

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[Table of Contents](#)

Filed Pursuant to Rule 424(b)(5)
Registration No. 333-248690

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be registered⁽¹⁾	Maximum Offering Price Per Share	Maximum Aggregate Offering Price	Amount of Registration Fee⁽²⁾⁽³⁾
Common Stock, \$0.0001 par value	4,791,665	\$60.00	\$287,499,900.00	\$37,317.49

- (1) Includes shares of Common Stock that may be purchase by the underwriters pursuant to their option to purchase additional shares of Common Stock
- (2) Calculated in accordance with Rule 457(r) under the Securities Act of 1933, as amended.
- (3) Pursuant to Rule 457(p) under the Securities Act of 1933, as amended, the registrant hereby offsets the total registration fee due under this Registration Statement by the amount of the filing fee associated with the unsold securities from the registrant's Form S-3 Registration Statement (File No. 333-214577) filed with the Securities and Exchange Commission on November 14, 2016 and became effective on November 28, 2016 (the "Prior Registration Statement"). The Prior Registration Statement registered the offer and sale of an indeterminate number of common stock with an aggregate offering price not to exceed \$200,000,000, of which \$93,574,750.00 of such securities (the "Unsold Securities") remained unsold as of the expiration date of the Prior Registration Statement. The associated registration fees are being moved from the Prior Registration Statement to this Registration Statement. Pursuant to Rule 457(p), the associated filing fee of \$10,845.31 relating to such Unsold Securities under the Prior Registration Statement, calculated under Rule 457(o), is hereby used to partially offset the current registration fee of \$37,317.49 due. As a result, a filing fee of \$26,472.17 is being paid herewith.
-

4,166,666 Shares



NATERA, INC.

COMMON STOCK

We are offering 4,166,666 shares of our common stock. Our common stock is listed on The Nasdaq Global Select Market under the symbol "NTRA." The last reported sale price of our common stock on September 9, 2020 was \$63.12 per share.

Investing in our common stock involves risk. See "Risk Factors" beginning on page 6.

	Price to public	Underwriting discounts and commissions ⁽¹⁾	Proceeds to Natera, Inc., before expenses
Per Share	\$60.00	\$3.45	\$56.55
Total	\$249,999,960.00	\$14,374,997.70	\$235,624,962.30

(1) See the section entitled "Underwriting" for a description of the compensation payable to the underwriters.

We have granted the underwriters the right to purchase up to an additional 624,999 shares at the public offering price, less underwriting discounts and commissions.

The Securities and Exchange Commission and state securities regulators have not approved or disapproved these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on or about September 15, 2020.

**J.P. Morgan
Baird**

Morgan Stanley

Cowen

**SVB Leerink
Craig-Hallum Capital Group**

September 10, 2020.

TABLE OF CONTENTS

	<u>Page</u>
Forward-Looking Statements	ii
Where You Can Find More Information	iv
Incorporation by Reference	iv
Prospectus Summary	1
Natera, Inc.	1
The Offering	4
Summary Financial Data	5
Risk Factors	6
Use of Proceeds	54
Dividend Policy	54
Capitalization	55
Material U.S. Federal Income Tax Considerations for Non-U.S. Holders	57
Underwriting	60
Legal Matters	70
Experts	70

Neither we nor the underwriters have authorized anyone to provide you with any information other than the information contained or incorporated by reference in this prospectus or any free writing prospectus prepared by or on behalf of us in connection with this offering to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurances as to the reliability of, any other information that others may give you. The information contained or incorporated by reference in this prospectus or any such free writing prospectus provided in connection with this offering is accurate only as of the date thereof, regardless of the time of delivery of such document or of any sale of our common stock. Our business, financial condition and results of operations may have changed since those dates. It is important for you to read and consider all the information contained in this prospectus, including the documents incorporated by reference herein or any free writing prospectus prepared by or on behalf of us in connection with this offering, in making your investment decision.

Neither we nor the underwriters are offering to sell, or seeking offers to buy, shares of our common stock in any jurisdictions where offers and sales are not permitted. The distribution of this prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus outside the United States. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

In this prospectus, unless otherwise indicated or the context otherwise requires, the terms "Natera," "Company," "we," "us" and "our" refer to Natera, Inc.

FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 "anticipate," "believe," "continue," "could," "design," "estimate," "expect," "intend," "may," "plan," "possible," "potential," "predict," "project," "seek," "should," "target," "will," "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 prospectus and in the documents that are incorporated by reference herein. 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 prospectus, or, in the case of any document incorporated by reference herein in this prospectus, as of the date of such document. 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 prospectus and the documents incorporated by reference herein 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:

- the extent and duration of the impact of the COVID-19 pandemic on our business, results of operations, financial condition or stock price;
- our expectation that, for the foreseeable future, a significant portion of our revenues will be derived from sales of Panorama and Horizon;
- our ability to increase demand for Panorama and Horizon, 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, including our expectations regarding the results of our SNP-based Microdeletion and Aneuploidy RegisTry, or SMART, Study and our expectations that the results from such study may support broader use and reimbursement for the use of Panorama in average risk pregnancies and for microdeletions;
- our expectations of the reliability, accuracy, and performance of our tests, as well as expectations of the benefits of our tests to patients, providers, and payers;
- our ability to successfully develop additional revenue opportunities and expand our product offerings to include new tests;
- our efforts to successfully develop and commercialize our oncology and organ health products;
- the achievement or effect of improvements in our cost of goods sold;
- our estimates of the total addressable markets for our current and potential product offerings;

- our ability and expectations regarding obtaining, maintaining and expanding third-party payer coverage of, and reimbursement for, our tests;
- the effect of changes in the way we account for our revenue;
- our ability to successfully commercialize our products through strategic or commercial partnerships, such as our agreements with BGI Genomics Co., Ltd. and Foundation Medicine, Inc., and our ability to enter into additional partnerships in the future;
- the scope of protection we establish and maintain for, and developments or disputes concerning, our intellectual property or other proprietary rights;
- our ability to successfully compete in the markets we serve;
- our reliance on collaborators such as medical institutions, contract laboratories, laboratory partners, and other third parties;
- our ability to operate our laboratory facility and meet expected demand, and to successfully scale our operations;
- our reliance on a limited number of suppliers, including sole source suppliers, which may impact our ability to maintain a continued supply of laboratory instruments and materials and to run our tests;
- our expectations of the rate of adoption of Panorama, Horizon and of any of our other current or future tests by laboratories, clinics, clinicians, payers, and patients;
- our ability to complete clinical studies and publish compelling clinical data in peer-reviewed medical publications regarding our existing and future tests, including our SMART Study and our ongoing and planned trials in oncology and transplant rejection;
- our reliance on our partners to market and offer our tests in the United States and in international markets;
- our estimates regarding our costs and risks associated with our international operations and international expansion;
- our ability to retain and recruit key personnel;
- our reliance on our direct sales efforts;
- our expectations regarding acquisitions and strategic operations;
- our expectations regarding the conversion of our outstanding 2.25% convertible senior notes due 2027, or the Convertible Notes, in the aggregate principal amount of \$287.5 million and our ability to make debt service payments under the Convertible Notes to the extent such Convertible Notes are not converted;
- 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;
- anticipated trends and challenges in our business and the markets in which we operate; and
- the anticipated use of the net proceeds from this offering.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the shares of common stock offered by this prospectus, which is part of the registration statement. This prospectus, and any document incorporated by reference herein, do not contain all of the information set forth in the registration statement and its exhibits and schedules, portions of which have been omitted as permitted by the rules and regulations of the SEC. For further information about us and our common stock, we refer you to the registration statement and to its exhibits. Statements in this prospectus about the contents of any contract, agreement or other document are not necessarily complete and in each instance we refer you to the copy of such contract, agreement or document filed as an exhibit to the registration statement, with each such statement being qualified in all respects by reference to the document to which it refers.

We file periodic and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains periodic and current reports, proxy and information statements and other information about issuers, such as us, who file electronically with the SEC. The address of that website is <http://www.sec.gov>. Our website address is www.natera.com. The information on our website, or the information that can be accessed through our website, however, is not, and should not be deemed to be, a part of this prospectus.

INCORPORATION BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference herein is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below (except the information contained in such documents to the extent "furnished" and not "filed") and any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (except the information contained in such documents to the extent "furnished" and not "filed"):

- [our Annual Report on Form 10-K for the fiscal year ended December 31, 2019](#);
- the information in our [Definitive Proxy Statement on Schedule 14A, filed on April 16, 2020](#), to the extent incorporated by reference into our [Annual Report on Form 10-K for the fiscal year ended December 31, 2019](#);
- our Quarterly Reports on Form 10-Q for the fiscal quarters ended [March 31, 2020](#) and [June 30, 2020](#);
- our Current Reports on Form 8-K filed on [March 12, 2020](#), [April 13, 2020](#), [April 16, 2020](#), [May 12, 2020](#) and [June 3, 2020](#); and
- [the description of our Common Stock contained in our Registration Statement File No. 001-37478 on Form 8-A as amended and filed with the SEC on June 26, 2015, including any amendment or report filed for the purpose of updating such description](#).

We will provide without charge upon written or oral request a copy of any or all of the documents that are incorporated by reference herein into this prospectus, other than exhibits which are specifically incorporated by reference herein into such documents. Requests should be directed to our Investor Relations department at Natera, Inc., 201 Industrial Road, Suite 410, San Carlos, California 94070. Our telephone number is (650) 249-9090.

Any statement contained in a document incorporated or deemed to be incorporated by reference herein into this prospectus shall be deemed to be modified or superseded for the purposes of this prospectus to the extent that a statement contained in this prospectus (or in any document incorporated by reference herein therein) or in any other subsequently filed document that is or is deemed to be incorporated by reference herein into this prospectus modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

PROSPECTUS SUMMARY

You should read the following summary together with the entire prospectus and the documents incorporated by reference herein, including our consolidated financial statements and related notes as well as any free writing prospectus prepared by us or on our behalf. You should carefully consider, among other things, the matters discussed in the sections entitled "Risk Factors" included or incorporated by reference in this prospectus.

NATERA, INC.

Overview

We are a diagnostics company with proprietary molecular and bioinformatics technology that we are deploying to change the management of disease worldwide. Our novel molecular assays reliably measure many informative regions across the genome from samples as small as a single cell. Our statistical algorithms combine these measurements with data available from the broader scientific community to identify genetic variations covering a wide range of serious conditions with best-in-class accuracy and coverage. Our technology has been proven clinically and commercially in the reproductive health space, in which we develop and commercialize non- or minimally- invasive tests to evaluate risk for, and thereby enable early detection of, a wide range of genetic conditions, such as Down syndrome. We are now translating our success in reproductive health and applying our core technology to the oncology market, in which we are commercializing a blood-based DNA test to detect residual disease and monitor disease progression and treatment response, as well as to the organ transplant market, with a test to assess kidney transplants for rejection. We seek to enable even wider adoption of our technology through our global cloud-based distribution model. In addition to our direct sales force in the United States, we have a global network of over 100 laboratory and distribution partners, including many of the largest international laboratories.

Since 2009, we have launched a comprehensive suite of ten products in reproductive health, as well as our personalized molecular monitoring test for use in oncology and our transplant rejection test. We intend to continue to launch new products in the future.

We launched Panorama, our non-invasive prenatal test, or NIPT, in March 2013 and have since gone from being the fourth company to enter the NIPT market to being the market leader by volume in the United States in 2019. We launched our Horizon carrier screening test in 2012. Panorama and Horizon together represent the significant majority of our revenues. Our revenues were \$302.3 million in 2019 compared to \$257.7 million in 2018 and \$209.6 million in 2017. Our product revenues, which have been primarily generated from testing in reproductive health, were \$269.9 million, \$240.4 million and \$203.8 million for the years ended December 31, 2019, 2018 and 2017, respectively. Our net losses decreased to \$124.8 million in 2019 from \$128.2 million in 2018, which in turn decreased from \$137.6 million in 2017.

In reproductive health, oncology and transplant rejection, the use of blood-based tests offers significant advantages over older methods, but the significant technological challenge is that such testing requires the measurement of very small amounts of relevant genetic material circulating—fetal DNA in reproductive health, tumor DNA in oncology, and donor DNA in transplant rejection—within a much larger blood sample. Our approach combines proprietary molecular biology and computational techniques to measure genomic variations in tiny amounts of DNA, as small as a single cell. Our molecular biology techniques are based on measuring thousands of single nucleotide polymorphisms, or SNPs, simultaneously using massively multiplexed polymerase chain reaction, or mmPCR, to multiplex, or target, many thousands of regions of the genome simultaneously in a single test reaction. Our method avoids losing molecules, which can happen when samples are split into separate reaction tubes, so that relevant variants can be detected. We believe our approach represents a fundamental advance in molecular biology. In reproductive health, this approach is distinct from the approach employed with

other commercially available NIPTs, which use first-generation "quantitative", or counting, methods to compare the relative number of sequence reads from a chromosome of interest to a reference chromosome. Based on extensive data published in the journals *Obstetrics & Gynecology*, *American Journal of Obstetrics & Gynecology*, *Prenatal Diagnosis*, and others, we believe Panorama is the most accurate NIPT commercially available in the United States. In oncology, our assay has demonstrated the ability to detect circulating tumor DNA, or ctDNA, with a high degree of sensitivity and specificity, and we believe it is the only ctDNA test that is custom designed for, informed by and specific to, the tumor DNA for each patient. In transplant rejection, published studies of our test performance in both clinical and analytical validation report higher sensitivity and higher area under the curve, or AUC, than both the current standard of care and the current commercially available test. The current standard of care in transplant rejection detection uses functional impairment assessed by serum creatinine or estimated glomerular filtration rate, or eGFR, which are clinically accepted but potentially inaccurate approaches for assessing active transplant rejection.

For a description of our business, financial condition, results of operations and other important information regarding us and our business, we refer you to our filings with the SEC, incorporated by reference in this prospectus. For instructions on how to find copies of these documents, see "Where You Can Find More Information."

Recent Developments

Signatera

On September 3, 2020, the CMA Molecular Diagnostics Program, or MOLDX, finalized a local coverage determination to provide Medicare benefits for serial use of our Signatera test in patients with Stage II or III colorectal cancer. The coverage decision covers the use of Signatera for patient risk stratification after surgical resection, to inform adjuvant treatment decisions, and for recurrence monitoring with the same frequency as the carcinoembryonic antigen test in patients with a previous cancer diagnosis but no ongoing evidence of disease.

Signatera is our personalized ctDNA blood test for molecular residual disease, or MRD, assessment and surveillance of disease recurrence in patients previously diagnosed with cancer, including colorectal cancer. We launched Signatera in 2017 for research use only to cancer researchers and biopharmaceutical companies, and in May 2019 for clinical use as a laboratory developed test in our own CLIA-certified and CAP-accredited laboratory.

SMART Study

On September 2, 2020, we announced that results of our SMART Study were un-blinded, with related public disclosure and publications expected in 2021. The objective of the SMART Study was to evaluate the performance of SNP-based NIPT for 22q11.2 deletion syndrome by tracking birth outcomes in the general population among over 18,000 women who presented clinically and elected Panorama microdeletion and aneuploidy screening as part of their routine care.

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. We do not incorporate the information on, or accessible through, our website into this prospectus, and you should not consider any information on, or accessible through, our website as part of this prospectus.

Natera, Panorama, Horizon and other trademarks or service marks of Natera appearing in this prospectus are the property of Natera. This prospectus contains additional trade names, trademarks and service marks of ours and of other companies. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

THE OFFERING

Common stock offered by Natera	4,166,666 shares of common stock.
Common stock to be outstanding after this offering	83,884,045 shares of common stock (84,509,044 shares if the underwriters exercise their option to purchase additional shares in full).
Option to purchase additional shares	We have granted to the underwriters the option, exercisable for 30 days from the date of this prospectus, to purchase up to 624,999 additional shares of our common stock.
Use of proceeds	We intend to use the net proceeds from this offering for working capital and general corporate purposes and continued investments in research and development for our core technology and development of our product offerings. In addition, we may use a portion of the net proceeds for acquisitions of complementary businesses, technologies or other assets. However, we have no current understandings, agreements or commitments for any material acquisitions at this time. See "Use of Proceeds."
Risk factors	Investing in our common stock involves a high degree of risk. See "Risk Factors" in this prospectus and other information included or incorporated into this prospectus for a discussion of the factors you should carefully consider before deciding to invest in our securities.
The Nasdaq Global Select Market Symbol	NTRA

The number of shares of common stock that will be outstanding after this offering is based on 79,717,379 shares outstanding as of June 30, 2020, and excludes:

- 4,056,000 shares of common stock issuable upon the vesting and settlement of restricted stock units outstanding as of June 30, 2020;
- 7,822,038 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2020 with a weighted-average exercise price of \$11.26 per share;
- 10,921 shares of common stock issuable upon the exercise of options granted between July 1, 2020 and August 31, 2020, with a weighted-average exercise price of \$62.92 per share;
- 157,104 shares of common stock issuable upon the vesting and settlement of restricted stock units granted between July 1, 2020 and August 31, 2020; and
- 7,036,019 shares of common stock, subject to increase on an annual basis, reserved for future grant or issuance under our stock-based compensation plans, consisting of:
 - 4,714,939 shares of common stock as of June 30, 2020 reserved for future grants under our 2015 Equity Incentive Plan, or the 2015 Plan; and
 - 2,321,080 shares of common stock as of June 30, 2020 reserved for future issuance under our 2015 Employee Stock Purchase Plan, or the 2015 ESPP.

Unless otherwise indicated, all information in this prospectus assumes no exercise by the underwriters of their option to purchase additional shares.

SUMMARY FINANCIAL DATA

The following tables set forth a summary of our historical financial data as of and for the periods presented. The summary historical financial data set forth below includes the results of operations and balance sheet data as of June 30, 2020 and 2019 and for the six months ended June 30, 2020 and 2019, and the years ended, and as of, December 31, 2019, 2018 and 2017. The summary financial data as of June 30, 2020 and six months ended June 30, 2020 and 2019 have been derived from our unaudited condensed financial statements included in our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which is incorporated herein by reference. The summary historical financial data as of and for each of the three years in the period ended December 31, 2019 have been derived from our audited financial statements included in our Annual Report on [Form 10-K for the year ended December 31, 2019](#), which is incorporated herein by reference. The unaudited condensed financial data have been prepared on a basis consistent with our audited financial statements, and in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation. Historical results are not necessarily indicative of the results to be expected in the future, and results for the six months ended June 30, 2020 are not necessarily indicative of results to be expected for the full year ended December 31, 2020.

The information below should be read in conjunction with (i) our financial statements (and notes thereto) contained in our [Annual Report on Form 10-K for the year ended December 31, 2019](#) and our unaudited condensed financial statements (and notes thereto) contained in our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), and (ii) "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 in our [Annual Report on Form 10-K for the year ended December 31, 2019](#), and Part I, Item 2 of our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), each incorporated by reference herein.

(in thousands, except per share data)	Six months ended June 30, (unaudited)		Year ended December 31,		
	2020	2019	2019	2018	2017
Selected Consolidated Statement of Operations Data:					
Total revenues	\$ 180,484	\$ 141,179	\$ 302,328	\$ 257,654	\$ 209,625
Total cost and expenses	(267,016)	(201,561)	(418,615)	(372,282)	(344,966)
Interest expense and other income (expense), net	(8,439)	(4,156)	(6,541)	(13,205)	(1,833)
Income tax expense	(38)	(1,969)	(1,999)	(321)	(454)
Net loss	<u>\$ (95,009)</u>	<u>\$ (66,507)</u>	<u>\$ (124,827)</u>	<u>\$ (128,154)</u>	<u>\$ (137,628)</u>
Net loss per share, basic	<u>\$ (1.21)</u>	<u>\$ (1.01)</u>	<u>\$ (1.79)</u>	<u>\$ (2.22)</u>	<u>\$ (2.58)</u>
Net loss per share, diluted	<u>\$ (1.21)</u>	<u>\$ (1.01)</u>	<u>\$ (1.79)</u>	<u>\$ (2.22)</u>	<u>\$ (2.59)</u>

	As of June 30, 2020 (unaudited)	As of December 31,	
		2019	2018
Selected Consolidated Balance Sheet Data:			
Cash, cash equivalents and restricted cash	\$ 77,377	\$ 61,981	\$ 51,004
Short-term investments	493,852	379,065	107,461
Inventory	18,033	12,394	13,633
Property and equipment, net	25,925	23,283	24,336
Total assets	723,261	582,656	268,171
Debt	247,529	123,779	123,510
Total liabilities	418,994	303,945	236,009
Total stockholders' equity	304,267	278,711	32,162

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information contained in this prospectus or any document incorporated by reference herein. The risks described in this prospectus or any document incorporated by reference herein are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Many of the following risks and uncertainties and those contained in the documents incorporated by reference herein are, and will be, exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. If any of the unfavorable events or circumstances described in the risk factors actually occurs, our business may suffer, the trading price of our common stock and other securities could decline, and you could lose all or part of your investment.

Risks Related to Our Business and Industry

We face risks related to health epidemics, including the current COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

Our business has been and continues to be adversely affected by the ongoing pandemic of respiratory illness caused by a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19. Global health concerns relating to the COVID-19 pandemic have been weighing on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty.

The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. For example, our personnel located at our headquarters in California and elsewhere in the United States and in other countries have been subject to shelter-in-place or stay-at-home orders from state and local governments for the past several months. These measures have adversely impacted and may further impact our employees and operations, and the operations of our customers, suppliers and business partners, and may negatively impact spending patterns, payment cycles and insurance coverage levels. These measures have adversely affected and are expected to continue to adversely affect demand for our tests. Many of our customers, including hospitals and clinics, have suspended non-emergency appointments and services, which resulted in a significant decrease in our test volume. In addition, because we rely heavily on our direct sales force to sell our tests, we expect our sales cycle, particularly for new customers, will continue to be significantly impacted. Travel bans, restrictions and border closures have also impacted our ability to ship test kits to and receive samples from our customers. In addition, certain aspects of our business, such as laboratory processes, cannot be conducted remotely. These measures by government authorities may continue to remain in place for a significant period of time and they are likely to continue to adversely affect our test volume, sales activities and results of operations for an indefinite period of time.

In addition, it may be more difficult for us to develop new products for commercial release, as we expect it will be more difficult to complete our research and development efforts and commence and complete clinical trials while the pandemic is ongoing. It is also possible that demand for products that we may pursue could be materially and adversely affected as a result of COVID-19, disruptions to our or our customers' operations, and any related economic impact.

The spread of COVID-19 has caused us to modify our business practices (including employee travel, mandating that all non-essential personnel work from home, temporary closures of our offices, and cancellation of physical participation in sales activities, meetings, events and conferences) and incur some operating costs, and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, customers and business partners. Such

actions could also impact our ability to fully integrate businesses we may acquire in the future. There is no certainty that such actions will be sufficient to mitigate the risks posed by the virus or otherwise be satisfactory to government authorities. If significant portions of our workforce, and particularly our laboratory staff, are unable to work effectively, including due to illness, quarantines, social distancing, government actions or other restrictions in connection with the COVID-19 pandemic, our operations will be impacted.

The extent to which the COVID-19 pandemic impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration and spread of the pandemic, its severity, the actions to contain the virus or address its impact, and how quickly and to what extent normal economic and operating activities can resume. The COVID-19 pandemic could limit the ability of our customers, suppliers and business partners to perform under their contracts with us, including third-party payers' ability to make timely payments to us during and following the pandemic. We may also experience a shortage of laboratory supplies and reagents or a suspension of services from other laboratories or third parties. We have also become increasingly dependent on growing and maintaining a network of mobile phlebotomy specialists who can provide testing capabilities, as many consumers are unable to visit clinics, hospitals or other testing facilities as a result of the pandemic. Even after the pandemic has subsided, we may continue to experience an adverse impact to our business as a result of its global economic impact, including any recession that has occurred or may occur in the future.

Specifically, difficult macroeconomic conditions, such as decreases in per capita income and level of disposable income and related health insurance coverage, increased and prolonged unemployment or a decline in consumer confidence as a result of the pandemic, as well as limited or significantly reduced points of access of our products, could have a material adverse effect on the demand for some of our products, such as our products targeted for the IVF market. Decreased demand for our tests, particularly in the United States, could negatively affect our overall financial performance. A significant portion of our revenue is concentrated in the United States, where the impact of COVID-19 continues to be significant, and the potential decrease in demand for our tests could have a disproportionately negative impact on our business and financial results.

In addition, the stock market has been unusually volatile during the COVID-19 pandemic and such volatility may continue, and financial markets generally have experienced periods of significant volatility. Our stock price has also experienced volatility during this time, including occasional significant declines, and such declines may repeat or continue for the foreseeable future.

We do not yet know the full extent and duration of the impact of the COVID-19 pandemic on our business, our operations, and the global economy as a whole, and there are no comparable recent events which may provide guidance in this respect. However, the effects have impacted our business and operations, we expect that they will continue to have a material adverse impact on our business and results of operations.

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

Historically, including for the six months ended June 30, 2020 and the year ended December 31, 2019, the significant majority of our revenues were derived from sales of our Panorama NIPT and our Horizon carrier screening, or HCS, test, and we expect this to continue to be the case. With respect to Panorama in particular, continued and additional market demand for Panorama, and reimbursement for the average risk population and for microdeletions, are key elements to our future success. In the three months ended June 30, 2020, we performed over 105,000 tests for microdeletions. The market demand for NIPTs and carrier screening tests continue to evolve. We cannot guarantee that physicians

will recommend and order Panorama or Horizon, and our laboratory distribution partners and licensees may not actively or effectively market Panorama or Horizon.

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

- the market for our tests may not grow as we expect; in particular, NIPTs may not gain acceptance for use in the average-risk pregnancy population or as a screen for microdeletions, which would limit the market for Panorama, and we may fail to compete successfully in this market, whatever size;
- if we are unable to demonstrate that our tests are superior to competing tests, laboratories, clinics, clinicians, physicians, payers and patients may not adopt the use of Panorama, Horizon or our other tests on a broad basis, and may not be willing to pay the price premium over competing tests that we have, to date, been able to achieve;
- third-party payers, such as commercial insurance companies and government insurance programs, may decide not to reimburse for Panorama or Horizon, 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 any reimbursements at prices that do not allow us to cover our expenses; in fact, many third-party payers currently have negative coverage determinations or otherwise do not reimburse for average-risk patient populations or for microdeletions screening and we expect low reimbursement rates for microdeletions screening to continue, at least in the near term; also, most state Medicaid programs currently either reimburse at low rates or do not reimburse for our tests;
- third-party payers have increasingly required that prior authorization be obtained prior to conducting genetic testing as a condition to reimbursing for it, which has reduced and/or delayed the reimbursement amounts we receive for Panorama, Horizon and our other tests, which has impacted our results of operations since the fourth quarter of 2017, when these requirements began to take effect;
- the results of our SMART Study evaluating the performance of Panorama, when published, may fail to convince laboratories, clinics, clinicians, physicians or patients of the benefits of utilizing Panorama in average risk pregnancies or for microdeletions and may not increase reimbursement for Panorama;
- the results of our clinical trials and any additional clinical and economic utility data that we may develop, present and publish in the future or that comes from the commercial use of our tests may be inconsistent with our existing data, including the data from our SMART Study, and may raise questions about the performance of our tests, or may fail to convince laboratories, clinics, clinicians, physicians, payers or patients of the value of our tests; we may experience supply constraints, including those due to the failure of our key suppliers to provide required sequencers and reagents in sufficient amounts or of adequate quality or disputes with our key suppliers, including those with respect to the required sequencers and reagents from our supplier, Illumina, Inc., or Illumina, who is also one of our main NIPT competitors through its subsidiary, Verinata Health Inc., or Verinata, and with whom we are currently involved in patent proceedings as further described in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Unaudited Interim Condensed Consolidated Financial Statements, which are incorporated by reference herein;
- we may experience increased cost of product revenues, and cost of licensing and other revenues, as a percentage of total revenues, as has been the case in previous fiscal 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, Horizon or our other tests, including requiring FDA clearance or approval for the sale of Panorama or Horizon or of the sequencers, reagents, kits and other consumable products that we purchase from third parties in order to perform our testing;
- our laboratory partners may choose to develop their own tests that are competitive with ours or offer tests provided by our competitors due to pricing or other reasons as has happened in the past, or otherwise fail to effectively market our tests; and competitors may develop and commercialize more effective and/or less expensive tests that deliver comparable results as our tests;
- we may fail to adequately protect or enforce our intellectual property relating to our tests, leading to increased competition; or other parties may claim that the practice of our technology by us or our licensees and collaborators infringes such other party's intellectual property rights, as each of Illumina, CareDX, Inc., or CareDx, and Ravgen, Inc., or Ravgen, have done in lawsuits filed against us, as discussed further in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Unaudited Interim Condensed Consolidated Financial Statements in our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which is incorporated by reference herein; 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 our tests, we may experience increased costs in running our tests, and we may be unable to pass such costs on to our customers;
- we may be unable to dedicate adequate resources to the maintenance and further technological advancement of Panorama and Horizon that are necessary for such tests to be competitive in the marketplace because of the demands placed on our research and development and product teams with respect to our continuously expanding portfolio of products and programs, including our Signatera and Prospera tests;
- in the event that it is in our commercial or financial interest or we are forced to transition sequencing platforms for Panorama, we may be unable to do so in a commercially sustainable way and that could survive claims of infringement of intellectual property rights of Illumina and other competitors, in a timely manner or at all; and
- we may not be successful in commercializing our cloud-based distribution model.

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

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

We have incurred net losses each year since our inception in 2003. To date, we have financed our operations primarily through private placements of preferred stock, convertible debt and other debt instruments, our initial public offering and our registered public equity offerings. Our net loss for the six months ended June 30, 2020 and 2019 was \$95.0 million and \$66.5 million, respectively. As of June 30, 2020, and December 31, 2019, we had an accumulated deficit of \$794.6 million and \$699.2 million, respectively. Such losses may continue to increase in the future as we continue to devote a substantial portion of our resources to efforts to increase the adoption of, and reimbursement for, Panorama, Horizon and our other products, improve these products, and research and develop and commercialize new products, which increasingly are in industries that are new to us, such as oncology and organ health.

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

As further discussed in the risk factor entitled "*We may not be successful in commercializing our cloud-based distribution model,*" our results of operations may be adversely affected if we do not sell a sufficient volume of tests under our cloud-based distribution model to offset the lower revenues per test performed under that model. 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 prospectus. If our assumptions regarding these risks and uncertainties are incorrect or these risks and uncertainties change, or if we do not address these risks successfully, our operating and financial results may differ materially from our expectations, and our business may suffer.

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

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

We have relatively limited experience developing and commercializing cell-free DNA tests outside of the reproductive health space, and we may not be successful in our current or future efforts to do so. We also have limited experience forecasting our future financial performance from our new products, including non-NIPT types of cell-free DNA tests, and our actual results may fall below our financial guidance or other projections, or the expectations of analysts or investors, which could cause

the price of our common stock to decline. We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new tests and result in increased costs and the diversion of management's attention and resources from other business matters, such as from our Panorama and Horizon product offerings, which currently represent the significant majority of our revenues. For example, any tests that we may enhance or develop may not prove to be clinically effective in clinical trials or commercially, or may not meet our desired target product profile, be offered at acceptable cost and with the sensitivity, specificity and other test performance metrics necessary to address the relevant clinical need or commercial opportunity; our test performance in commercial experience may be inconsistent with our validation or other clinical data; we may not be successful in achieving market awareness and demand, whether through our own sales and marketing operations or through collaborative arrangements; healthcare providers may not order or use, or third-party payers may not reimburse for, any tests that we may enhance or develop; or we may otherwise have to abandon a test or service in which we have invested substantial resources. In particular, we are subject to the risk that the biological characteristics of the genetic mutations we seek to target, and upon which our technologies rely, are uncertain and difficult to predict. For example, in our efforts to detect and analyze circulating tumor DNA in plasma for MRD assessment and recurrence surveillance, our success depends on tumors shedding mutant DNA into the bloodstream in sufficient quantities such that our technology can detect such mutations. As further discussed in the risk factor entitled "*If our products do not perform as expected, our operating results, reputation and business will suffer,*" we may also experience unforeseen difficulties when implementing updates to our processes, as we have occasionally experienced with Panorama and with Horizon.

We cannot assure you that we can successfully complete the clinical development of any new or enhanced product, or that we can establish or maintain the collaborative relationships that may be essential to our clinical development and commercialization efforts. Clinical development requires large numbers of patient specimens and, for certain products, may require large, prospective, and controlled clinical trials. We may not be able to enroll patients or collect a sufficient number of appropriate specimens in a timely manner; or we may experience delays during clinical development due to slower than anticipated enrollment, which we experienced in the past with our SNP-based Microdeletions and Aneuploidy RegisTry, or SMART, Study, or due to changes in study design or other unforeseen circumstances, such as our decisions in the past to expand our SMART Study; or we may be unable to afford or manage the large-sized clinical trials that some of our planned future products may require.

On September 2, 2020, we announced that results of our SMART Study were un-blinded, with related public disclosure and publications expected in 2021. The objective of the SMART Study was to evaluate the performance of SNP-based NIPT for 22q11.2 deletion syndrome by tracking birth outcomes in the general population among over 18,000 women who presented clinically and elected Panorama microdeletion and aneuploidy screening as part of their routine care. There is no assurance that the results of our SMART Study, when released, will convince laboratories, clinics, clinicians, physicians or patients of the benefits of utilizing Panorama in average risk pregnancies or for microdeletions. We also cannot be certain whether, or to what extent, the SMART Study may impact insurance coverage and reimbursement for Panorama in the average-risk population or for microdeletions. Further, the data collected from any studies we complete in the future may not be favorable or consistent with our existing data or may not be statistically significant or compelling to the medical community or to third-party payers seeking such data for purposes of determining coverage for our tests.

The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for tests such as ours, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any test that is the subject of a study. Peer-reviewed publications regarding our tests may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from, clinical studies, as well as delays

in the review, acceptance and publication process. If our tests or the technology underlying our current tests or future tests do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption of our tests and positive reimbursement coverage determinations for our tests could be negatively affected.

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

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

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

Our quarterly results of operations, including our revenues, gross margin, net loss and cash flows, may vary from period to period as a result of a variety of factors, many of which are outside of our control, including those listed elsewhere in this "Risk Factors" section, and as a result, period-to-period comparisons of our operating results may not be meaningful. Our quarterly results should not be relied upon as an indication of future performance. In addition, to the extent that we continue to spend considerably on our internal sales and marketing and research and development efforts, we expect to incur costs in advance of achieving the anticipated benefits of such efforts. Fluctuations in quarterly results and key metrics may cause our results to fall below our financial guidance or other projections, or the expectations of analysts or investors, which could adversely affect the price of our common stock. We also face competitive pricing and reimbursement pressures, and we may not be able to maintain our premium pricing in the future, which would adversely affect our operating results.

Competition in our industry is intense; if we are unable to compete successfully with respect to our current or future products or services, we may be unable to increase or sustain our revenues or achieve profitability.

We compete primarily in the molecular testing field, which is characterized by rapid technological changes, frequent new product introductions, reimbursement challenges, emerging competition, intellectual property disputes and litigation, price competition, aggressive marketing practices, evolving industry standards and changing customer preferences. Our principal competition in reproductive health comes from existing testing methods, technologies and products that are used by OB/GYNs, MFM specialists or IVF centers. These include other NIPTs and carrier screening tests offered by our competitors, as well as established, traditional first-line prenatal screening methods, such as serum protein measurement, where doctors measure certain hormones in the blood, and invasive prenatal diagnostic tests like amniocentesis, which have been used for many years and are therefore difficult to displace or supplement. In addition, new testing methods may be developed which may displace or be preferred over NIPTs, such as whole genome sequencing or single cell analysis. We are new to the fields of oncology and organ health, and face competition in these business areas from other

companies, many of which are larger, more established and have more experience and more resources than we do. Some companies in the ctDNA-based liquid biopsy field are expanding their research and development efforts to include tracking more tumor-specific variants and/or other biomarkers in addition to ctDNA, on the basis that these analyses may collectively result in improved sensitivity and earlier detection than currently available tests, such as Signatera. We cannot assure you that research, discoveries or other advancements by other companies will not render our existing or potential products and services uneconomical or result in products and services that are superior or otherwise preferable to our current or future products and services.

We compete with numerous companies in the genetic diagnostics space. Our primary competitors in NIPT include Sequenom, which was recently acquired by LabCorp; Illumina, through its subsidiary Verinata; Ariosa, a subsidiary of Roche; Myriad Genetics, Inc., which has acquired Counsyl, Inc; Invitae Corp.; Bio-Reference, a business unit of OPKO Health, Inc.; Quest; Premaitha Health PLC; BGI; Progenity, Inc., or Progenity; and NxGen. All of our main NIPT competitors in the United States are owned or controlled by companies much larger than ours and with much greater resources for sales, marketing and research and development efforts. Our primary competitors in carrier screening include LabCorp; Myriad Genetics, Inc.; Mount Sinai Genomics, Inc. d/b/a Sema4; Invitae Corp.; Progenity; Quest; Recombine Inc.; GeneDx, Inc., a subsidiary of Bio-Reference; and GenPath Diagnostics, a business unit of Bio-Reference. In the field of ctDNA-based MRD assessment and recurrence surveillance, we face competition from various companies that offer or seek to offer competing solutions, such as Roche Diagnostics, a division of Roche; Guardant Health, Inc., Adaptive Biotechnologies, Personal Genome Diagnostics, Inc.; Exact Sciences Corp.; Inivata, Inc.; C2i Genomics, Inc.; and ArcherDX, Inc., or ArcherDX, which has entered into an agreement to be acquired by Invitae Corp. In the field of transplant rejection, our primary competitors include CareDx and Eurofins Viracor, Inc. We expect that competition in these spaces will continue to increase.

Some of our competitors' products and services are sold at a lower price than ours, which could cause sales of our tests and services to decline or force us to reduce our prices. Our current and future competitors could have greater technological, financial, reputational and market access advantages than us, and we may not be able to compete effectively against them. Increased competition is likely to result in pricing pressures, which could harm our revenues, operating income or market share. We are increasingly subject to litigation with our competitors; for example, as disclosed elsewhere in these risk factors, we are or have recently been in active litigation with competitors in each of the reproductive health, oncology and organ transplantation fields, which involve considerable costs to us as well as management time and attention. If we are unable to compete successfully, we may be unable to increase or sustain our revenues or achieve profitability.

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

We utilize a cloud-based distribution model to deploy our bioinformatics technology for use by other laboratories. Under this model, clinical laboratories around the world, including in the U.S., license our technology to develop and run their own NIPT or other molecular testing assays in their own facilities as LDTs, and then access our proprietary algorithms through our cloud-based Constellation software to analyze the assay results. In the diagnostics industry, the market for cloud-based solutions and services is not as mature as the market for on-premise enterprise software, and it remains uncertain whether and to what extent our cloud-based distribution model will achieve and sustain high levels of customer demand and market acceptance. As of August 31, 2020, only 15 licensees are using Constellation commercially to market NIPT products and one licensee is using Constellation commercially to market its non-invasive prenatal paternity test in the United States and internationally. The rate of adoption of our cloud-based distribution model continues to be slower than we anticipated, and depends on a number of factors, including the cost, performance and perceived value associated with our solution, as well as our ability to address security, privacy and regulatory

requirements or concerns. In particular, all of our licensees under our cloud-based distribution model are required to use Illumina sequencers and reagents to run their tests that they develop based on our technology. As further described in the risk factor entitled "*We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers,*" we are aware that Illumina has required our licensees to pay an additional license fee in certain jurisdictions in order to secure a supply agreement for the sequencers and reagents necessary to run NIPT under our cloud-based distribution model. Furthermore, Illumina competes with us through its subsidiary Verinata, and may not charge a similar license fee for Verinata's licensed-based offering to other laboratories. As a result, our potential or current licensees may be unable to commercially launch their tests under our cloud-based distribution model in a financially viable manner, which has dissuaded and could continue to dissuade potential or current licensees from licensing from us or launching a test based on our technology. In addition, if a test developed by any of our licensees under our cloud-based distribution model in the United States is found not to be an LDT, the licensee may not be able to market its test, and we would not receive the anticipated revenues from that licensee.

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

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

- our and our licensees' ability to obtain required regulatory authorizations from the FDA and international regulatory agencies as further described in the risk factor entitled "*Reimbursement and Regulatory Risks Related to Our Business—Failure to obtain necessary regulatory approvals may adversely affect our ability to expand our operations internationally, including our ability to continue commercializing our cloud-based distribution model;*"
- supply constraints, including with respect to the blood collection tubes that are used for our Panorama test and that are supplied by Streck, Inc., or Streck, as further described in the risk factor entitled "*We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers;*"
- allegations or potential third-party claims that the tests, based on our technology, developed by our licensees violate such third parties' intellectual property rights in the territories in which our licensees commercialize their tests;
- licensing portions of our proprietary technology to third parties that may not take the same security precautions as we do to protect this information; and
- an inability to achieve anticipated benefits and costs savings.

If we or other cloud-based solution providers experience security incidents, loss of customer data or disruptions in delivery or other problems, the market for cloud-based solutions in the diagnostics industry, including our solutions, may be adversely affected. Such events could also result in potential lawsuits and liability claims, which could have a material adverse effect on our business. If there is a reduction in demand for cloud-based solutions caused by technological challenges, weakening economic conditions, security or privacy concerns, competing technologies and products or other challenges, we

may not be successful in executing our Constellation business model, and our results of operations may be adversely affected.

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

Approximately 86% and 80% of our total revenues for the six months ended June 30, 2020 and the year ended December 31, 2019, respectively, were attributable to our U.S. direct sales. We have had to expand our training and compliance efforts in line with our increasing reliance on personnel in our sales, marketing and billing functions, and our expansion of these functions in line with the overall growth in our business. We continue to monitor our personnel, but we have in the past experienced, and may in the future experience, situations in which employees fail to strictly adhere to our policies. In addition, sales and marketing activities in the healthcare space are subject to various rules and regulations, as described in the risk factor entitled "*Reimbursement and Regulatory Risks Related to Our Business—If we or our laboratory distribution partners, consultants or commercial partners act in a manner that violates healthcare fraud and abuse laws or otherwise engage in misconduct, we may be subject to civil or criminal penalties;*" moreover, our billing and marketing messaging can be complex and nuanced, and there may be errors or misunderstandings in our employees' communication of such messaging. Furthermore, we utilize text messaging, email, phone calls and other similar methods to communicate with patients who are existing or potential users of our products for various business purposes. These activities subject us to laws and regulations relating to communications with consumers, such as the CAN-SPAM Act and the Telephone Consumer Protection Act, violations of which could subject us to claims by consumers, who may seek actual or statutory damages, which could be material in the aggregate. As described further in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Unaudited Interim Condensed Consolidated Financial Statements in our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which is incorporated by reference herein, a purported class action lawsuit has been filed against us, alleging that we sent an unauthorized text message to a plaintiff's cellular telephone. As we continue to scale up our sales and marketing efforts in line with the growth in our business, in particular our increased pace of product launches as well as further geographical expansion, we face an increased need to continuously monitor and improve our policies, processes and procedures to maintain compliance with a growing number and variety of laws and regulations, including with respect to consumer marketing. To the extent that there is any violation, whether actual, perceived or alleged, of our policies or applicable laws and regulations, we may incur additional training and compliance costs, may receive inquiries from third-party payers or other third parties, or be held liable or otherwise responsible for such acts of non-compliance. Any of the foregoing could adversely affect our cash flow and financial condition.

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

We currently maintain a data center at our laboratory facilities in San Carlos, California. In addition, our proprietary bioinformatics algorithms are a crucial component of our test processing, and combine information derived from our mmPCR assay workflows with publicly available data from the broader scientific community to analyze and return test results. We host the significant majority of these algorithms on a cloud-based software platform pursuant to an agreement with DNAnexus, Inc., or DNAnexus, and both we and our Constellation licensees access our algorithms through the DNAnexus platform. The DNAnexus platform is hosted on third-party data center hosting facilities operated by Amazon Web Services, or AWS, located primarily in the United States and in the European Union. These algorithms cannot currently be run other than through the DNAnexus platform; they are currently used to run our Panorama NIPT and NIPT analysis for our Constellation licensees, as well as Horizon, Signatera, Prospera and certain of our research and development activities, and we plan to

utilize the platform for additional applications in the future. In the event of any technical problems that may arise in connection with our on-site data center, the DNAnexus platform or the AWS servers on which the DNAnexus platform is hosted, or difficulties in or termination of our relationship with DNAnexus, we could experience interruptions in our laboratory operations or our cloud-based services, and we and our Constellation licensees may be unable to access our proprietary algorithms and therefore be unable to process tests or conduct any other activities that require access to such algorithms. We do not have any backup platform, server or other means to host our algorithms, and may be unable to find and implement an alternative platform that is satisfactory for our needs on commercially reasonable terms, in a timely manner, or at all. These types of problems may be caused by a variety of factors, including infrastructure changes, human or software errors, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. Interruptions in our operations or service may reduce our revenue, cause us to issue refunds, result in the loss of customers, cause laboratory licensees to terminate their contracts with us, adversely affect our ability to attract new laboratory licensees, or harm our reputation. We could also be exposed to potential lawsuits and liability claims.

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

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

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

In addition, as further discussed in the risk factor entitled "*If we are unable to successfully grow revenues for our current or future products or services in addition to Panorama, our business and results of operations may be adversely affected,*" our Vistara NIPT is a relatively new test offering, as are Signatera and Prospera. Any failure to meet consumer expectations could harm our reputation.

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

We and our subsidiaries outsource the portions of testing that we do not perform in-house to third-party CLIA certified laboratories. For example, a portion of our Horizon carrier screening testing

and our Vistara single-gene mutations testing is performed by third-party laboratories. These third-party laboratories are subject to contractual obligations to perform these services for us, but are not otherwise under our control. We therefore do not control the capacity and quality control efforts of these third-party laboratories other than through our ability to enforce contractual obligations on volume and quality systems, and we have no control over such laboratories' compliance with applicable legal and regulatory requirements. We also have no control over the timeliness of such laboratories' performance of their obligations to us, and third-party laboratories that we have contracted with have in the past had, and occasionally continue to have, issues with delivering results to us or resolving issues with us within the time frames we expected or established in our contracts with them, which sometimes results in longer than expected turnaround times for, or negatively impacts the performance of, these tests and services. We may not have sufficient alternative backup if one or more of the third-party laboratories that we contract with are unable to satisfy their obligations to us with sufficient performance, quality and timeliness, including as a result of the COVID-19 pandemic. Any natural or other disaster, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at one or more of our third-party laboratories' facilities that causes a loss of capacity would heighten the risks that we face. Changes to or termination of our agreements or inability to renew our agreements with these third-party laboratories or enter into new agreements with other laboratories that are able to perform such portions of our service offerings could impair, delay or suspend our efforts to market and sell these tests and services. In the event of any adverse developments with these third-party laboratories or their ability to perform their obligations to us in a timely manner and in accordance with the standards that we and our customers expect, our ability to service our customers may be delayed, interrupted or otherwise adversely affected, which could result in a loss of customers and harm to our reputation. Furthermore, when these issues arise, we have had to expend time, management attention and other resources to address and remedy such issues. In addition, certain third-party payers, including some state Medicaid payers, that we are under contract with may take the position that sending out testing to third-party laboratories and billing for such tests is contrary to the terms of our provider agreement and may refuse to pay us for the testing. If any of these events occur, our business, financial condition and results of operations could suffer. Further, some state laws impose anti-markup restrictions that prevent an entity from realizing a profit margin on outsourced testing. If we or our subsidiaries are unable to markup outsourced testing, our revenues and operating margins may suffer.

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

Our ability to successfully grow revenues for products or services in addition to Panorama and Horizon, is uncertain and is subject to many of the risks we face with respect to Panorama and Horizon. 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 or superior to competing products or services; third-party payers may not reimburse for our tests, or may set the amounts of such reimbursements at prices that do not allow us to cover our expenses; we may fail to compete successfully in the relevant product markets, or our laboratory distribution partners may choose to more actively or exclusively market tests by competitors; we may experience supply constraints; and we may fail to adequately protect our intellectual property relating to our products or others may claim we infringe their intellectual property rights, which has occurred, as disclosed elsewhere in these Risk Factors, with respect to litigation with Illumina regarding Panorama, with ArcherDX regarding Signatera, with CareDx regarding Prospera and with Ravgen regarding Panorama, Vistara, Signatera and Prospera. In addition, because our revenues from Horizon now represent a significant proportion of our overall revenues, any adverse impact we experience with respect to Horizon could result in an impact to our overall revenues, or a component of such overall revenues; for example, a decline in our reimbursement rates for, and therefore our average selling price of, Horizon,

could result in a decline in our overall blended average selling price. If we are not able to increase adoption of and grow revenues for our products or services, our business and results of operations may be adversely affected.

We began offering our Vistara single-gene mutations screening test in May 2017; our Signatera cancer recurrence monitoring offering for research use only in August 2017; our twin pregnancies screening capability for Panorama in October 2017; and, on a limited basis, both our Signatera CLIA test and Prospera transplant rejection test in 2019, with full-scale commercial launches of both Signatera and Prospera in 2020. Our success with these offerings is subject to many of the risks affecting our business generally, as well as the inherent difficulties with launching a new offering and in new markets, including risks inherent in launching multiple new offerings simultaneously. Our Signatera and Prospera offerings, while based upon our core molecular diagnostic technology, are in fields that are new to us; and Vistara is subject to the risks inherent in commercializing a product with a laboratory partner. We have had to review and, in some cases, revise our processes, procedures and agreements with our business partners to address unforeseen operational issues and other contingencies, and will likely continue to do so as these areas of our business grow. We cannot assure you that our Vistara, Signatera or Prospera offerings will be successful.

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

We have recently expanded our laboratory operations capacity in Austin, Texas to support continued growth in our Panorama and Horizon tests and to help ensure business continuity. We are still ramping up our test processing capacity and abilities at this location, including by obtaining recognition as a Medicaid provider in certain states in which we are not already credentialed, which is required in order for us to obtain reimbursement from each such states' Medicaid program, as further described in the risk factor entitled "*—Our revenues may be adversely affected if we are unable to successfully obtain reimbursement from the Medicare program and state Medicaid programs.*" We currently otherwise have no backup or redundant facility to perform our main product and source of revenue, Panorama, which we perform at our primary San Carlos, California laboratory facility. Our Signatera and Prospera tests are currently also performed at our San Carlos facility, and our efforts in oncology and organ health represent significant areas of focus for us, both operationally and financially. Our San Carlos facility is situated near active earthquake fault lines. Our facility may be harmed or rendered inoperable, or samples could be damaged or destroyed, by natural or manmade disasters, including earthquakes, flooding, power outages and contamination, including as a result of the COVID-19 pandemic, 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 San Carlos facility is inoperable for even a short period of time may result in the loss of customers or harm our reputation.

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

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

For example, our molecular diagnostics tests are currently only validated to perform on Illumina's sequencing platform; in addition, Illumina is currently the sole supplier of our sequencers and related reagents for Panorama, Horizon, Signatera and Prospera, along with certain hardware and software, pursuant to a supply agreement that expires in May 2030. Without sequencers and the related reagents,

we would be unable to run our tests and commercialize our products. In addition, all of the licensees under our cloud-based distribution model do not have alternatives other than to use Illumina sequencers and reagents to run the tests that they develop based on our technology. In addition, Illumina and Sequenom, which was 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. Illumina has granted us certain rights to Illumina's intellectual property related to NIPT, including the pooled intellectual property, for running our own tests; however, we do not have an express license to grant rights under the pooled intellectual property to the licensees under our cloud-based distribution model. We are aware that Illumina has required our licensees, in order to secure a supply agreement for the sequencers and reagents necessary to run NIPT under our cloud-based distribution model, to pay an additional fee for a license under the pooled intellectual property in jurisdictions in which Illumina believes certain of the pooled intellectual property is enforceable. This additional fee has dissuaded and could continue to dissuade potential or current licensees from licensing from us or launching a test based on our technology. In addition, we have been involved in patent infringement litigation against Illumina, as further described in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Unaudited Interim Condensed Consolidated Financial Statements in our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which is incorporated by reference herein, which we and Illumina have largely settled; however, there remains outstanding a challenge by Illumina to the validity of our patent that was subject to the litigation, as well as a pending patent opposition proceeding by us against a European patent held by Illumina. In addition, Illumina directly competes with us in the NIPT market through its subsidiary, Verinata. We understand Illumina supplies the same or similar sequencers and consumables to Verinata. Because of Illumina's ownership of Verinata, we face increased risk and uncertainty regarding continuity of a successful working relationship with Illumina under our supply agreement, as well as in our ability to compete with Verinata in the marketplace in view of economic advantages enjoyed by Verinata with respect to the cost of sequencers and related consumables. Our failure to maintain a continued supply of the sequencers and reagents, along with the right to use certain hardware and software, would adversely impact our business, financial condition, and results of operations. In particular, while we are seeking to validate our tests on additional sequencing platforms, such as under our license agreement with BGI Genomics Co., Ltd., or BGI Genomics, we have not, to date, validated any alternative sequencing platform on which our testing could be run in a commercially viable manner. These efforts will require significant resources, expenditures and time and attention of management, and there is no guarantee that we will be successful in implementing any such sequencing platforms in a commercially sustainable way. We also cannot guarantee that we will appropriately prioritize or select alternative sequencing platforms on which to focus our efforts, in particular given our limited product and research and development resources and various business initiatives, which could result in increased costs and delayed timelines or otherwise impact our business and results of operations.

In addition, our Panorama test is currently only validated to be performed using Streck's blood collection tubes, and Streck is the sole supplier of the blood collection tubes included in our Panorama test under a supply arrangement with Streck under which we are required to exclusively use Streck tubes. Similarly, all of the licensees under our cloud-based distribution model also have no current alternative but to use these blood collection tubes to run the tests that they develop based on our technology. We also only use Streck tubes for the primary analysis of Signatera results, and for our Prospera test. Furthermore, the blood collection tubes supplied by Streck are intended for research use only and are labeled as RUO. Our sequencers, sourced from Illumina, as well as certain other reagents we use for Panorama and our other tests, are also labeled as RUO. As discussed further in the risk factor entitled *"Reimbursement and Regulatory Risks Related to Our Business—Changes in the way the*

FDA regulates the reagents, other consumables, and testing equipment we use when developing, validating, and performing our tests could result in delay or additional expense in bringing our tests to market or performing such tests for our customers," the FDA may determine that a product labeled RUO is, nonetheless, intended to be used diagnostically, and could take enforcement action against the supplier of the product. If this were to occur with respect to Streck, Illumina or any of our other suppliers of RUO products, we could be required to obtain one or more alternative sources of these products, and we may not be able to do so on commercially reasonable terms or at all. In addition, Streck's blood collection tubes have not been registered as a medical device in all countries in which we market our Panorama test. As discussed in the risk factor entitled *"Reimbursement and Regulatory Risks Related to Our Business—Failure to obtain necessary regulatory approvals may adversely affect our ability to expand our operations internationally, including our ability to continue commercializing our cloud-based distribution model,"* the regulatory authorities in some of these countries may determine that such registration is required, which could impact our ability to offer Panorama in such countries. Furthermore, because our licensees under our cloud-based distribution model also exclusively use such sole-sourced components to run the tests they develop based on our technology, and our laboratory distribution partners must use certain of such sole-sourced components in order to utilize our tests, any enforcement action against the supplier by the FDA or any other regulatory authority in the jurisdictions in which our licensees and laboratory distribution partners are located could have an adverse impact on our business.

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

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

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

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

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

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

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy. Although we take measures to protect sensitive information from unauthorized access, use or disclosure, our information technology and infrastructure, and that of our technology and other third party service providers and their subcontractors, are nevertheless inherently vulnerable, to some extent, to cyber-attacks by hackers or viruses or breaches due to employee error, technical error, malfeasance or other disruptions. Any such breach or interruption, whether of our systems or that of our third party service providers or their subcontractors, 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 or penalties under laws and regulations that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, European data privacy regulations, such as the General Data Protection Regulation, or GDPR, or state privacy regulations, such as the California Consumer Privacy Act. 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, 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. We are also subject to these risks as a result of our relationships with third party vendors and their subcontractors, whose systems may be breached and may cause our sensitive data, including patient data, to be compromised. We have on occasion experienced such disruptions.

For example, in May 2019, we were notified of a data security incident that compromised the computer systems of Retrieval-Masters Creditors Bureau, Inc. d/b/a American Medical Collection Agency, or AMCA, one of our third party vendors, and affected a limited number of our patients whose data was stored in AMCA's systems. While the accessed data did not include Social Security numbers, the credit card information of a small number of the patients was compromised. We notified the affected individuals as required by HIPAA. Further, in August 2020, we were notified of a data security incident that compromised the systems of another third party vendor, which affected a number of our patients whose data was stored in the vendor's systems. The compromised information included protected health information of such patients, but did not include Social Security numbers, financial information or test results. The vendor is in the process of making the required notifications.

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

The marketing, sale, and use of Panorama, Horizon 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, Horizon and our other products could lead to product liability claims against us if someone were to allege that our test failed to perform as it was designed or as claimed in our promotional materials, was performed pursuant to incorrect or inadequate laboratory procedures, if we delivered incorrect or incomplete test results, or if someone were to misinterpret test results. In addition, we may be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide, or for failure to provide such information, in connection with our marketing and promotional activities or as part of the results generated by Panorama, Horizon and our other products. For example, Panorama could provide a low-risk result which a patient or physician may rely upon to make a conclusion about the health of the fetus, which may, in fact, have the condition for which we delivered a low-risk result because the Panorama result was a so-called false negative. Even though Panorama and our other tests are highly accurate, they are not 100% accurate and we may report false negative results. If the resulting baby with the condition is born, the family may file a lawsuit against us claiming product or professional liability, as has happened in the past and may happen in the future. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain product and professional liability insurance, our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates, cause our insurance coverage to be terminated or prevent us from securing insurance coverage in the future. Additionally, any product liability or professional liability lawsuit could harm our reputation, result in a cessation of our services or cause our partners to terminate our agreements with them, any of which could adversely impact our results of operations.

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

Our overall test volumes grew from approximately 515,200 to 668,600 and further to 804,300 tests processed during the years ended December 31, 2017, 2018 and 2019, respectively, and since 2009 we have launched 16 product offerings, four of them in 2017 alone and additional products launched or planned for 2020. In addition, we regularly evaluate and refine our testing process, often significantly updating our workflows, as with Panorama in 2017 and Horizon in 2018. As our test volumes and product offerings continue to grow, we will need to continue to ramp up our testing capacity and implement increases in scale. We will need additional or new equipment, laboratory space and qualified laboratory personnel, and will need to increase office and laboratory space, expand our customer service capabilities, implement billing and systems process improvements, enhance our controls and procedures and expand our internal quality assurance program and technology platform. The value of Panorama, Horizon and our other products depends on our ability to perform the tests on a timely basis and at an exceptionally high standard of quality, and on maintaining our reputation for such timeliness and quality. Failure to implement necessary procedures, transition to new facilities, equipment or processes or to hire the necessary personnel in a timely and effective manner could result in higher processing costs or an inability to meet market demand, or could otherwise affect our operating results, as we have experienced in the past.

In addition, our efforts to scale our operations may be unable to keep pace with an increase in the frequency of our launches of new or enhanced products and services. Since January 1, 2017, we have launched eight new products, three of which are in markets or industries new to us. As we continue to launch additional offerings and product enhancements, we will need to manage our resources among various initiatives, and such competing priorities could lead to delays in one or more of our business initiatives. Conversely, to the extent that we scale our operations, infrastructure and other resources but do not ultimately meet our anticipated timelines in our product development efforts, we will experience higher costs and expenses than necessary until our project timelines and operational resources become aligned. We may also, intentionally or unintentionally, allocate resources to new products or initiatives in a manner disproportionate to the amount of revenue that such initiatives generate compared to our existing or core offerings. We cannot assure you that our efforts to scale our commercial operations will not negatively affect the quality of our test process or results, or that we will be successful in managing the growing complexity of our business operations.

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

adequately protect our trade secrets and other proprietary information, the value of our technology and products could be significantly diminished."

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

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

Part of our business strategy is to develop relationships with laboratory and other partners to sell our other products, both in the United States and internationally. For example, we have entered into an agreement with BGI Genomics pursuant to which, among others, we will commercialize Signatera in China and develop reproductive health tests on BGI Genomics's sequencing platform; and an agreement with Foundation Medicine to develop and commercialize personalized circulating tumor DNA monitoring assays for use by biopharmaceutical and clinical customers who order Foundation Medicine's companion diagnostic cancer test. Developing and commercializing products with third parties reduces our control over such development and commercialization efforts and subjects us to the various risks inherent in a joint effort with a third party, such as delays, operational issues, technical difficulties and other contingencies outside of our influence or control. Distributing Panorama, Signatera 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 third parties could weaken, or they could terminate their relationship with us and/or stop selling our products, as has happened in the past; reduce their marketing efforts in respect of our products; develop and commercialize or otherwise sell competing products in addition to or in lieu of our tests, as has also occurred; merge with or be acquired by a competitor of ours or a company that chooses to de-prioritize the efforts to sell our products; or otherwise breach their agreements with us. For example, as further described in "*Note 3—Revenue Recognition—Licensing and Other Revenues—Qiagen*" of our unaudited condensed financial statements included in our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which is incorporated by reference herein, we had entered into a license, distribution and development agreement with Qiagen pursuant to which, among others, Qiagen would distribute an NIPT based on our Panorama test on a sequencer to be developed by us and Qiagen; however, Qiagen has announced that it has discontinued the development of its Next Generation Sequencing Platform and has now partnered with Illumina to develop next-generation sequencing based tests. Furthermore, our laboratory partners may misappropriate our trade secrets or use our proprietary information in such a way as to expose us to litigation and potential liability; and our compliance risk may increase to the extent that we are responsible for our partners' sales and marketing activities. Disagreements or disputes with our laboratory partners, including disagreements over customers, proprietary rights or our or their compliance with contractual obligations, might cause delays or impair the commercialization of Panorama, Signatera or our other tests, lead to additional responsibilities for us with respect to new tests, or result in litigation or arbitration, any of which would divert management attention and resources and be time-consuming and expensive. As is typical for companies in our industry, we are continually evaluating and pursuing various strategic or commercial partnerships, relationships, or collaborations, some of which may involve the sale and issuance of our common stock, which could result in additional dilution of the percentage ownership of our stockholders and could cause the price of our common stock to decline.

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

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

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

We are subject to the Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Our reliance on independent laboratories to sell Panorama and other products internationally demands a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with foreign government officials. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and we could be subject to severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures, any of which could result in a material adverse effect on our business, prospects, financial condition, or results of operations.

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

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

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

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

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

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

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

From time to time, we may enter into transactions to acquire or dispose of businesses, products or technologies or to engage in other strategic transactions. Because we have not made any such acquisitions to date, our ability to do so successfully is unproven. Even if we identify suitable transactions, we may not be able to complete such transactions on favorable terms or at all. Any acquisitions or other strategic transactions we consummate may not strengthen our competitive

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

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

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

- our ability to achieve broader commercial success with Panorama, Horizon and our other products;
- the costs and success of our research, development, and commercialization efforts for potential new products;
- our ability to obtain more extensive coverage and reimbursement for our tests, including in the average-risk patient population and for microdeletions screening in NIPT, as well as in additional indications in oncology as we continue to expand our offerings in that field;
- our ability to generate sufficient revenues from our cloud-based distribution model;
- our ability to collect on our accounts receivable;
- our need to finance capital expenditures and further expand our clinical laboratory operations;
- our ability to manage our operating costs; and
- the timing and results of any regulatory authorizations that we are required to obtain for our tests.

Additional capital, if needed, may not be available on satisfactory terms or at all. Furthermore, any additional capital raised through the sale of equity or equity-linked securities, or grant of equity or equity-linked securities in connection with any debt financing, will dilute stockholders' ownership interests in us and may have an adverse effect on the price of our common stock. In addition, the terms of any financing may adversely affect stockholders' holdings or rights. Debt financing, if available, may include restrictive covenants, and may impose other constraints on us and our operations, as was the case under our 2017 Term Loan with OrbiMed. 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 programs, which could lower the economic value of those programs to our company.

We have incurred substantial indebtedness that may decrease our business flexibility, access to capital, and/or increase our borrowing costs, which may adversely affect our operations and financial results.

In April 2020, we issued \$287.5 million aggregate principal amount of 2.25% Convertible Senior Notes due 2027, or the Convertible Notes. Our indebtedness may:

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
- limit our ability to use our cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes;
- require us to use a substantial portion of our cash flow from operations to make debt service payments;
- limit our flexibility to plan for, or react to, changes in our business and industry;
- place us at a competitive disadvantage compared to our less leveraged competitors; and
- increase our vulnerability to the impact of adverse economic and industry conditions.

Further, the indenture governing the Convertible Notes does not restrict our ability to incur additional indebtedness and we and our subsidiaries may incur substantial additional indebtedness in the future, subject to the restrictions contained in any future debt instruments existing at the time, some of which may be secured indebtedness.

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

DNA testing, like that conducted using Panorama, Horizon, Signatera, and our other products, has raised ethical, legal and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genomic information or genomic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Patients may also refuse to use genetic tests even if permissible, for similar reasons; they may also refuse genetic testing due to concerns regarding eligibility for life or other insurance. Ethical and social concerns may also influence U.S. and foreign patent offices and courts with regard to patent protection for technology relevant to our business. These and other ethical, legal and social concerns may limit market acceptance of our tests or reduce the potential markets for services and products enabled by our technology platform, either of which could harm our business.

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

We have a significant amount of net operating loss, or NOL, carryforwards that can be used to offset potential future taxable income and related income taxes. As of December 31, 2019, we had federal and state NOL carryforwards of approximately \$514.0 million and \$271.6 million, respectively, which, if not utilized, begin to expire in 2027 and 2028, respectively. Approximately \$194.2 million of these federal NOLs can be carried forward indefinitely. We also had federal research and development credit carryforwards of approximately \$15.7 million, which begin to expire in 2027, and state research and development credit carryforwards of approximately \$13.0 million, which can be carried forward indefinitely. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change, by value, in equity ownership over any three-year period), the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may experience ownership changes in the future as a result of shifts in our stock ownership, some of which may not be within our control. Our ability to use these carryforwards could be limited if we experience an "ownership change."

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

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

Reimbursement and Regulatory Risks Related to Our Business

If we are unable to expand, maintain or obtain third-party payer coverage and reimbursement for Panorama, Horizon 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 and maintain adequate reimbursement coverage from third-party payers and patients. Third-party reimbursement for our testing represents a significant portion of our revenues, and we expect third-party payers such as insurance companies and government healthcare programs to continue to be our most significant source of payments. In particular, we believe that the following will be necessary for us to continue to achieve commercial success: expanding insurance coverage from the high-risk to the average-risk pregnancy population, which represents roughly 80% of the United States pregnancy market, and for microdeletions screening, and obtaining positive coverage determinations and favorable reimbursement rates from commercial third-party payers, the Centers for Medicare & Medicaid, or CMS, and state reimbursement programs for our tests. On September 2, 2020, we announced that results of our SMART Study were un-blinded, with related public disclosure and publications expected in 2021. The objective of the SMART Study was to evaluate the performance of SNP-based NIPT for 22q11.2 deletion syndrome by tracking birth outcomes in the general population among over 18,000 women who presented clinically and elected Panorama microdeletion and aneuploidy screening as part of their routine care. Historically, we have not received reimbursement for a significant number of Panorama tests that we have performed for average-risk patients and for microdeletions. We cannot be certain whether, or to what extent, the SMART Study may impact insurance coverage and reimbursement for Panorama in the average-risk population or for microdeletions. In addition, on September 3, 2020 we received a positive local coverage determination from MOLDX to provide Medicare benefits for serial use of our Signatera test in patients with Stage II or III colorectal cancer. However, we cannot guarantee that our test will be reimbursed at the rate we expect. Furthermore, while we have recently received a positive coverage decision for our Prospera test, we cannot guarantee that our test will continue to be reimbursed at the same or a similar rate as we have received thus far. If we are unable to obtain or maintain adequate reimbursement coverage from, or achieve in-network status with, third-party payers for our existing or future tests, our ability to generate revenues will be limited. For example, physicians may be reluctant to order our tests due to the potential of a substantial cost to the patient if reimbursement coverage is unavailable or insufficient.

In making coverage determinations, third-party payers often rely on practice guidelines issued by professional societies. The American College of Medical Genetics, or ACMG, has issued updated guidelines recommending informing pregnant women that NIPT is the most sensitive screening option for Patau, Edwards and Down syndromes, as well as of the availability of the expanded use of NIPT to screen for clinically relevant copy number variants, or CNVs, in the context of counseling that includes the risks/benefits and limitations of screening for CNVs. A CNV is a genetic mutation in which a segment of the genome has been deleted or duplicated, including microdeletions in which a small segment of a chromosome is deleted. The International Society for Prenatal Diagnosis, or ISPD, has issued guidelines that are supportive of performing NIPT in average-risk pregnancies, as well as

high-risk pregnancies. However, the Society for Maternal Fetal Medicine, or SMFM, has issued guidelines for NIPT stating that, while all pregnant women should be informed of the option to receive NIPT, conventional screening methods, such as traditional serum screening, rather than NIPT, remain the most appropriate choice for first-line screening for average-risk pregnancies. While we expect the ACMG and SMFM guidelines to result in an increase in the number of average-risk women who are informed of NIPT and that may request it as a result, not all third-party payers reimburse for NIPT for these average-risk patients. Currently, Aetna Inc., UnitedHealthcare Insurance Company and a number of other third-party payers (with the exception of a temporary expansion in coverage by one such third-party payer as a result of the COVID-19 pandemic) have negative coverage determinations for NIPT in average-risk patient populations, meaning that their policy is not to reimburse for NIPT for patients in the average-risk population. The SMFM guidelines also echoed a previous statement from SMFM that routine screening for microdeletions should not be performed. Many third-party payers do not reimburse for microdeletions screening. While we have published data on the performance of Panorama for the 22q11.2 deletion syndrome, we have and may continue to experience low reimbursement rates for Panorama for microdeletions. We expect to publish data from our SMART Study evaluating the performance of Panorama in 2021. If we are unable to present satisfactory additional data on the performance of Panorama for 22q11.2 deletion syndrome, including data from our SMART study, we may be unable to obtain positive coverage determinations for our test. If third-party payers do not reimburse for NIPT for average-risk pregnancies or microdeletions in the future, our future revenues and results of operations would be adversely affected, particularly to the extent that we continue to perform large volumes of tests for which third-party payors do not reimburse.

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

The reimbursement environment, particularly for molecular diagnostics, is continually changing and our efforts to broaden reimbursement for our tests with third-party payers may not be successful. Third-party payers from whom we have received reimbursement may withdraw coverage or decrease the amount of reimbursement coverage for our tests at any time and for any reason. In some cases, our tests or their uses within certain populations, such as for microdeletions, are considered experimental by third-party payers and, as a result, some payers have decided not to reimburse for such tests. In addition, some third-party payers bundle payment for multiple tests or tests that screen for multiple conditions, such as our Horizon test or our Panorama test and the separate Panorama screen for microdeletions, into a single payment rate, thereby limiting our reimbursement in those situations. Payers may also dispute our billing or coding. Based on any of the foregoing, third-party payers may also decide to deny payment or recoup payment for testing that they contend to have been not medically necessary, against their coverage determinations, or for which they have otherwise overpaid, and we may be required to refund reimbursements already received. We deal with requests for recoupment from third-party payers from time to time in the ordinary course of our business, and it is likely that we will continue to do so in the future. See "Note 8—Commitments and Contingencies—Third-Party Payer Reimbursement Audits" in the Notes to Unaudited Interim Condensed Consolidated Financial Statements in our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which is incorporated by reference herein. If a third-party payer denies payment for testing, reimbursement revenue for our testing could decline. If a third-party payer successfully proves that payment for prior testing was in breach of contract or otherwise contrary to law, they may recoup

payment, which amounts could be significant and would impact our results of operations, and it may decrease reimbursement going forward. We may also decide to negotiate and settle with a third-party payer in order to resolve an allegation of overpayment. Any of these outcomes might require us to restate our financials from a prior period, which would likely cause our stock price to decline. For example, in 2018 we reached a settlement with certain government payers regarding past reimbursement submissions; although the settlement involved no admission of fault by us and no corporate integrity agreement, we cannot guarantee that we will not be subject to similar claims, resulting in additional settlements or repayments, in the future.

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

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

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

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

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

It is estimated that nearly half of all births in the United States are to state Medicaid program recipients. Each state's Medicaid program has its own coverage determinations related to our testing, and many state Medicaid programs do not provide their recipients with coverage for our testing. Even if our testing is covered by a state Medicaid program, we must be recognized as a Medicaid provider by the state in which the Medicaid recipient receiving the services resides in order for us to be reimbursed by a state's Medicaid program, including under a Medicaid managed care plan. Our primary San Carlos laboratory is currently recognized by 48 states as a Medicaid provider, and we are currently in the process of obtaining recognition of our Austin laboratory as a Medicaid provider in states in which the Austin laboratory is not already credentialed; however, even if we are recognized as a Medicaid provider in a state, if Medicare's CLFS rate for our services and tests are low, the Medicaid reimbursement amounts are sometimes as low, or lower, than the Medicare reimbursement rate. In addition, from time to time we receive requests from state Medicaid programs seeking information or documents to determine eligibility for and the amount of Medicaid reimbursement. As a result of all of these factors, many state Medicaid programs only reimburse our testing at a very low dollar amount, or not at all. Low or zero-dollar Medicaid reimbursement rates for our tests could have an adverse effect on our business and revenues.

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

We are in network, or under contract, with the significant majority of third-party payers from whom we receive reimbursement; this means that we have agreements with most third-party payers that govern approval or payment terms. However, these contracts do not guarantee reimbursement for all testing we perform. For example, many third-party payers with whom we have written agreements have policies that state they will not reimburse for use of NIPTs for average-risk pregnancies or for the screening of microdeletions, or don't have a policy in place to reimburse for microdeletions screening. In addition, the terms of certain of our agreements require a physician or qualified practitioner's signature on test requisitions or require other controls and procedures prior to conducting a test. In particular, third-party payers have increasingly required prior authorization to be obtained prior to conducting a test, as a condition to reimbursing for the test. This has placed a burden on our billing operations as we have to dedicate or source resources to ensuring that these requirements are met and

to conduct follow-up and address issues as they arise, and has also impacted our results of operations, including our gross margins, since the fourth quarter of 2017, when these requirements began to take effect. To the extent we or the physicians ordering our tests do not follow the prior authorization requirements, we may be subject to claims for recoupment of reimbursement amounts previously paid to us, or may not receive some or all of the reimbursement payments to which we would otherwise be entitled. This has occurred in some cases and may occur more frequently in the future, which does and would have an adverse impact on our revenues.

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

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

Billing for clinical laboratory testing services is complex. We perform tests in advance of payment and without certainty as to the outcome of the billing process. In cases where we expect to receive a fixed fee per test due to our reimbursement arrangements, we may nevertheless encounter disputes over pricing and billing. Among the factors complicating our billing of third-party payers are disparity in coverage among various payers; disparity in, and increasingly difficult, information and billing requirements among payers, including with respect to prior authorization requirements and procedures and establishing medical necessity; and incorrect or missing billing information, which is required to be provided by the ordering healthcare practitioner. These billing complexities, and the associated uncertainty in obtaining payment for our tests, could result in reduced reimbursement of our tests, which could harm our business, financial condition and results of operations.

In the United States, the AMA generally assigns specific billing codes for laboratory tests under a coding system known as Current Procedure Terminology, or CPT, which we and our ordering healthcare providers must use to bill and receive reimbursement for our diagnostic tests. Once the CPT code is established by the AMA, CMS establishes payment levels and coverage rules under Medicare while private payers independently establish rates and coverage rules. A CPT code specific to NIPT for aneuploidies, and a CPT code for microdeletions, are in place, and CMS has established a pricing benchmark for aneuploidy and microdeletions testing. However, our microdeletions reimbursement has decreased since the implementation of the microdeletions CPT code because third-party payers are declining to reimburse under this code or reimbursing at a much lower rate than we had previously received. Furthermore, we cannot guarantee that we will be able to negotiate favorable rates for this code or receive reimbursement at all if we are unable to collect and publish additional data, including from our SMART Study, and obtain positive coverage determinations for Panorama for microdeletions. In addition, a CPT code for expanded carrier screening tests has been implemented, which has caused and may continue to cause reimbursement rates for our Horizon expanded carrier screening tests to decline. We do not currently have assay-specific CPT codes assigned for all of our tests, and there is a

risk that we may not be able to obtain such codes or, if obtained, we may not be able to negotiate favorable rates for such codes. We currently submit for reimbursement using CPT codes based on the guidance of outside coding experts and legal counsel. There is a risk that the codes we currently submit may be rejected or withdrawn or that third-party payers will seek refunds of amounts that they claim were inappropriately billed based on either the CPT code used, or the number of units billed. In addition, third-party payers may not establish positive coverage policies for our tests or adequately reimburse for any CPT code we may use, or seek recoupment for testing previously performed, which have occurred in the past.

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

We currently offer a number of genetic tests, and each of those tests is an LDT. An LDT is generally considered to be a test that is designed, developed, validated and used within a single laboratory. The FDA takes the position that it has the authority to regulate such tests as medical devices under the FDC Act, but it has generally exercised enforcement discretion with regard to LDTs. This means that even though the FDA believes it can impose regulatory requirements on LDTs, such as requirements to obtain premarket approval or clearance of LDTs, it has generally chosen not to enforce those requirements to date.

The FDA has previously laid out elements of a potential LDT regulatory framework, but has not established any regulatory requirements. On August 19, 2020, the United States Department of Health and Human Services, or HHS, announced that FDA will no longer require premarket review of LDTs absent notice-and-comment rulemaking. HHS rescinded all guidance documents and informal statements of policy concerning LDTs. The FDA's activities around regulating LDTs had 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 on the regulation of LDTs and substantially modify the regulation of IVDs.

In the meantime, the regulation by the FDA of LDTs remains uncertain. If FDA premarket clearance, approval or authorization is required for any of our existing or future tests, or for any components or materials we use in 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 or our supplier work to obtain FDA clearance, approval or authorization. Our business would be adversely affected while such review is ongoing and if we or our supplier are ultimately unable to obtain premarket clearance, approval or de novo authorization. For example, the regulatory premarket clearance, approval or de novo authorization process may involve, among other things, successfully completing analytical, pre-clinical and/or clinical studies beyond the studies we have already performed or plan to perform for each of our products and would involve submitting a premarket notification, or 510(k), a de novo application, or filing a PMA application with the FDA. As further described in the risk factor entitled "*Uncertainty in the development and commercialization of our enhanced or new tests or services could materially adversely affect our business, financial condition and results of operations,*" completing such studies requires the expenditure of time, attention and financial and other resources, and may not yield the desired results, which may delay, limit or prevent regulatory clearances, approvals or authorizations. In addition, we may require cooperation in our filings for FDA clearance, approval or authorization from third-party manufacturers of the components of our tests. If we are unable to obtain such required cooperation, we may be unable to achieve the desired regulatory clearances, approvals or authorizations, or may be delayed or be required to expend additional costs and other resources in doing so. For example, Illumina currently is our sole sequencer and sequencing reagent supplier. If we seek to achieve regulatory clearance, approval or authorization for Panorama, to the extent that Panorama incorporates Illumina's sequencer or sequencing reagents, we may require Illumina's

cooperation in the regulatory process. We may face difficulty obtaining cooperation from Illumina because Illumina is the parent company of Verinata, a direct competitor of ours in the NIPT field. In addition, we have been party to certain intellectual property proceedings with Illumina as described in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Unaudited Interim Condensed Consolidated Financial Statements in our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which is incorporated by reference herein. Furthermore, if FDA premarket clearance, approval or de novo authorization is required, our cash flows may be adversely affected until we obtain such clearance, approval or authorization, as most third-party payers, including Medicaid, will not reimburse for use of medical devices which are required to be cleared or approved but which have not been.

In May 2019, the FDA granted Breakthrough Device designation for our Signatera test for use in the post-surgical detection and quantification of ctDNA in the blood of patients previously diagnosed with certain types of cancer and in combination with certain drugs, which enables us to have increased interactions with FDA. We cannot assure you that this designation will lead to accelerated review or approval of our regulatory submissions for Signatera.

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

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

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

An important part of our business strategy is to expand and offer our tests internationally, either by providing our testing services directly or through our laboratory partners, or through our licensees under our Constellation cloud-based distribution model. As we do so, we will become increasingly subject to or impacted by the regulatory requirements of foreign jurisdictions, which are varied and complex. Our tests, and certain components of our tests, may be subject to the regulatory approval requirements in each foreign country in which they are sold by us or a laboratory partner, or by our licensees under our cloud-based distribution model, and our future performance would depend on us or our partners or licensees obtaining any necessary regulatory approvals in a timely manner. For example, while we have entered into a license agreement with BGI Genomics to commercialize our Signatera test in China and to develop reproductive health tests in select markets using BGI Genomics's sequencing instruments and platform, such commercialization and development activities will be subject to obtaining and maintaining necessary regulatory approvals in the relevant jurisdictions. In addition, while we have obtained a CE Mark from the European Commission for our Constellation software and

the key reagents required for our licensees to run their NIPT based on our technology, we have not obtained a CE Mark for our Panorama test as a whole. Therefore, while we are able to offer Constellation in the European Union and other countries that accept a CE Mark, we are unable to offer Panorama as an IVD directly in these jurisdictions. This, coupled with our use of our Panorama brand name under our Constellation model, has caused regulatory authorities to question whether we, our laboratory partners or our licensees may be marketing, commercializing or otherwise offering our tests without required approvals. We are occasionally required to address inquiries from regulatory authorities in various countries, such as those in the European Union, regarding the regulatory status of our Panorama or Constellation offerings, and expect that we will continue to face similar inquiries. If we do not continue to satisfactorily address any such questions in the future, we may be required to cease offering our products, either directly or through our partners or licensees, in the relevant country. This may in turn result in similar concerns, and subsequent cessation of our sources of revenue, in other countries.

We may also be at a competitive disadvantage in the European Union to our competitors who have obtained a CE Mark for their end to end NIPT. In addition, as further described in the risk factor entitled "*Risks Related to Our Business and Industry—We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers,*" blood collection tubes sourced solely from Streck are required to run our tests. These blood collection tubes are CE Marked by the European Commission; however, if such blood collection tubes are not registered in jurisdictions that do not accept a CE Mark, we may be unable to expand our business in such jurisdictions.

We may also need to obtain regulatory clearance, approval or authorization in the United States for our Constellation software in order for it to be used by third parties in the development and commercialization of their diagnostic tests based on our technology. We have discussed with the FDA the regulatory status of a portion of our Constellation software, the copy number calculator, or CNC, to make calls of copy number variants, which are genetic mutations in which relatively large regions of the genome have been deleted or duplicated. The FDA has indicated that the CNC may be appropriate for review under the de novo classification process, which is less burdensome than the premarket approval, or PMA, process. The FDA stated that it would not prevent us from marketing Constellation in the United States while we discuss with the FDA how it will be regulated; however, it is possible that the FDA may reverse itself either on the appropriate regulatory review path or on the issue of our ability to continue to market Constellation. In addition, the 21st Century Cures Act, enacted in 2016, included a number of changes to the FDA's regulatory approach to software that may have bearing on the regulatory status of our Constellation software. We cannot guarantee that we will be able to obtain such clearance, approval or authorization for our Constellation software, in the event that we are required to do so. If we are unable to do so, we would be unable to commercialize our cloud-based distribution model in the United States. If we are able to do so, we will be subject to ongoing FDA obligations and continued regulatory oversight and review, including compliance with requirements such as the quality system regulation, or QSR, which establishes extensive requirements for quality assurance and control as well as manufacturing procedures; the listing of our devices with the FDA; adverse event and malfunction reporting; corrections and removals reporting; and labeling and promotional requirements. We may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance to the extent required, we may not be permitted to offer our Constellation software and may be subject to enforcement action by the FDA, such as the issuance of warning or untitled letters, fines, injunctions and civil penalties; recall or seizure of products; operating restrictions and criminal prosecution.

Regulatory approval can be a lengthy, expensive and uncertain process. In addition, regulatory processes are subject to change, and new or changed regulations can result in unanticipated delays and cost increases. For example, the European Commission has adopted revised in-vitro diagnostic

regulations, or IVDR, which are expected to become effective in 2022. Among others, the new regulations introduce risk-based classification for IVDs and will require notified body involvement for various classes of devices, including reproductive health tests such as Panorama, which will be classified as a Class C product. As such, we will also be required to submit clinical evidence and post-market performance data to regulators. We or our partners or licensees may not be able to obtain regulatory approvals on a timely basis, if at all, which may cause us to incur additional costs or prevent us from marketing our tests in the United States or in foreign countries.

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

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

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

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

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

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

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations require clinical laboratories to obtain a certificate and mandate specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management and quality assurance. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers, for our tests. Our laboratories located in San Carlos, California and Austin, Texas

are both CLIA certified, and our main laboratory in San Carlos, CA is accredited by the College of American Pathologists, or CAP, a CMS-approved accreditation organization. We intend to seek CAP accreditation for our Austin, TX laboratory as well. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA and/or state inspectors may conduct random inspections of our clinical laboratory or conduct an inspection as a result of a complaint or reported incident, as has occurred. Any failure to address identified deficiencies, or to otherwise comply with CLIA, CAP or state requirements, can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA and/or CAP certificate of accreditation or state laboratory permit, as well as a directed plan of correction, on-site monitoring, civil monetary penalties, civil actions for injunctive relief, criminal penalties, suspension or exclusion from the Medicare and Medicaid programs and significant adverse publicity. Bringing our laboratory back into compliance with CLIA requirements could cause us to incur significant expenses and potentially lose revenues in order to address deficiencies and achieve compliance.

Some states require that we hold licenses or permits to test samples from patients in those states and as a result we are also required to maintain standards related to state licensure to conduct testing in our laboratories under state law. California state laboratory laws and regulations establish standards for the operation of our clinical laboratory and performance of test services in San Carlos, California as well as in our Austin, Texas laboratory, because our Texas laboratory receives specimens originating from California; the State of Texas does not impose state licensure or registration requirements upon a laboratory facility outside of maintaining CLIA certification. Additionally, all personnel involved in testing in our California laboratory must maintain a California state license or be supervised by licensed personnel. We maintain a license in good standing with the California Department of Public Health, or CAPH, for both our California and Texas laboratories. In addition, because we test specimens originating from New York at our San Carlos, California laboratory, we have obtained a state laboratory permit for our San Carlos laboratory from the New York Department of Health, or DOH, which mandates proficiency testing regardless of whether the laboratory is physically located in New York. We do not test specimens originating from New York at our Texas laboratory. The New York state laboratory laws, regulations and rules are at least as stringent than the CLIA regulations and establish standards for the operation of a clinical laboratory and performance of test services; and the laboratory director must maintain a Certificate of Qualification issued by New York's DOH. As under CLIA, we are subject to routine on-site inspections or inspections in response to a complaint under both California and New York state laboratory laws and regulations. If we are found to be out of compliance with either California or New York requirements, CAPH or New York's DOH may suspend, restrict or revoke our license or laboratory permit, respectively (and, with respect to California, may exclude persons or entities from owning, operating or directing a laboratory for two years following such license revocation), assess civil monetary penalties, or impose specific corrective action plans, among other sanctions. We cannot assure you that the regulators in any state from which we have obtained a required license or permit will at all times find us to be in compliance with the applicable laws of their respective state, which may result in suspension, limitation, revocation or annulment of our laboratory's license for that state or negative impact to our CLIA certificate, censure, or civil monetary penalties, and would result in our inability to test samples from patients in that state. Any such consequences could materially and adversely affect our business by prohibiting or limiting our ability to offer testing.

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

The U.S. government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. Government healthcare policy has been and will likely continue to be a topic of extensive legislative and executive activity in the U.S. federal government and many U.S. state governments. As a result, our business could be affected by potentially significant and unanticipated

changes in government healthcare policy, such as changes in reimbursement levels by government third-party payers. Any such changes could substantially impact our revenues, increase costs and divert management attention from our business strategy. We cannot predict the impact, if any, of governmental healthcare policy changes on our business, financial condition and results of operations.

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

In addition to the PPACA, various healthcare reform proposals have also emerged from federal and state governments. The Protecting Access to Medicare Act of 2014, or PAMA, introduced a multi-year pricing program for services payable under the CLFS that is designed to bring Medicare allowable amounts in line with the often lower negotiated payment rates paid by private payers. The implementation of the PAMA rates have negatively impacted overall pricing and reimbursement for many clinical laboratory testing services and continue to be the subject of controversy in the industry. We believe that the new rates under PAMA will have minimal impact on our business in the near term because our revenues from Medicare are currently very low; however, we expect the new rates to have greater impact on us as we begin billing for our Signatera and Prospera testing. In addition, federal budgetary limitations and changes in healthcare policy, such as the creation of broad limits for our tests and requirements that beneficiaries of government health plans pay for, or pay for higher portions of, clinical laboratory tests or services received, could substantially diminish the utilization of our tests, increase costs and adversely affect our ability to generate revenues and achieve profitability.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or how any such future legislation, regulation or initiative may affect us. Current or potential future federal legislation and the expansion of government's role in the U.S. healthcare industry, as

well as changes to the reimbursement amounts paid by third-party payers for our current and future tests, may adversely affect our test volumes and adversely affect our business, financial condition, results of operations, and cash flows.

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

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

- HIPAA, which created federal civil and criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and also imposes significant obligations with respect to maintenance of the privacy and security, and transmission, of individually identifiable health information;
- federal and state laws and regulations governing informed consent for genetic testing and the use of genetic material;
- federal and state laws and regulations governing the submission of claims, as well as billing and collection practices, for healthcare services;
- the federal Anti-Kickback Statute, which prohibits, among other things, the knowing and willful solicitation, receipt, offer or payment of remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare;
- the federal False Claims Act which prohibits, among other things, the presentation of false or fraudulent claims for payment from Medicare, Medicaid, or other government-funded third-party payers;
- federal laws and regulations governing the Medicare program, providers of services covered by the Medicare program, and the submission of claims to the Medicare program, as well as the Medicare Manuals issued by CMS and the local medical policies promulgated by the Medicare Administrative Contractors with respect to the implementation and interpretation of such laws and regulations;
- the federal Stark law, also known as the physician self-referral law, which, subject to certain exceptions, prohibits a physician from making a referral for certain designated health services covered by the Medicare program (and according to case law in some jurisdictions, the Medicaid program as well), including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services;
- the federal Civil Monetary Penalties Law, which, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program;
- the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which, among other things, prohibits the knowing or willful payment or offer, or the solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing;

- the prohibition on reassignment by the program beneficiary of Medicare claims to any party; and
- state law equivalents of the above U.S. federal laws, such as the Stark law, Anti-Kickback Statute and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state data privacy and security laws and which may be more stringent than HIPAA.

Furthermore, a development affecting our industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability for, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment by a federal governmental payer program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government for violations of the False Claims Act and permit such individuals to share in any amounts paid by the defendant to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it is subject to mandatory damages of three times the actual damages sustained by the government, plus mandatory civil penalties of up to approximately \$22,363 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. For example, in 2018 we reached a settlement with certain government payers regarding past reimbursement submissions. Although the settlement involved no admission of fault by us and no corporate integrity agreement, we cannot guarantee that we will not be subject to similar claims in the future.

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

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

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

and breach notification requirements with respect to, protected health information. 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.

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

The European Union's data privacy regulations, the General Data Protection Regulation, or GDPR, became subject to enforcement in May 2018. These regulations comprehensively reform the prior data protection rules of the European Union, and are more stringent, provide for higher potential liabilities, and apply to a broader range of personal data than those in the United States. The GDPR is applicable to U.S.-based companies, such as ours, that do business or offer services in, or that process or hold personal data of data subjects in, the European Union. While our current processes and practices comply with the GDPR, we will need to expend considerable time and resources, including management attention, to continue to revise our practices to ensure ongoing compliance with GDPR. Furthermore, the GDPR enables EU member states to enact jurisdiction-specific requirements in key areas, which could require us to modify our plans to comply with the GDPR, or otherwise to implement multiple policies unique to the jurisdictions in which we operate, which could make it more difficult and resource-intensive to continue to operate in the European Union.

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

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

Many of the sequencers, reagents, kits and other consumable products used to perform our testing, as well as the instruments and other capital equipment that enable the testing, are offered for sale for research use only, or RUO. In addition, we offer a version of our Signatera test as a research use only offering. Products that are intended for research use only and are labeled as RUO are exempt from compliance with FDA requirements, including the approval, clearance or authorization and other product quality requirements for medical devices. A product labeled RUO but which is actually intended for clinical diagnostic use may be viewed by the FDA as adulterated and misbranded under the FDC Act and subject to FDA enforcement action. The FDA has said that when determining the intended use of a product labeled RUO, it will consider the totality of the circumstances surrounding distribution of the product, including how the product is marketed and to whom. In addition, many of

the reagents used to perform our testing are offered for sale as analyte specific reagents, or ASRs. ASRs are medical devices and must comply with QSR provisions and other device requirements, but most are exempt from 510(k) and PMA premarket review. The FDA could disagree with a supplier's assessment that the supplier's products are ASRs, or could conclude that products labeled as RUO are actually intended for clinical diagnostic use, and could take enforcement action against the supplier, such as us with respect to Signatera (RUO), including requiring the supplier to cease offering the product while it seeks clearance, approval or authorization. Suppliers of RUO products that we employ in our other tests may cease selling their respective products, and we may be unable to obtain an acceptable substitute on commercially reasonable terms or at all, which could significantly and adversely affect our ability to provide timely testing results to our customers or could significantly increase our costs of conducting business.

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

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

Our research and development activities involve the controlled use of hazardous materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. In addition, we are subject on an ongoing basis to federal, state and local regulations governing the use, storage, handling and disposal of these materials and specified hazardous waste materials. An increase in the costs of compliance with such laws and regulations could harm our business and results of operations.

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

All clinical data and blood samples that we receive are required to have been collected from individuals who have provided appropriate informed consent for us to perform our testing, both commercially and in clinical trials. We seek to ensure that the individuals from whom the data and samples are collected do not retain or have conferred any proprietary or commercial rights to the data or any discoveries derived from them. Our partners operate in a number of different countries in addition to the United States, and, to a large extent, we rely upon them to comply with the individual's informed consent and with U.S. and international laws and regulations. The collection of data and samples in many different states and foreign countries results in complex legal questions regarding the adequacy of informed consent and the status of genetic material under a large number of different legal systems. The individual's informed consent obtained in any particular country could be challenged

in the future, and those informed consents could be deemed invalid, unlawful or otherwise inadequate for our purposes. Any findings against us, or our partners, could deny us access to, or force us to stop testing samples in, a particular country or could call into question the results of our clinical trials. We could also be precluded from billing third-party payers for tests for which informed consents are challenged, or could be requested to refund amounts previously paid by third-party payers for such tests. We could become involved in legal challenges, which could require significant management and financial resources and adversely affect our revenues and results of operations.

Risks Related to Our Intellectual Property

Litigation or other proceedings resulting from either third-party claims of intellectual property infringement, or asserting infringement by third parties of our technology, is costly, 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, and our ability to successfully prevent third parties from infringing our intellectual property. 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. Third parties, including our competitors, have asserted and may in the future assert that we are infringing their intellectual property rights.

We are or have recently been engaged in patent infringement lawsuits and other intellectual property disputes against Illumina, CareDx, Ravgen, Progenity and ArcherDX, as described in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Unaudited Interim Condensed Consolidated Financial Statements in our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which is incorporated by reference herein. We may become subject to and/or initiate future intellectual property litigation as our product portfolio, and the level of competition in our industry segments, grow.

Should we be unsuccessful defending against patent infringement claims, we may be required to pay substantial royalties, money damages, or be enjoined from offering certain products or services. We may be required to change our marketing practices, pay large damages awards, and in the case of patent infringement, pay unsustainably high royalties to obtain licenses from third parties. In addition, we could experience delays in product introductions or sales growth while we attempt to develop non-infringing alternatives. Any of these or other adverse outcomes could prevent us from offering our tests or otherwise have a material adverse effect on our business, financial condition and our results of operations.

We cannot predict whether, or offer any assurance that, the patent infringement claims we have initiated or may initiate in the future will be successful. We are and may become subject to counterclaims by patent infringement defendants. Our patents may be declared invalid or unenforceable, or narrowed in scope. Even if we prevail in an infringement action, we cannot assure you that we would be adequately compensated for the harm to our business. If we are unable to enjoin third-party infringement, our revenues may be adversely impacted and we may lose market share; and such third-party product may continue to exist in the market, but fail to meet our regulatory or safety standards, thereby causing irreparable harm to our reputation as a provider of quality products, which in turn could result in loss of market share and have a material adverse effect on our business, financial condition and our results of operations.

In addition, our agreements with some of our customers, suppliers, and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in patent infringement claims, including the types of claims described in this risk factor. We have agreed, and may in the future agree, to defend or indemnify third parties if we determine it to be in the best interests of our business relationships. If we are required or agree to defend or indemnify third parties

in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, financial condition and results of operations.

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

Our success and ability to compete depend to a large extent on our ability to develop proprietary products and technologies and to maintain adequate protection of our intellectual property in the United States and other countries; this becomes increasingly important as we expand our operations and enter into strategic collaborations with partners to develop and commercialize products. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and we may encounter difficulties in establishing and enforcing our proprietary 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 protected by valid and enforceable patents or are effectively maintained as trade secrets. We have worked to procure patents protecting our technologies, but our procurement efforts may not always be successful, and any patents we successfully procure may be challenged in ways that lead to post-procurement scope reduction or invalidity. For example, our U.S. Patent No. 8,682,592 is currently the subject of a petition for *inter partes* review filed by Illumina, which petition has been instituted, as described in "Note 8—Commitments and Contingencies—Legal Proceedings" in the Notes to Unaudited Interim Condensed Consolidated Financial Statements in our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which is incorporated by reference herein. These challenges may impede our ability to protect our proprietary rights from unauthorized use. In addition, any 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.

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 and proprietary know-how protection for our confidential and proprietary information and have taken security measures to protect this information. These measures, however, may not provide adequate protection. For example, we have a policy of requiring our consultants, advisors and collaborators, including, for example, our strategic collaborators with whom we seek to develop and commercialize products, to enter into confidentiality agreements and our employees to enter into invention, non-disclosure and non-compete agreements. However, breaches of our physical or electronic security systems, or breaches caused by our employees failing to abide by their confidentiality obligations during or upon termination of their employment with us, could compromise these

protection efforts. Any action we take to enforce our rights may be time-consuming, expensive, and possibly unsuccessful. Even if successful, the resulting remedy may not adequately compensate us for the harm caused by the breach. 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 and time-consuming, and possibly unsuccessful. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to infringe on other marks.

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

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

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

Risks Related to our Convertible Notes

Servicing our debt will require a significant amount of cash. We may not have sufficient cash flow from our business to pay our outstanding debt, and we may not have the ability to raise the funds necessary to settle conversions of the Convertible Notes in cash or to repurchase the Convertible Notes upon a fundamental change, which could adversely affect our business and results of operations.

Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the amounts payable under the Convertible Notes, depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our indebtedness and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or

obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Further, holders of the Convertible Notes have the right to require us to repurchase all or a portion of their Convertible Notes upon the occurrence of a "fundamental change" (as defined in the indenture governing the Convertible Notes) before the maturity date at a repurchase price equal to 100% of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Convertible Notes being converted. However, we may not have enough available cash, or be able to obtain sufficient financing, at the time we are required to repurchase the Convertible Notes.

The conditional conversion feature of the Convertible Notes, when triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the Convertible Notes is triggered, holders of the Convertible Notes will be entitled to convert their Convertible Notes at any time during specified periods at their option. If one or more holders elect to convert their Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation in cash, which could adversely affect our liquidity.

In addition, even if holders of Convertible Notes do not elect to convert their Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible debt securities that may be settled in cash, such as the Convertible Notes, could have a material effect on our reported financial results.

The accounting method for reflecting the Convertible Notes on our balance sheet, accruing interest expense for the Convertible Notes and reflecting the underlying shares of our common stock in our reported diluted earnings per share may adversely affect our reported earnings and financial condition.

We expect that, under applicable accounting principles, the initial liability carrying amount of the Convertible Notes will be the fair value of a similar debt instrument that does not have a conversion feature, valued using our cost of capital for straight, unconvertible debt. We have reflected the difference between the net proceeds from the sale of the Convertible Notes and the initial carrying amount as a debt discount for accounting purposes, which is amortized into interest expense over the term of the Convertible Notes. As a result of this amortization, the interest expense to be recognized for the Convertible Notes for accounting purposes will be greater than the cash interest payments we will pay on the Convertible Notes, which results in lower reported net income. The lower reported income (or higher net loss) resulting from this accounting treatment could depress the trading price of our common stock and the Convertible Notes.

Under historical accounting standards, under certain circumstances we would be eligible to use the treasury stock method to reflect the shares underlying the Convertible Notes in our diluted earnings per share. Under this method, if the conversion value of the Convertible Notes exceeds their principal amount for a reporting period, then we will calculate our diluted earnings per share assuming that all the Convertible Notes were converted and that we issued shares of our common stock to settle the excess. However, if reflecting the Convertible Notes in diluted earnings per share in this manner is

anti-dilutive, or if the conversion value of the Convertible Notes does not exceed their principal amount for a reporting period, then the shares underlying the Convertible Notes will not be reflected in our diluted earnings per share. In August 2020, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40). This guidance, which will be effective for fiscal years beginning after December 15, 2021 (including interim periods within those fiscal years) eliminated the treasury stock method for convertible instruments such as the Convertible Notes and instead requires application of the "if-converted" method. Under that method, once adopted, diluted earnings per share would generally be calculated assuming that all the Convertible Notes were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. The application of the if-converted method may reduce our reported diluted earnings per share.

Furthermore, if any of the conditions to the convertibility of the Convertible Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the Convertible Notes as a current, rather than a long-term, liability. This reclassification could be required even if no noteholders convert their Convertible Notes and could materially reduce our reported working capital.

Conversion of the Convertible Notes will dilute the ownership interest of existing stockholders, including holders who had previously converted their Convertible Notes, or may otherwise depress the price of our common stock.

The conversion of some or all of the Convertible Notes will dilute the ownership interests of stockholders to the extent we deliver shares of our common stock upon such conversion. The Convertible Notes are currently convertible and may from time to time in the future be convertible at the option of their holders prior to their scheduled terms under certain circumstances. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Convertible Notes may encourage short selling by market participants because the conversion of the Convertible Notes could be used to satisfy short positions, or anticipated conversion of the Convertible Notes into shares of our common stock could depress the price of our common stock.

Risks Related to Ownership of Our Common Stock

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

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

- actual or anticipated variations in our and our competitors' results of operations, as well as how those results compare to analyst and investor expectations;
- announcements by us or our competitors of new products, significant acquisitions, other strategic transactions, including strategic and commercial partnerships and relationships, joint ventures, divestitures, collaborations or capital commitments;
- changes in reimbursement practices by current or potential payers;
- 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;
- actual or anticipated changes in regulatory oversight of our products;
- development of 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;
- 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, including us, that have experienced volatility in the trading price of their stock have been the subject of securities class action litigation. For example, we have in the past been subject to a purported securities class action lawsuit filed against us, our directors and certain of our officers and stockholders related to our initial public offering. 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 former underwriters, 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.

Commencing December 31, 2019, we were no longer an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies no longer apply to us.

As of December 31, 2019, we ceased to qualify as an "emerging growth company", as defined by the Jumpstart Our Businesses Act of 2012, or the JOBS Act, because as of June 30, 2019, the market value of our common stock that was held by non-affiliates exceeded \$700 million. As a result, we are no longer permitted to take advantage of reduced regulatory and reporting requirements that are otherwise generally applicable to public companies. These include, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding non-binding advisory votes on executive compensation and golden parachute payments. As we are no longer an emerging growth company, we expect to incur additional expenses and devote substantial management effort toward ensuring compliance with those requirements applicable to companies that are not emerging growth companies. Compliance with these additional laws, rules and regulations has and will continue to increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. In addition, management's attention may be diverted from other business concerns and our costs and expenses will increase, which could harm our business and operating results. We may also need to hire more employees in the future or engage additional outside consultants to comply with these requirements, which will increase our costs and expenses.

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.

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.

Although we determined that our internal controls over financial reporting were effective as of December 31, 2019, we must continue to monitor and assess our internal controls over financial reporting. If we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. If we identify material weaknesses in our internal controls over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal controls over financial reporting are effective, or, when required in the future, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities.

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

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

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

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

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

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

We may issue our shares of common stock or securities convertible into our common stock, such as our Convertible Notes, 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 price of our common stock to decline.

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

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

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

As of June 30, 2020, our directors and executive officers and their affiliates beneficially owned, in the aggregate, approximately 11.56% of our outstanding capital stock. As a result, these stockholders are and will continue to be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or its assets. This concentration of ownership could limit stockholders' ability to influence corporate matters and may have the effect of delaying or preventing a third party from acquiring control over us.

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

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

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

- permit the board of directors to establish the number of directors;
- provide that directors may only be removed "for cause" and only with the approval of 75% of our stockholders;
- require super-majority voting to amend some provisions in our amended and restated certificate of incorporation and amended and restated bylaws; and
- provide that the board of directors is expressly authorized to make, alter or repeal our amended and restated bylaws.

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

In addition, if a "fundamental change" (as defined in the indenture governing the Convertible Notes) occurs prior to the maturity date of the Convertible Notes, holders of the Convertible Notes will have the right, at their option, to require us to repurchase all or a portion of their Convertible Notes. If a "make-whole fundamental change" (as defined in the indenture governing the Convertible Notes) occurs prior to the maturity date, we will in some cases be required to increase the conversion rate of the Convertible Notes for a holder that elects to convert its Convertible Notes in connection with such make-whole fundamental change. Furthermore, we are prohibited from engaging in certain mergers or acquisitions unless, among other things, the surviving entity of such transaction assumes our obligations under the Convertible Notes.

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.

Changes in accounting standards and their interpretations could adversely affect our operating results.

U.S. GAAP is subject to interpretation by the Financial Accounting Standards Board, or FASB, the Public Company Accounting Oversight Board, or PCAOB, the SEC, and various other bodies that promulgate and interpret appropriate accounting principles. These principles and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. A change in these principles or interpretations, including the implementation of ASU 2016-02, Leases (Topic 842), or accounting for the Convertible Notes, could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before or after the announcement of a change in such principles. Additionally, the adoption of these standards may potentially require enhancements or changes in our systems and will require significant time and cost on behalf of our financial management. A discussion of these standards and other pending changes in

GAAP, are further discussed in "Note 2—Summary of Significant Accounting Policies" in the Notes to Unaudited Interim Condensed Consolidated Financial Statements in our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which is incorporated by reference herein.

Risks Relating to This Offering

Our management team may invest or spend the net proceeds of this offering in ways with which you may not agree or in ways which may not yield significant return.

Our management will have broad discretion over the use of the net proceeds from this offering. We currently intend to use the net proceeds from this offering for working capital and general corporate purposes and continued investments in research and development for our core technology and development of our product offerings. In addition, we may use a portion of the net proceeds for acquisitions of complementary business, technologies or other assets. However, we have no current understandings, agreements or commitments for any material acquisitions at this time. You will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds may be used for working capital and corporate purposes that do not increase our operating results or enhance the value of our common stock.

USE OF PROCEEDS

We estimate that the net proceeds to us from the issuance of our common stock in this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately \$235.3 million, or approximately \$270.6 million if the underwriters exercise their option to purchase additional shares in full.

We currently intend to use the net proceeds from this offering for working capital and general corporate purposes and continued investments in research and development for our core technology and development of our product offerings. In addition, we may use a portion of the net proceeds for acquisitions of complementary businesses, technologies or other assets. However, we have no current understandings, agreements or commitments for any material acquisitions at this time. We have not yet determined the manner in which we will allocate the net proceeds from this offering, and as a result, management will have broad discretion in the allocation and use of the net proceeds. Pending the application of the net proceeds, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities.

DIVIDEND POLICY

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.

CAPITALIZATION

The following table sets forth our cash and cash equivalents, restricted cash and capitalization as of June 30, 2020, as follows:

- on an actual basis; and
- on an as adjusted basis to give effect to the issuance and sale by us of 4,166,666 shares in this offering, at the public offering price of \$60.00, and the receipt of the net proceeds from our sale of these shares, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us (assuming no exercise of the underwriters' option to purchase additional shares).

You should read this table in conjunction with the sections titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes appearing in our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which is incorporated by reference in this prospectus.

	As of June 30, 2020	
	Actual ⁽¹⁾	As Adjusted ⁽¹⁾
	(in thousands, except share and per share data)	
	(unaudited)	
Cash and cash equivalents	\$ 77,322	\$ 312,588
Restricted Cash	55	55
Long-term debt financing	197,476	197,476
Stockholders' equity		
Preferred stock, par value \$0.0001 per share: 50,000,000 shares authorized, no shares issued and outstanding, actual and as adjusted	—	—
Common stock, par value \$0.0001 per share: 750,000,000 shares authorized, 79,717,379 shares issued and outstanding, actual and 750,000,000 shares authorized, 83,884,045 shares issued and outstanding, as adjusted ⁽¹⁾	8	8
Additional paid-in capital	1,093,072	1,328,338
Accumulated deficit	(794,583)	(794,583)
Accumulated other comprehensive income	5,770	5,770
Total stockholders' equity	304,267	539,533
Total capitalization	\$ 501,743	\$ 737,009

(1) The number of shares in the table above excludes the following:

- 4,056,000 shares of common stock issuable upon the vesting and settlement of restricted stock units outstanding as of June 30, 2020;
- 7,822,038 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2020, with a weighted-average exercise price of \$11.26 per share;
- 10,921 shares of common stock issuable upon the exercise of options granted between July 1, 2020 and August 31, 2020, with a weighted-average exercise price of \$62.92 per share;
- 157,104 shares of common stock issuable upon the vesting and settlement of restricted stock units granted between July 1, 2020 and August 31, 2020; and

- 7,036,019 shares of common stock, subject to increase on an annual basis, reserved for future grant or issuance under our stock-based compensation plans, consisting of:
 - 4,714,939 shares of common stock as of June 30, 2020 reserved for future grants under our 2015 Plan; and
 - 2,321,080 shares of common stock as of June 30, 2020 reserved for future issuance under our 2015 ESPP.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

The following is a general discussion of the material U.S. federal income tax considerations with respect to the ownership and disposition of shares of our common stock applicable to non-U.S. holders (as defined below) who acquire such shares in this offering and hold such shares as a capital asset within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended, or the Code, (generally, property held for investment). For purposes of this discussion, a "non-U.S. holder" means a beneficial owner of our common stock (other than an entity or arrangement that is treated as a partnership for U.S. federal income tax purposes) that is not, for U.S. federal income tax purposes, any of the following:

- an individual citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in the United States or under the laws of the United States, any state thereof or the District of Columbia, or any other corporation treated as such;
- an estate, the income of which is includable in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more "U.S. persons," as defined under the Code, have the authority to control all substantial decisions of the trust or (ii) such trust has made a valid election to be treated as a U.S. person for U.S. federal income tax purposes.

This discussion is based on current provisions of the Code, existing, temporary and proposed Treasury regulations promulgated thereunder, or Treasury Regulations, judicial opinions, published positions of the Internal Revenue Service and other applicable authorities, all of which are subject to change (possibly with retroactive effect). This discussion does not address all aspects of U.S. federal income taxation that may be important to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, nor does it address any aspects of the unearned income Medicare contribution tax pursuant to the Health Care and Education Reconciliation Act of 2010, any U.S. federal estate and gift taxes, any U.S. alternative minimum taxes or any state, local or non-U.S. taxes. This discussion may not apply, in whole or in part, to particular non-U.S. holders in light of their individual circumstances or to holders subject to special treatment under the U.S. federal income tax laws (such as insurance companies, tax-exempt organizations, financial institutions, brokers or dealers in securities, "controlled foreign corporations," "passive foreign investment companies," non-U.S. holders that hold our common stock as part of a straddle, hedge, conversion transaction or other integrated investment and certain U.S. expatriates).

If a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner therein will generally depend on the status of the partner and the activities of the partnership. Partners of a partnership holding our common stock should consult their tax advisors as to the particular U.S. federal income tax consequences applicable to them.

THIS SUMMARY IS NOT INTENDED TO CONSTITUTE A COMPLETE DESCRIPTION OF ALL TAX CONSEQUENCES FOR NON-U.S. HOLDERS RELATING TO THE OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK. PROSPECTIVE HOLDERS OF OUR COMMON STOCK SHOULD CONSULT WITH THEIR TAX ADVISORS REGARDING THE TAX CONSEQUENCES TO THEM (INCLUDING THE APPLICATION AND EFFECT OF ANY STATE, LOCAL, ESTATE, FOREIGN INCOME AND OTHER TAX LAWS) OF THE OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK.

DIVIDENDS

In general, the gross amount of any distribution we make to a non-U.S. holder with respect to its shares of our common stock will be subject to U.S. withholding tax at a rate of 30% to the extent the distribution constitutes a dividend for U.S. federal income tax purposes, unless the non-U.S. holder is eligible for a reduced rate of withholding tax under an applicable tax treaty and the non-U.S. holder provides proper certification of its eligibility for such reduced rate. A distribution will constitute a dividend for U.S. federal income tax purposes to the extent of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. To the extent any distribution does not constitute a dividend, it will be treated first as reducing the adjusted basis in the non-U.S. holder's shares of our common stock and then, to the extent it exceeds the adjusted basis in the non-U.S. holder's shares of our common stock, as gain from the sale or exchange of such stock. Any such gain will be subject to the treatment described below in "—Gain on Sale or Other Disposition of Common Stock."

Dividends we pay to a non-U.S. holder that are effectively connected with its conduct of a trade or business within the United States (and, if required by an applicable tax treaty, are attributable to a U.S. permanent establishment of such non-U.S. holder) will not be subject to U.S. withholding tax, as described above, if the non-U.S. holder complies with applicable certification and disclosure requirements. Instead, such dividends generally will be subject to U.S. federal income tax on a net income basis, at regular U.S. federal income tax rates. Dividends received by a foreign corporation that are effectively connected with its conduct of a trade or business within the United States may be subject to an additional branch profits tax at a rate of 30% (or such lower rate as may be specified by an applicable tax treaty).

GAIN ON SALE OR OTHER DISPOSITION OF COMMON STOCK

In general, and subject to the discussions below regarding backup withholding and FATCA, a non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of the non-U.S. holder's shares of our common stock unless:

- the gain is effectively connected with a trade or business carried on by the non-U.S. holder within the United States (and, if required by an applicable tax treaty, is attributable to a U.S. permanent establishment of such non-U.S. holder);
- the non-U.S. holder is an individual and is present in the United States for 183 days or more in the taxable year of disposition and certain other conditions are met; or
- we are or have been a U.S. real property holding corporation for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding such disposition or such non-U.S. holder's holding period of our common stock.

Gain that is effectively connected with the conduct of a trade or business in the United States (or so treated) generally will be subject to U.S. federal income tax on a net income tax basis, at regular U.S. federal income tax rates. If the non-U.S. holder is a foreign corporation, the branch profits tax described above also may apply to such effectively connected gain. An individual non-U.S. holder who is subject to U.S. federal income tax because the non-U.S. holder was present in the United States for 183 days or more during the year of sale or other disposition of our common stock will be subject to a flat 30% tax on the gain derived from such sale or other disposition, which may be offset by U.S.-source capital losses. We believe that we are not, and we do not anticipate becoming, a U.S. real property holding corporation for U.S. federal income tax purposes.

NON-U.S. HOLDERS SHOULD CONSULT THEIR TAX ADVISORS REGARDING ANY APPLICABLE TAX TREATIES THAT MAY PROVIDE FOR DIFFERENT RULES.

Withholdable Payments to Foreign Financial Entities and Other Foreign Entities

Under the Foreign Account Tax Compliance Act, or FATCA, withholding tax of 30% applies to certain payments to foreign financial institutions, investment funds and certain other non-U.S. persons that fail to comply with certain information reporting and certification requirements pertaining to their direct and indirect U.S. securityholders and/or U.S. accountholders and do not otherwise qualify for an exemption. Under applicable Treasury Regulations and Internal Revenue Service guidance, this withholding currently applies to payments of dividends, if any, on, and, subject to the proposed Treasury Regulations discussed below, gross proceeds from the sale or other disposition of, our common stock. An intergovernmental agreement between the U.S. and a foreign country may modify the requirements described in this paragraph.

Although withholding under existing FATCA regulations would also apply to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

Backup Withholding, Information Reporting and Other Reporting Requirements

We must report annually to the Internal Revenue Service and to each non-U.S. holder the amount of dividends paid to, and the tax withheld with respect to, each non-U.S. holder. These reporting requirements apply regardless of whether withholding was reduced or eliminated by an applicable tax treaty. Copies of this information reporting may also be made available under the provisions of a specific tax treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established.

A non-U.S. holder will generally be subject to backup withholding for dividends on our common stock paid to such holder unless such holder certifies under penalties of perjury that, among other things, it is a non-U.S. holder (and the payer does not have actual knowledge or reason to know that such holder is a U.S. person) or otherwise establishes an exemption.

Information reporting and backup withholding generally are not required with respect to the amount of any proceeds from the sale or other disposition of our common stock by a non-U.S. holder outside the United States through a foreign office of a foreign broker that does not have certain specified connections to the United States. However, if a non-U.S. holder sells or otherwise disposes of its shares of common stock through a U.S. broker or the U.S. offices of a foreign broker, the broker will generally be required to report the amount of proceeds paid to the non-U.S. holder to the Internal Revenue Service and impose backup withholding on that amount unless such non-U.S. holder provides appropriate certification to the broker of its status as a non-U.S. holder (and the payer does not have actual knowledge or reason to know that such holder is a U.S. person) or otherwise establishes an exemption.

Backup withholding is not an additional income tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder generally can be credited against the non-U.S. holder's U.S. federal income tax liability, if any, or refunded, provided that the required information is furnished to the Internal Revenue Service in a timely manner. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Cowen and Company, LLC and SVB Leerink LLC are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

<u>Name</u>	<u>Number of Shares</u>
J.P. Morgan Securities LLC	1,309,167
Morgan Stanley & Co. LLC	1,309,167
Cowen and Company, LLC	652,917
SVB Leerink LLC	652,917
Robert W. Baird & Co. Incorporated	194,166
Craig-Hallum Capital Group LLC	48,332
Total	<u>4,166,666</u>

The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' option to purchase additional shares except to the extent such option is exercised as described below. The underwriting compensation in connection with this offering will not exceed 8% of the gross proceeds of the offering.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at that price less a concession not in excess of \$2.070 per share. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives. Sales of the shares made outside of the United States may be made by affiliates of the underwriters.

We have granted to the underwriters an option to purchase additional shares, exercisable for 30 days from the date of this prospectus, to purchase up to 624,999 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. To the extent the option to purchase additional shares is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise

and full exercise of the underwriters' option to purchase up to an additional 624,999 shares of common stock.

		Total	
	Per Share	No Exercise	Full Exercise
Public offering price	\$ 60.00	\$ 249,999,960.00	\$ 287,499,900.00
Underwriting discounts and commissions	3.45	14,374,997.70	16,531,244.25
Proceeds, before expenses, to us	\$ 56.55	\$ 235,624,962.30	\$ 270,968,655.75

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$358,317. The underwriters have agreed to reimburse us for a portion of our out-of-pocket expenses.

Canaccord Genuity LLC is acting as our financial advisor for this transaction, for which it will receive a customary fee.

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

We and our directors and executive officers, during the period ending 60 days after the date of this prospectus, (the "restricted period"), have agreed that, without the prior written consent of J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC on behalf of the underwriters, we and they will not:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock or publicly disclose the intention to engage in any such transaction; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock;

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, without the prior written consent of J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC on behalf of the underwriters, (i) our directors and officers will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock and (ii) we will not file any registration statement with the Securities and Exchange Commission relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock. In addition, our directors and officers agreed and consented to the entry of stop transfer instructions with our transfer agent and registrar against the transfer of each such person's shares of common stock except in compliance with the below restrictions.

The restrictions described in the immediately preceding paragraph do not apply to us with respect to:

- the sale of shares by us pursuant to the underwriting agreement;
- our issuance of common stock upon the exercise of an option or a warrant or the conversion of a security outstanding on the date of and disclosed in this prospectus;
- our issuance of common stock or restricted stock units pursuant to employee benefit plans described in our filings with the Securities and Exchange Commission incorporated by reference in this prospectus; provided that if such shares or other securities vest during the restricted period, the recipient signs and delivers a lock-up agreement;

- our filing of a registration statement on Form S-8 with respect to employee benefit plans described in our filings with the Securities and Exchange Commission incorporated by reference in this prospectus; and
- our sale or issuance of or entry into an agreement to sell or issue shares of common stock in connection with our acquisition of one or more businesses, products or technologies or in connection with joint ventures, commercial relationships or other strategic transactions; provided that (i) the aggregate number of shares of common stock that we may sell or issue or agree to sell or issue may not exceed 5% of the total number of shares of common stock outstanding immediately following the closing of the offering and (ii) each recipient of these shares of common stock executes and delivers a lock-up agreement.

The restrictions described in the preceding paragraph do not apply to our executive officers and directors with respect to:

- transactions by a securityholder relating to shares of common stock or other securities acquired in open market transactions after the completion of the offering of the shares; provided that no filing under Section 16(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, is required or voluntarily made in connection with subsequent sales of the common stock or other securities acquired in such open market transactions;
- the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required or voluntarily made by or on behalf of the person or us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period;
- the sale of shares of common stock pursuant to a 10b5-1 trading plan (provided that such plan was established prior to the execution of the lockup agreement); provided that any filing under Section 16(a) of the Exchange Act that is made in connection with any such sales during the restricted period shall state that such sales have been executed under a 10b5-1 trading plan and shall also state the date such 10b5-1 trading plan was adopted;
- transfers of shares of common stock or any security convertible into or exercisable or exchangeable for common stock (i) as a bona fide gift, charitable contribution, will, or intestacy (ii) to an immediate family member or a trust for the direct or indirect benefit of the transferor or such immediate family of the transferor, (iii) to any corporation, partnership, or business entity controlled or managed, or under common control or management by the transferor or the immediate family of the transferor, or (iv) by a stockholder that is a trust to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust, provided in each case that (a) each donee, transferee or distributee signs and delivers a lock-up agreement and (b) no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares shall be required or voluntarily made during the restricted period;
- distributions by a partnership, limited liability company or corporation of shares of common stock or any security convertible into common stock to general or limited partners, members or stockholders of such partnership, limited liability company or corporation or transfers of shares of common stock or any security convertible into or exercisable or exchangeable for common stock to another corporation, partnership or other business entity that controls, is controlled by or is under common control with a partnership, limited liability company or corporation; provided that in the case of any transfer or distribution pursuant to this bullet, (a) each donee, transferee or distributee signs and delivers a lock-up agreement and (b) no filing under

Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares shall be required or voluntarily made during the restricted period;

- the exercise of options to purchase common stock granted under any stock incentive plan or stock purchase plan described in this prospectus, provided that the underlying shares shall continue to be subject to the restrictions on transfer set forth in the lock-up agreement; provided further that if any filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made during the restricted period such filing shall clearly indicate in the footnotes thereto that no shares were sold by the transferor and that the shares received upon exercise of the stock option are subject to a lock-up agreement with the underwriters;
- the transfer of common stock or any security convertible into common stock to us upon a vesting event of our securities or upon the exercise of options to purchase our securities on a "cashless" or "net exercise" basis or to cover tax withholding obligations of the transferor in connection with such vesting or exercise, provided that if any filing under Section 16(a) of the Exchange Act reporting a disposition of shares of common stock or other public announcement shall be required or shall be made voluntarily in connection with such vesting or exercise, such filing shall clearly indicate in the footnotes thereto that such disposition of shares was solely to us;
- the sale of shares of common stock underlying restricted stock units held by the signatory that are vested and settled to satisfy income tax withholding and remittance obligations in connection with the vesting of such restricted stock units that are outstanding as of the date of the prospectus;
- the transfer to the Company of common stock or any security convertible into common stock granted under any stock incentive plan or stock purchase plan of the Company described in this prospectus pursuant to agreements under which we have the option to repurchase such shares or a right of first refusal with respect to transfers of such shares;
- the transfer of common stock or any security convertible into common stock that occurs pursuant to a qualified domestic order or in connection with a divorce settlement, provided that each transferee signs and delivers a lock-up agreement and provided further that any filing required to be made under Section 16(a) of the Exchange Act shall state that such transfer is by operation of law, pursuant to a qualified domestic order or in connection with a divorce settlement;
- the transfer of shares of common stock or any security convertible into common stock pursuant to a bona fide third party tender offer, merger, consolidation or other similar transaction made to all holders of the common stock involving a change of control of the company, provided that in the event that the tender offer, merger, consolidation or other such transaction is not completed, the common stock beneficially owned by the signatory and initially transferred as described in this bullet, shall remain subject to the restrictions on transfer set forth in the lock-up agreement; and
- J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above at any time.

In order to facilitate this offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the option to purchase additional shares. The underwriters can close out a covered short sale by exercising the option to purchase

additional shares or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the option to purchase additional shares. The underwriters may also sell shares in excess of the option to purchase additional shares, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

In addition, in connection with this offering certain of the underwriters (and selling group members) may engage in passive market making transactions in our common stock on The Nasdaq Global Select Market prior to the pricing and completion of this offering. Passive market making consists of displaying bids on The Nasdaq Global Select Market no higher than the bid prices of independent market makers and making purchases at prices no higher than these independent bids and effected in response to order flow. Net purchases by a passive market maker on each day are generally limited to a specified percentage of the passive market maker's average daily trading volume in the common stock during a specified period and must be discontinued when such limit is reached. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of these transactions. If passive market making is commenced, it may be discontinued at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for

that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Selling Restrictions

European Economic Area and United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom, or each a Relevant State, no shares of our common stock have been offered or will be offered pursuant to this offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares of our common stock which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares of our common stock may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- a. to any legal entity which is a qualified investor as defined in the Prospectus Regulation;
- b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares of our common stock shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares of our common stock or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares of our common stock being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares of our common stock acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares of our common stock to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of our common stock in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of our common stock, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to

investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person who is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Hong Kong

The shares of our common stock have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Israeli Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares of common stock is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Singapore

Singapore SFA Product Classification—In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of shares, we have determined, and hereby notify all relevant persons (as defined in Section 309A(1) of the SFA), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Each representative has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each representative has represented and agreed that it has not offered or sold any shares or caused the shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares or cause the shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, whether directly or indirectly, to any person in Singapore other than:

(a) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA;

(b) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA and in accordance with the conditions specified in Section 275 of the SFA; or

(c) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 276(4)(i)(B) of the SFA;

(ii) where no consideration is or will be given for the transfer;

(iii) where the transfer is by operation of law;

(iv) as specified in Section 276(7) of the SFA; or

(v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Japan

The shares of our common stock have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Australia

This prospectus:

- does not constitute a product disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth), or the Corporations Act;
- has not been, and will not be, lodged with the Australian Securities and Investments Commission, or ASIC, as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document under Chapter 6D.2 of the Corporations Act;
- does not constitute or involve a recommendation to acquire, an offer or invitation for issue or sale, an offer or invitation to arrange the issue or sale, or an issue or sale, of interests to a "retail client" (as defined in section 761G of the Corporations Act and applicable regulations) in Australia; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, or Exempt Investors, available under section 708 of the Corporations Act.

The shares of our common stock may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this prospectus will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Switzerland

The shares of our common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or

CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Dubai International Financial Centre, or DIFC

This prospectus relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

In relation to its use in the DIFC, this prospectus is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Canada

The shares of our common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, Redwood City, California. Davis Polk & Wardwell LLP, Menlo Park, California is representing the underwriters in this offering.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our [Annual Report on Form 10-K for the year ended December 31, 2019](#), and the effectiveness of our internal control over financial reporting as of December 31, 2019, as set forth in their reports, which are incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's reports, given on their authority as experts in accounting and auditing.

4,166,666 Shares



Conceive. Deliver. Thrive.

COMMON STOCK

PROSPECTUS

September 10, 2020

**J.P. Morgan
Baird**

Morgan Stanley

Cowen

**SVB Leerink
Craig-Hallum Capital Group**
