001-37478	10.23	3/23/2016	
10.19	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	
21.1	List of Subsidiaries of the Registrant.					X
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
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.



**Natera, Inc.**

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