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

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report: January 20, 2021
(Date of earliest event reported)

Invitae Corporation
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-36847
(Commission
File Number)

27-1701898
(I.R.S. employer
identification number)

1400 16th Street, San Francisco, California 94103
(Address of Principal Executive Offices) (zip code)

(415) 374-7782
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.0001 par value per share	NVTA	The New York Stock Exchange LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

Invitae Corporation (the “Company”) has provided preliminary financial results for its three months ended December 31, 2020, included in Exhibit 99.2 to this Current Report on Form 8-K and incorporated by reference herein.

The information in Item 2.02 of this Current Report on Form 8-K, including the preliminary financial results for the quarter ended March 31, 2020 contained in Exhibit 99.2, shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On January 20, 2021, the Company announced that it has commenced an underwritten public offering of its common stock. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The Company has updated its disclosures. The disclosures are filed herewith as Exhibit 99.2 and are incorporated by reference herein.

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to, statements regarding: the Company’s preliminary financial results; the impact of COVID-19 on the Company’s business and the actions it may take in response thereto; the Company’s strategy; the Company’s business plan, including expectations regarding future partnerships, acquisitions and networks; the Company’s beliefs with respect to the size of the total addressable markets for its tests; the Company’s beliefs with respect to the effect of its expertise and technology in the medical industry; future growth and the keys to such growth; the expected benefits from past and future acquisitions; continued investment in the Company’s business; future operations; future operating results and expense levels; and the prospects, plans and objectives of management. The Company has based these forward-looking statements on its current expectations and projections about future events and trends that the Company believes may affect its financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial requirements. Forward-looking statements are subject to known and unknown risks, uncertainties and assumptions that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the completion of the quarter and the quarterly close process and 2020 audit; the effect of the COVID-19 pandemic on the Company’s business and the success of any measures it has taken or may take in the future in response thereto; risks associated with the Company’s ability to develop and commercialize new tests and expand into new markets; the Company’s ability to use rapidly changing genetic data to interpret test results accurately, consistently and quickly; the Company’s history of losses; the Company’s need to scale its infrastructure in advance of demand for its tests and its ability to increase demand for its tests; the Company’s ability to drive revenue; the impact of current and future litigation on the Company’s business; the Company’s ability to integrate and scale acquired businesses and realize the intended benefits of such acquisitions; the risk that the Company may not obtain or maintain sufficient levels of reimbursement for its tests; the ability of the Company to obtain required regulatory approvals for its tests; laws and regulations applicable to the Company’s business, including potential regulation by the Food and Drug Administration and measures taken by government authorities in response to the COVID-19 pandemic; the risk that Medicare and other payers may change the pricing or other terms for reimbursement, or not reimburse for the Company’s tests in the future, or fail to make timely payments; the impact of economic conditions, unemployment levels and loss of health insurance on the Company’s business; the Company’s ability to compete; and the other risks set forth in Exhibit 99.2 filed herewith and the Company’s filings with the Securities and Exchange Commission, including the risks set forth in the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020. These forward-looking statements speak only as of the date hereof, and the Company disclaims any obligation to update these forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 [Press Release dated January 20, 2021.](#)

99.2 [Disclosures.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INVITAE CORPORATION

Date: January 20, 2021

By: /s/ Shelly D. Guyer

Name: Shelly D. Guyer

Title: Chief Financial Officer

Invitae Announces Proposed Public Offering of Common Stock

SAN FRANCISCO, January 20, 2021 — Invitae Corporation (NYSE: NVTA) today announced that it has commenced an underwritten public offering of \$400.0 million of shares of its common stock, before deducting underwriting discounts and commissions and other offering expenses. All of the shares are being offered by Invitae. In addition, Invitae expects to grant the underwriters a 30-day option to purchase up to an additional \$60.0 million of shares of its common stock at the public offering price, less underwriting discounts and commissions. The offering is subject to market and other conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

Invitae currently intends to use the net proceeds from this offering for working capital and other general corporate purposes, including investing in its platform, oncology and reproductive product extensions and international expansion. Invitae may also use a portion of the net proceeds from this offering to acquire or invest in complementary businesses, assets or technologies, although it has no present commitments or agreements to do so.

J.P. Morgan Securities LLC, Morgan Stanley, Cowen and Company, LLC and SVB Leerink LLC are acting as the book-running managers for the proposed offering.

An automatic shelf registration statement relating to the shares was filed with the Securities and Exchange Commission and became effective on March 4, 2019. A copy of the preliminary prospectus supplement and accompanying prospectus relating to the offering, when available, may be obtained from J.P. Morgan Securities LLC, c/o Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, NY 11717, or by telephone at (866) 803-9204, or by email at prospectus-req_fi@jpmchase.com; from Morgan Stanley & Co. LLC, 180 Varick Street, 2nd Floor, New York, NY, 10014, Attention: Prospectus Department; from Cowen and Company, LLC, c/o Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, NY 11717, Attn: Prospectus Department, by email at PostSaleManualRequests@broadridge.com, or by telephone at (833) 297-2926; or from SVB Leerink LLC, One Federal Street, 37th Floor, Boston, MA 02110, Attention: Syndicate Department, by telephone at (800) 808-7535, ext. 6132, or by email at syndicate@svbleerink.com.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

About Invitae Corporation

Invitae Corporation (NYSE: NVTA) is a leading medical genetics company whose mission is to bring comprehensive genetic information into mainstream medicine to improve healthcare for billions of people. Invitae's goal is to aggregate the world's genetic tests into a single service with higher quality, faster turnaround time, and lower prices.

Forward-Looking Statements

This press release contains forward-looking statements within the Private Securities Litigation Reform Act of 1995, including statements that relate to the timing, size and completion of the proposed public offering, the grant to the underwriters of the option to purchase additional shares, and other information that is not historical information. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include risks and uncertainties related to completion of the public offering on the anticipated terms or at all, market conditions and the satisfaction of customary closing conditions related to the public offering. More information about the risks and uncertainties faced by Invitae is contained in the section captioned "Risk factors" in the preliminary prospectus supplement related to the public offering filed with the Securities and Exchange Commission. Invitae disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Source: Invitae Corporation

Contact:

Laura D'Angelo
ir@invitae.com
(628) 213-3369
###

Our Company

We are in the business of delivering genetic testing services that support a lifetime of patient care – from inherited disease diagnoses, to family planning, to proactive health screening to the personalized diagnosis, treatment and monitoring of cancer.

Our tests are delivered via a unique, rapidly expanding platform that serves patients, healthcare providers, payors, biopharma companies and advocacy partners, thereby capturing the broad potential of genetics and expanding its use across the healthcare continuum. Through the custom design and application of automation, robotics and bioinformatics software solutions tailored to the complexity of sample processing and complex variant interpretation, we believe we can apply our world-class clinical expertise to medical interpretation at scale, simplify the process of obtaining and utilizing affordable genetic data, apply high-quality genetic information to inform critical healthcare decisions and leverage genomic information to speed the discovery and development of personalized medical therapies—all while making genetic testing available for billions of people around the world.

We are focused on making comprehensive, high-quality genetic information more accessible by lowering the cost of genetic testing, by utilizing a testing delivery platform that is accessible to patients throughout their lives, by enabling a growing network of partners to increase the utility of genetic information across the healthcare continuum, and, ultimately, by managing that information on behalf of our customers, their improved health and the advancement of molecular medicine around the globe.

We estimate the total addressable market for genetic testing in age groups 0-17, 18-40, 41-65 and 65+ to be approximately \$26 billion, \$5 billion, \$60 billion and \$63 billion, respectively. These estimates were developed by us using external sources for 2021 and our internal estimates, and we assigned various testing categories to their peak incidence age groups.

We launched our first commercial offering in November 2013 with an offering of approximately 200 genes, growing our test menu over time to include more than 20,000 genes to help diagnose disease, inform family planning, and serve healthy individuals. We offer our testing across multiple clinical areas, including hereditary cancer, cardiology, neurology, pediatrics, personalized oncology, metabolic conditions and rare diseases. To augment our offering and realize our mission, we have acquired multiple assets including three businesses in 2020, which expanded our suite of genome management offerings and established a broader entry into oncology therapy selection, personalized cancer treatment and recurrence monitoring and, subsequently, early stage cancer screening.

In October 2020, we completed the acquisition of ArcherDX, Inc., or ArcherDX, a genomics company democratizing precision oncology by offering a suite of products and services that are accurate, personal, actionable and easy to use in local settings, thereby empowering clinicians to control the sample, data, patient care and economics. ArcherDX's development platform, including its proprietary Anchored Multiplex PCR, or AMP, chemistry at the core, enables clinical tests and services that will allow for therapy optimization and cancer monitoring in community locations for the first time at scale.

We have experienced rapid growth. For the years ended December 31, 2019, 2018 and 2017, our revenue was \$216.8 million, \$147.7 million and \$68.2 million, respectively, and we incurred net losses of \$242.0 million, \$129.4 million and \$123.4 million, respectively. For the nine months ended September 30, 2020 and 2019, our revenue was \$179.2 million and \$150.5 million, respectively, and we incurred net losses of \$367.8 million and \$165.1 million, respectively. At September 30, 2020, our accumulated deficit was \$1.1 billion. To meet the demands of scaling our business, we increased our number of employees to approximately 1,500 at September 30, 2020 from approximately 1,100 at September 30, 2019. Our sales force grew to approximately 270 at September 30, 2020 from approximately 190 at September 30, 2019. Upon the closing of the ArcherDX acquisition, our headcount increased by approximately 400 employees to approximately 1,900 in October 2020. We expect our headcount will continue to increase as we add staff to support our anticipated growth.

Sales of our tests have grown significantly. In 2019, 2018, 2017, 2016 and 2015, we accessioned 482,000, 303,000, 150,000, 59,000 and 21,000 samples, respectively. In 2019, 2018 and 2017, we generated 469,000, 292,000 and 145,000 billable tests, respectively. In the nine months ended September 30, 2020, we accessioned 444,000 samples and generated 421,000 billable tests compared to approximately 334,000 accessioned samples and 322,000 billable tests in the same period in 2019. Approximately 41% of the billable tests we performed in the first nine months of 2020 were billable to institutions and patients, and the remainder were billable to third-party payers. Many of the gene tests on our assays are tests for which insurers reimburse. However, when we do not have reimbursement policies or contracts with private insurers, our claims for reimbursement may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive and may not result in payment. Even if we are successful in achieving reimbursement, we may be paid at lower rates than if we were under contract with the third-party payer. When there is not a contracted rate for reimbursement, there is typically a greater coinsurance or copayment requirement from the patient which may result in further delay in payment for these tests.

We expect to incur operating losses for the near-term future and we may need to raise additional capital in order to fund our operations. If we are unable to achieve our revenue growth objectives and successfully manage our costs, we may not be able to achieve profitability.

We believe that the keys to our future growth will be to increase billable test unit volumes, achieve broad reimbursement coverage for our tests from third-party payers, drive down the price for genetic analysis and interpretation, steadily increase the amount of genetic content we offer, consistently improve the client experience, drive physician and patient utilization of our website for ordering and delivery of results and increase the number of strategic partners working with us to add value for our clients. We also believe that providing a unique genetic testing platform that is agnostic to stage of life, disease category or sequencing technology will deliver unique benefits to customers, payors and other institutions that are seeking to make genetic information a standard element of healthcare decisions in the future.

Recent Developments

Recent acquisitions and collaborations

On January 13, 2021, we announced a collaboration with Pacific Biosciences of California, Inc., or PacBio, a provider of high-quality, long-read sequencing platforms, to begin development of a production-scale high-throughput sequencing platform leveraging the power of PacBio's highly accurate HiFi sequencing to expand our whole genome testing capabilities.

We completed our acquisition of ArcherDX in October 2020. The aggregate consideration consisted of \$325.0 million in cash and 30.0 million shares of our common stock, plus up to an additional 27.0 million shares of our common stock payable in connection with the achievement of certain milestones. One of these milestones

was achieved in November 2020, which resulted in the issuance of 4,999,983 million shares of our common stock to former ArcherDX stockholders.

In connection with our acquisition of ArcherDX, we entered into a Credit Agreement and Guaranty, or the credit agreement, pursuant to which we borrowed an aggregate principal amount of \$135.0 million, which is secured by a first priority lien on all of our and our subsidiaries' assets, including our intellectual property, and is guaranteed by certain of our subsidiaries. Also in connection with the acquisition, we sold 16,320,476 shares of our common stock in a private placement for gross proceeds of approximately \$275.0 million.

Preliminary estimated fourth quarter 2020 and fiscal year 2020 financial results and other data (unaudited)

Our estimated unaudited financial results and certain business metrics as of and for the quarter and the year ended December 31, 2020 presented below are preliminary and are subject to the close of the quarter, completion of our period-end closing procedures, completion of our 2020 audit and further financial review. The preliminary financial and business information presented below has been prepared by and is the responsibility of our management and is based upon information available to us as of the date hereof. Our independent registered public accounting firm has not audited, reviewed, compiled or performed any procedures with respect to this preliminary financial information. Accordingly, our independent registered public accounting firm does not express an opinion or any other form of assurance with respect thereto. These estimates are not a comprehensive statement of our financial results for these periods and should not be viewed as a substitute for interim financial statements prepared in accordance with generally accepted accounting principles. Our actual results may differ from these estimates as a result of the completion of our period-end closing procedures, review adjustments, audit adjustments, the impact of the ongoing COVID-19 pandemic and other developments that may arise between now and the time our financial results for these periods are finalized. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020.

Preliminary estimated fourth quarter 2020 results (unaudited)

- Revenue for the fourth quarter of 2020 is expected to be more than \$99.0 million (which includes approximately \$16.2 million of revenue from ArcherDX in the fourth quarter of 2020), an increase of over 49% compared to \$66.3 million in the same period in 2019.
- Billable units for the fourth quarter of 2020 are expected to be more than 235,000 (which includes approximately 50,000 billable units from ArcherDX in the fourth quarter of 2020), an increase of over 60% compared to approximately 147,000 in the same period in 2019.
- Cost of revenue for the fourth quarter of 2020 is expected to be between \$67.2 million and \$70.7 million (which includes approximately \$9.5 million from ArcherDX in the fourth quarter of 2020), compared with \$36.7 million in the same period in 2019. Non-GAAP cost of revenue for the fourth quarter of 2020 is expected to be between \$53.8 million and \$57.3 million (which includes approximately \$7.9 million from ArcherDX in the fourth quarter of 2020), compared with \$34.7 million in the same period in 2019. This range includes acquisition costs which are difficult to predict prior to completion of the quarter-end closing process.
- Operating expenses, which exclude cost of revenue, for the fourth quarter of 2020 are expected to be between \$358.6 million and \$378.6 million, compared to \$108.6 million in the same period in 2019. Non-GAAP operating expenses, which exclude cost of revenue, for the fourth quarter of 2020 are expected to be between \$140.8 million and \$160.8 million, compared with \$89.2 million in the same period in 2019. This number includes acquisition costs which are difficult to predict prior to completion of the quarter-end closing process.

-
- Gross profit for the fourth quarter of 2020 is expected to be between \$28.3 million and \$31.8 million (which includes approximately \$9.5 million in cost of revenue from ArcherDX in the fourth quarter of 2020), compared to \$29.6 million in the same period in 2019. Non-GAAP gross profit for the fourth quarter of 2020 is expected to be between \$41.7 million and \$45.2 million (which includes approximately \$9.5 million in cost of revenue from ArcherDX in the fourth quarter of 2020), compared to \$31.6 million in the same period in 2019.
 - Cash, cash equivalents, restricted cash, and marketable securities is expected to total over \$360.0 million as of December 31, 2020, as compared with \$368.0 million as of September 30, 2020. The net increase in cash, cash equivalents, restricted cash and marketable securities was more than \$16.2 million in the fourth quarter of 2020.
 - Non-GAAP cash burn for the fourth quarter of 2020 is expected to be less than \$444.0 million, which includes \$352.7 million for cash paid for acquisitions, primarily of ArcherDX, and \$13.6 million for cash paid for acquisition-related expenses, primarily of ArcherDX. Cash burn for the fourth quarter of 2020 would have been less than \$77.0 million (which includes approximately \$29.1 million of cash burn by ArcherDX in the fourth quarter of 2020) without these acquisition and acquisition-related costs.

Preliminary estimated fiscal year 2020 results (unaudited)

- Revenue for 2020 is expected to be more than \$278.0 million (which includes approximately \$16.2 million of revenue from ArcherDX in the fourth quarter of 2020), an increase of over 28% compared to \$216.9 million in 2019.
- Billable units for 2020 are expected to be more than approximately 655,000 (which includes 50,000 billable units from ArcherDX in the fourth quarter of 2020), an increase of over 40% compared to approximately 469,000 in 2019.
- Cost of revenue for 2020 is expected to be between \$197.2 million and \$200.7 million (which includes approximately \$9.5 million from ArcherDX in the fourth quarter of 2020), compared with \$118.1 million in 2019. Non-GAAP cost of revenue for 2020 is expected to be between \$171.7 million and \$175.2 million (which includes approximately \$7.9 million from ArcherDX in the fourth quarter of 2020), compared with \$113.7 million in 2019. This range includes acquisition costs which are difficult to predict prior to completion of the year end closing process.
- Operating expenses, which exclude cost of revenue, for 2020 are expected to be between \$728.5 million and \$748.5 million, compared to \$342.8 million in 2019. Non-GAAP operating expenses, which exclude cost of revenue, for 2020 are expected to be between \$451.0 million and \$471.0 million, compared with \$293.6 million in 2019. This range includes acquisition costs which are difficult to predict prior to completion of the year end closing process. We have not included non-GAAP operating expenses for the comparable period in 2019 because we did not previously report that information.
- Gross profit for 2020 is expected to be between \$77.3 million and \$80.8 million (which includes approximately \$9.5 million in cost of revenue from ArcherDX in the fourth quarter of 2020), compared to \$98.7 million in 2019. Non-GAAP gross profit is expected to be between \$102.8 million and \$106.3 million (which includes approximately \$9.5 million in cost of revenue from ArcherDX in the fourth quarter of 2020), compared to \$103.1 million in 2019.
- Cash, cash equivalents, restricted cash, and marketable securities is expected to total over \$360.0 million as of December 31, 2020, as compared with \$398.0 million as of December 31, 2019. Our net decrease in cash, cash equivalents, restricted cash and marketable securities was less than \$28.4 million.

-
- Non-GAAP cash burn for 2020 is expected to be less than \$696.0 million, which includes \$410.4 million for cash paid for acquisitions, primarily of ArcherDX, and \$13.6 million for cash paid for acquisition-related expenses, primarily of ArcherDX. Cash burn for the fiscal year 2020 would have been less than \$272.0 million (which includes approximately \$29.1 million of cash burn by ArcherDX in the fourth quarter of 2020) without the acquisition and acquisition-related costs.

Non-GAAP financial measures

In addition to the preliminary financial information presented in accordance with U.S. generally accepted accounting principles, or GAAP, we are providing certain preliminary non-GAAP financial measures. Management uses these financial measures in the management of our business and believes these non-GAAP financial measures are useful to investors in evaluating our ongoing operating results and trends. The preliminary non-GAAP financial measures have limitations as analytical tools, and you should not consider them in isolation or as substitute for the most directly comparable preliminary financial measures prepared in accordance with GAAP. There are a number of limitations related to the use of these non-GAAP financial measures versus their nearest GAAP equivalents. Other companies, including companies in our industry, may calculate non-GAAP financial measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our preliminary non-GAAP financial measures as tools for comparison. Potential investors should not rely on any single financial measure to evaluate our business. Reconciliations for historical periods are included in exhibits to our Current Reports on Form 8-K for the applicable periods, and a reconciliation of certain of our preliminary non-GAAP financial measures for the three months and for the year ended December 31, 2020 to the most directly comparable preliminary GAAP financial measure appear below. However, certain of these measures and components of those measures cannot be reasonably projected or can only be projected at a summary level at this time. For example, some presented adjustments required for these reconciliations are estimates, and sufficient information is not available at this time to calculate certain adjustments required for such reconciliations, including stock-based compensation, amortization of intangible assets, income tax expense (benefit), and foreign currency (gains) losses, and, additionally, the accounting impact of our recent acquisition of ArcherDX is still in process. These components could significantly impact actual expenses incurred and net changes in cash, cash equivalents and restricted cash.

Reconciliation of preliminary estimated GAAP cost of revenue to non-GAAP cost of revenue

(in millions)

(unaudited)

	Three months ended		Year ended	
	December 31, 2020		December 31, 2020	
	Lower	Upper	Lower	Upper
GAAP cost of revenue	\$ 67.2	\$ 70.7	\$ 197.2	\$ 200.7
Amortization of acquired intangible assets	(9.8)	(9.8)	(21.9)	(21.9)
Acquisition-related stock-based compensation	(2.0)	(2.0)	(2.0)	(2.0)
Fair value adjustments to acquisition-related assets	(1.6)	(1.6)	(1.6)	(1.6)
Non-GAAP cost of revenue	<u>\$ 53.8</u>	<u>\$ 57.3</u>	<u>\$ 171.7</u>	<u>\$ 175.2</u>

Reconciliation of preliminary estimated GAAP operating expenses to non-GAAP operating expenses

(in millions)

(unaudited)

	Three months ended		Year ended	
	December 31, 2020		December 31, 2020	
	Lower	Upper	Lower	Upper
GAAP operating expenses	\$ 358.6	\$ 378.6	\$ 728.5	\$ 748.5
Amortization of acquired intangible assets	(2.0)	(2.0)	(4.7)	(4.7)
Acquisition-related stock-based compensation	(39.5)	(39.5)	(91.5)	(91.5)
Acquisition-related post-combination expenses	(125.9)	(125.9)	(126.6)	(126.6)
Fair value adjustments to acquisition-related liabilities	(50.4)	(50.4)	(54.7)	(54.7)
Non-GAAP operating expenses	<u>\$ 140.8</u>	<u>\$ 160.8</u>	<u>\$ 451.0</u>	<u>\$ 471.0</u>

Reconciliation of preliminary estimated cash, cash equivalents and restricted cash to non-GAAP cash burn

(in millions)

(unaudited)

	Three months ended	Year ended
	December 31, 2020	December 31, 2020
Net increase in cash, cash equivalents and restricted cash	\$ 16.2	\$ (28.4)
Adjustments:		
Net maturities of investments	(24.8)	(10.0)
Proceeds from public offering of common stock, net of issuance costs	(46.3)	(263.8)
Proceeds from issuance of common stock in private placement, net of issuance costs	(258.6)	(263.6)
Proceeds from issuance of debt, net of discounts and issuance costs	(129.2)	(129.2)
Proceeds from acquisition-related warrants	(0.6)	(1.0)
Cash burn	<u>\$ (443.3)</u>	<u>\$ (696.0)</u>

Reconciliation of preliminary gross profit to non-GAAP gross profit

(in millions)

(unaudited)

	Three months ended December 31, 2020		Year ended December 31, 2020	
	Lower	Upper	Lower	Upper
Revenue	\$ 99.0	\$ 99.0	\$278.0	\$278.0
GAAP cost of revenue	67.2	70.7	197.2	200.7
Gross profit	31.8	28.3	80.8	77.3
Amortization of acquired intangible assets	9.8	9.8	21.9	21.9
Acquisition-related post-combination expenses	2.0	2.0	2.0	2.0
Fair value adjustments for acquisition-related assets	1.6	1.6	1.6	1.6
Non-GAAP gross profit	<u>\$ 45.2</u>	<u>\$ 41.7</u>	<u>\$106.3</u>	<u>\$102.8</u>

Impact of the COVID-19 pandemic

Our test volumes decreased significantly in the second half of March 2020 as compared to the first few months of 2020 as a result of COVID-19 and related limitations and priorities across the healthcare system. Our daily test volumes have consistently increased from the low in March 2020, although we are currently still experiencing changes in product mix due to the impact of COVID-19. COVID-19 could have a material impact on our financial results for at least the next quarter and for the foreseeable future, particularly on product mix and as a result, the revenue we recognize. We have reviewed and adjusted for the impact of COVID-19 on our estimates related to revenue recognition and expected credit losses.

In response to the pandemic we have implemented measures to protect the health of all of our employees during this time with additional measures in place to better protect our on-site lab production and support teams. Our production facilities currently remain fully operational. While we have not experienced significant disruption in our supply chain, over the past several months, we have experienced supply delays as a result of the COVID-19 pandemic and have also had to obtain supplies from new suppliers. Although we do not yet know the full impact COVID-19 will have on our supply chain, we have increased our inventory on hand to respond to potential future disruptions that may occur.

Many announced healthcare guidelines call for a shift of regular physician visits and healthcare delivery activities to remote/telehealth formats. This is particularly important for patients who, despite the fall-out from COVID-19, continue to be diagnosed with critical diseases, like cancer, and for women who are pregnant or are trying to conceive. We believe our investments in new access platforms and technologies will position us well to provide a range of testing to clinicians and patients using a “clinical care from afar” model. An example is our rollout in April 2020 of our Gia telehealth platform. Gia, developed by Clear Genetics which we acquired in 2019, expands access to remote interaction between patients and clinicians as well as direct ordering of genetic tests. Such access helped to counteract some of the adverse in-office impacts of COVID-19, allowing continuation of key testing categories in a safe environment.

Given the unknown duration and extent of COVID-19’s impact on our business, and the healthcare system in general, we are adapting our spending and investment levels to evolving market conditions, including efforts to focus operating expense on increasing gross profit, otherwise managing cash burn, and focusing commercial execution on workflows that support remote ordering, online support and telehealth. Approximately 8% of our workforce as of March 2020 was impacted by a reduction in force in April 2020 in an initiative to manage costs and cash burn, which resulted in one-time costs in the second quarter of 2020 of \$3.8 million. In addition, effective May 2020, we reduced the salaries of our named executive officers by approximately 20%, which reductions ceased as of January 2021. For more information about the impact of the pandemic on our business, please see the subsection entitled “Risk factors—Risks related to our business and strategy—We face risks related to health epidemics, including the recent COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.”

Risk Factors

Risks related to our business and strategy

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

Our business has been and could continue to be adversely affected by a widespread outbreak of contagious disease, including the recent pandemic of respiratory illness caused by a novel coronavirus known as COVID-19. Global health concerns relating to COVID-19 have negatively affected 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, some of our personnel located at our headquarters and other offices in California, 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. 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 continue to negatively impact spending patterns, payment cycles and insurance coverage levels. These measures have adversely affected and may continue to adversely affect demand for our tests. Earlier this year, many of our customers, including hospitals and clinics, suspended non-emergency appointments and services, which resulted in a significant decrease in our test volume. Travel bans, restrictions and border closures have also impacted our ability to ship test kits to and receive samples from our customers. Some of these measures by government authorities have and may continue to remain in place for a significant period of time. Even if these measures are lifted, they may be implemented again if COVID-19 is not contained or returns, as has been the case recently. These measures have adversely affected and may continue to adversely affect our test volume, sales activities and results of operations.

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, cancellation of physical participation in sales activities, meetings, events and conferences and increasing inventories of certain supplies because, although we have not experienced significant disruption in our supply chain, over the past several months, we have experienced supply delays as a result of the COVID-19 pandemic and have also had to obtain supplies from new suppliers), 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 have acquired and those 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 are unable to work effectively, including due to illness, quarantines, social distancing, government actions or other restrictions in connection with COVID-19, our operations will be impacted.

The extent to which COVID-19 continues to impact 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, the actions to contain the virus and treat its impact, and how quickly and to what extent normal economic and operating activities can resume. COVID-19 could limit the ability of our customers, suppliers and business partners to perform, including third-party payers' ability to make timely payments to us during and following the pandemic. We have also experienced and may continue to experience a shortage of, or delays in, laboratory supplies and equipment, or a suspension of services from other laboratories or third parties. Even after COVID-19 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, and loss of health insurance coverage resulting from pandemic-related job losses.

Specifically, difficult macroeconomic conditions, such as decreases in per capita income and level of disposable income, increased and prolonged unemployment or a decline in consumer confidence as a result of COVID-19, as well as limited or significantly reduced points of access of our tests, could have a material adverse effect on the demand for our tests. Under difficult economic conditions, consumers may seek to reduce discretionary spending by forgoing our tests. Decreased demand for our tests, particularly in the United States, has negatively affected and could continue to negatively affect our overall financial performance. Because a significant portion of our revenue is concentrated in the United States, where the impact of COVID-19 has been significant, COVID-19 has had and could continue to have a disproportionately negative impact on our business and financial results.

There are no comparable recent events which may provide guidance as to the effect of the spread of COVID-19 and a pandemic, and, as a result, the ultimate impact of COVID-19 or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of COVID-19's impact on our business, our operations, or the global economy as a whole. However, the effects could have a material impact on our results of operations, and we continue to monitor the situation closely.

To the extent the COVID-19 pandemic continues to adversely affect our business and financial results, it may also have the effect of heightening many of the other risks described in this section.

We expect to continue incurring significant losses, and we may not successfully execute our plan to achieve or sustain profitability.

We have incurred substantial losses since our inception. For the nine months ended September 30, 2020, our net loss was \$367.8 million. For the years ended December 31, 2019, 2018 and 2017, our net losses were \$242.0 million, \$129.4 million and \$123.4 million, respectively. At September 30, 2020, our accumulated deficit was \$1.1 billion. While our revenue has increased over time, we expect to continue to incur significant losses as we invest in our business. We incurred research and development expenses of \$141.5 million, \$63.5 million and \$46.5 million in 2019, 2018 and 2017, respectively, and selling and marketing expenses of \$122.2 million, \$74.4 million and \$53.4 million in 2019, 2018 and 2017, respectively. We expect these losses may increase as we focus on scaling our business and operations and expanding our testing capabilities, which may also increase our operating expenses, and we have experienced and may continue to experience decreases in test volume due to the impact of COVID-19. In addition, as a result of the integration of acquired businesses, we may be subject to unforeseen or additional expenditures, costs or liabilities, including costs and potential liabilities

associated with litigation. Our prior losses and expected future losses have had and may continue to have an adverse effect on our stockholders' equity, working capital and stock price. Our failure to achieve and sustain profitability in the future would negatively affect our business, financial condition, results of operations and cash flows, and could cause the market price of our common stock to decline.

We began operations in January 2010 and commercially launched our initial assay in late November 2013; accordingly, we have a relatively limited operating history upon which you can evaluate our business and prospects. Our limited commercial history makes it difficult to evaluate our current business and makes predictions about our future results, prospects or viability subject to significant uncertainty. Our prospects must be considered in light of the risks and difficulties frequently encountered by companies in their early stage of development, particularly companies in new and rapidly evolving markets such as ours. These risks include an evolving and unpredictable business model and the management of growth. To address these risks, we must, among other things, increase our customer base; continue to implement and successfully execute our business and marketing strategy; identify, acquire and successfully integrate companies, assets or technologies in areas that are complementary to our business strategy; successfully enter into other strategic collaborations or relationships; obtain access to capital on acceptable terms and effectively utilize that capital; identify, attract, hire, retain, motivate and successfully integrate additional employees; continue to expand, automate and upgrade our laboratory, technology and data systems; obtain, maintain and expand coverage and reimbursement by healthcare payers; provide rapid test turnaround times with accurate results at low prices; provide superior customer service; and respond to competitive developments. We cannot assure you that we will be successful in addressing these risks, and the failure to do so could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and expand our operations.

We expect capital expenditures and operating expenses to increase over the next several years as we expand our infrastructure, commercial operations, research and development and selling and marketing activities and pursue and integrate acquisitions. We believe our existing cash and cash equivalents as of December 31, 2020, including revenue from sales of our tests, will be sufficient to meet our anticipated cash requirements for our currently-planned operations for the foreseeable future. We may raise additional capital to finance operations prior to achieving profitability, or should we make additional acquisitions. We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. In addition, the terms of the credit agreement restrict our ability to incur certain indebtedness and to issue certain equity securities. If we raise funds by issuing equity securities, dilution to our stockholders would result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings, if available, could impose significant restrictions on our operations.

The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to tests we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed,

we may have to delay, reduce the scope of or eliminate one or more research and development programs, selling and marketing initiatives, or potential acquisitions. In addition, we may have to work with a partner on one or more aspects of our tests or market development programs, which could lower the economic value of those tests or programs to our company.

We have acquired and may continue to acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, or cause us to incur debt or significant expense.

As part of our business strategy, we have pursued and expect to continue to pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. Since 2017, we have acquired several companies, including companies in family health genetic information services, the patient data collection industry, the non-invasive prenatal screen offering industry, the genetic information industry and the use of artificial intelligence in such industry, the pharmacogenetic testing industry, and the oncology industry.

With respect to our acquired businesses and any acquisitions we may make in the future, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Furthermore, as we experienced in the past, the loss of customers, payers, partners or suppliers following the completion of any acquisitions by us could harm our business. Changes in services, sources of revenue, and branding or rebranding initiatives may involve substantial costs and may not be favorably received by customers, resulting in an adverse impact on our financial results, financial condition and stock price. Integration of an acquired company or business also may require management's time and resources that otherwise would be available for ongoing development of our existing business. We may also need to divert cash from other uses in order to fund these integration activities and these new businesses. Ultimately, we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment, or these benefits may take longer to realize than we expected.

To finance any acquisitions or investments, we may raise additional funds, which could adversely affect our existing stockholders and our business, as discussed in the preceding risk factor. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. In addition, our stockholders may experience substantial dilution as a result of additional securities we may issue for acquisitions. Open market sales of substantial amounts of our common stock issued to stockholders of companies we acquire could also depress our stock price. Additional funds may not be available on terms that are favorable to us, or at all.

If third-party payers, including managed care organizations, private health insurers and government health plans do not provide adequate reimbursement for our tests or we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.

Our ability to increase the number of billable tests and our revenue will depend on our success achieving reimbursement for our tests from third-party payers. Reimbursement by a payer may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary, cost-effective and has received prior authorization. The commercial success of our distributed products, including STRATAFIDE, a pan-solid tumor in vitro diagnostic, or IVD, and our Personalized Cancer Monitoring product, or PCM, if approved, will depend on the extent to which our customers receive coverage and adequate reimbursement from third-party payors, including as managed care organizations and government payors (e.g., Medicare and Medicaid).

Since each payer makes its own decision as to whether to establish a policy or enter into a contract to cover our tests, as well as the amount it will reimburse for a test, seeking these approvals is a time-consuming and costly process. In addition, the determination by a payer to cover and the amount it will reimburse for our tests will likely be made on an indication by indication basis. To date, we have obtained policy-level reimbursement approval or contractual reimbursement for some indications for our tests from most of the large commercial third-party payers in the United States, and the Centers for Medicare & Medicaid Services, or CMS, provides reimbursement for our multi-gene tests for hereditary breast and ovarian cancer-related disorders as well as colon cancer. We believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from third-party payers may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive and may not result in payment. In cases where there is not a contracted rate for reimbursement, there is typically a greater coinsurance or copayment requirement from the patient, which may result in further delay or decreased likelihood of collection.

In cases where we have established reimbursement rates with third-party payers, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements often vary from payer to payer, and we have needed additional time and resources to comply with them. We have also experienced, and may continue to experience, delays in or denials of coverage if we do not adequately comply with these requirements. Our third-party payers have also requested, and in the future may request, audits of the amounts paid to us. We have been required to repay certain amounts to payers as a result of such audits, and we could be adversely affected if we are required to repay other payers for alleged overpayments due to lack of compliance with their reimbursement policies. In addition, we have experienced, and may continue to experience, delays in reimbursement when we transition to being an in-network provider with a payer.

We expect to continue to focus our resources on increasing adoption of, and expanding coverage and reimbursement for, our current tests and any future tests we may develop or acquire. If we fail to expand and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

We face intense competition, which is likely to intensify further as existing competitors devote additional resources to, and new participants enter, the market. If we cannot compete successfully, we may be unable to increase our revenue or achieve and sustain profitability.

With the development of next generation sequencing, the clinical genetics market is becoming increasingly competitive, and we expect this competition to intensify in the future. We face competition from a variety of sources, including:

- dozens of relatively specialized competitors focused on genetics applied to healthcare, such as Ambry Genetics, a subsidiary of Konica Minolta Inc.; Athena Diagnostics and Blueprint Genetics, subsidiaries of Quest Diagnostics Incorporated; Baylor-Miraca Genetics Laboratories; Caris Life Sciences, Inc.; Centogene AG; Connective Tissue Gene Test LLC, a subsidiary of Health Network Laboratories, L.P.; Cooper Surgical, Inc.; Emory Genetics Laboratory, a subsidiary of Eurofins Scientific; Foundation Medicine, a subsidiary of Roche Holding AG; Fulgent Genetics, Inc., Guardant Health, Inc.; GeneDx, a subsidiary of OPKO Health, Inc.; Integrated Genetics, Sequenom Inc., Correlagen, and MNG Laboratories, subsidiaries of Laboratory Corporation of America Holdings; Myriad Genetics, Inc.; Natera, Inc.; Perkin Elmer, Inc.; PreventionGenetics, LLC; Progenity, Inc.; and Sema4 Genomics;
- a few large, established general testing companies with large market share and significant channel power, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated;
- a large number of clinical laboratories in an academic or healthcare provider setting that perform clinical genetic testing on behalf of their affiliated institutions and often sell and market more broadly; and

-
- a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness including Illumina, Inc., which is also one of our suppliers.

Hospitals, academic medical centers and eventually physician practice groups and individual clinicians may also seek to perform at their own facilities the type of genetic testing we would otherwise perform for them. In this regard, continued development of equipment, reagents, and other materials as well as databases and interpretation services may enable broader direct participation in genetic testing and analysis.

Participants in closely related markets such as clinical trial or companion diagnostic testing could converge on offerings that are competitive with the type of tests we perform. Instances where potential competitors are aligned with key suppliers or are themselves suppliers could provide such potential competitors with significant advantages.

In addition, the biotechnology and genetic testing fields are intensely competitive both in terms of service and price, and continue to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition.

We also face competition as a result of our recently completed acquisition of ArcherDX. In particular, ArcherDX competes with numerous companies in the life sciences research, clinical diagnostics and drug development spaces, including, among others, Natera, QIAGEN N.V., Guardant Health, Inc., Thermo Fisher, Inc., Foundation Medicine, Caris Life Sciences, Inc., Tempus, Laboratory Corporation of America, Quest Diagnostics, Inc., NeoGenomics, Inc., BioReference Laboratories, Inc. and Illumina, Inc.

We believe the principal competitive factors in our market are:

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

Many of our competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration, higher margins on their tests, substantially greater financial, technological and research and development resources, selling and marketing capabilities, lobbying efforts, and more experience dealing with third-party payers. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests than we do, sell their tests at prices designed to win significant levels of market share, or obtain

reimbursement from more third-party payers and at higher prices than we do. We may not be able to compete effectively against these organizations. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payers are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies as use of next generation sequencing for clinical diagnosis and preventative care increases. Certain of our competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing policies and devote substantially more resources to website and systems development than we can. In addition, companies or governments that control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. In addition, some of our competitors have obtained approval or clearance for certain of their tests from the U.S. Food and Drug Administration, or FDA. If payers decide to reimburse only for tests that are FDA-approved or FDA-cleared, or if they are more likely to reimburse for such tests, we may not be able to compete effectively unless we obtain similar approval or clearance for our tests. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.

Our expected future growth could create a strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our tests, or satisfy customer demand as it grows. We may need to continue expanding our sales force to facilitate our growth, and we may have difficulties locating, recruiting, training and retaining sales personnel. Our ability to manage our growth effectively will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. As we grow, any failure of our controls or interruption of our production facilities or systems could have a negative impact on our business and financial operations. We plan to implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain, and failure to complete these activities in a timely and efficient manner could adversely affect our operations. Future growth in our business could also make it difficult for us to maintain our corporate culture. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

Security breaches, privacy issues, loss of data and other incidents could compromise sensitive or personal information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including protected health information, or PHI, personally identifiable information, genetic information, credit card information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payers and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based systems. We also communicate PHI and other sensitive patient data through our various customer tools and platforms. In addition to storing and transmitting sensitive data that is subject to multiple legal protections, these applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure, inappropriate modification, and the risk of our being

unable to adequately monitor and modify our controls over our critical information. Any technical problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions to our business and operations or exposure to security vulnerabilities. These types of problems may be caused by a variety of factors, including infrastructure changes, intentional or accidental human actions or omissions, software errors, malware, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take what we believe to be reasonable and appropriate measures, including a formal, dedicated enterprise security program, to protect sensitive information from various compromises (including unauthorized access, disclosure, or modification or lack of availability), our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. For example, ArcherDX has been subject to phishing incidents and we may experience additional incidents in the future. Any such breach or interruption could compromise our networks and the information stored therein could be accessed by unauthorized parties, altered, publicly disclosed, lost or stolen.

Further, our various customer tools and platforms are currently accessible through our online portal and/or through our mobile applications, and there is no guarantee we can protect them from a security breach. Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business) and damage our reputation, any of which could adversely affect our business.

In addition to data security risks, we also face privacy risks. Should we actually violate, or be perceived to have violated, any privacy promises we make to patients or consumers, we could be subject to a complaint from an affected individual or interested privacy regulator, such as the FTC, a state Attorney General, or an EU Member State Data Protection Authority. This risk is heightened given the sensitivity of the data we collect.

Any security compromise that causes an apparent privacy violation could also result in legal claims or proceedings; liability under federal, state, foreign, or multinational laws that regulate the privacy, security, or breach of personal information, such as but not limited to the HIPAA, HITECH, state data security and data breach notification laws, the European Union's General Data Protection Regulation, or GDPR, the UK Data Protection Act of 2018; and related regulatory penalties. Penalties for failure to comply with a requirement of HIPAA or HITECH vary significantly, and, depending on the knowledge and culpability of the HIPAA-regulated entity, may include civil monetary penalties of up to \$1.5 million per calendar year for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to \$50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. Penalties for unfair or deceptive acts or practices under the FTC Act or state Unfair and Deceptive Acts and Practices, or UDAP, statutes may also vary significantly.

There has been unprecedented activity in the development of data protection regulation around the world. As a result, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. The GDPR took effect on May 25,

2018. The GDPR applies to any entity established in the EU as well as extraterritorially to any entity outside the EU that offers goods or services to, or monitors the behavior of, individuals who are located in the EU. The GDPR imposes strict requirements on controllers and processors of personal data, including enhanced protections for “special categories” of personal data, which includes sensitive information such as health and genetic information of data subjects. The GDPR also grants individuals various rights in relation to their personal data, including the rights of access, rectification, objection to certain processing and deletion. The GDPR provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR or the related national data protection laws of the member states of the EU, which may deviate from or be more restrictive than the GDPR, may result in significant administrative fines issued by EU regulators. Maximum penalties for violations of the GDPR are capped at 20M euros or 4% of an organization’s annual global revenue, whichever is greater.

Further, the United Kingdom’s decision to leave the European Union, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is still unclear whether the transfer of personal information from the EU to the United Kingdom will in the future remain lawful under the GDPR. The United Kingdom-EU post-Brexit trade deal provides that transfers of personal information to the United Kingdom will not be treated as restricted transfers to a non-EU country for a period of up to six months from January 1, 2021. However, unless the EU Commission makes an “adequacy finding” with respect to the United Kingdom before the end of that transition period, from that date the United Kingdom will be a “third country” under the GDPR and transfers of personal information from the EU to the United Kingdom will require an “adequacy mechanism,” such as the SCCs.

Additionally, the implementation of GDPR has led other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, on June 28, 2018, California adopted the CCPA. The CCPA regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of consumers who reside in California. Among other things, the CCPA confers to California consumers the right to receive notice of the categories of personal information that will be collected by a business, how the business will use and share the personal information, and the third parties who will receive the personal information; the CCPA also confers rights to access, delete, or transfer personal information; and the right to receive equal service and pricing from a business after exercising a consumer right granted by the CCPA. In addition, the CCPA allows California consumers the right to opt out of the “sale” of their personal information, which the CCPA defines broadly as any disclosure of personal information to a third party in exchange for monetary or other valuable consideration. The CCPA also requires a business to implement reasonable security procedures to safeguard personal information against unauthorized access, use, or disclosure. California amended the law in September 2018 to exempt all PHI collected by certain parties subject to HIPAA, and further amended the law in September 2020 to clarify that de-identified data as defined under HIPAA will also be exempt from the CCPA. The California Attorney General’s final regulations implementing the CCPA took effect on August 14, 2020. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches resulting from a business’s failure to implement and maintain reasonable data security procedures that is expected to increase data breach litigation.

In addition, California voters recently approved the California Privacy Rights Act of 2020, or CPRA, that is scheduled to go into effect on January 1, 2023. The CPRA would, among other things, amend the CCPA to give California residents the ability to limit the use of their sensitive information, provide for penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the law. Other jurisdictions in the United States are beginning to propose laws similar to the CCPA. Some observers have noted that the CCPA could mark the beginning of a trend toward

more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business, results of operations, and financial condition.

It is possible the GDPR, CCPA and other data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country and state to state, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. We can provide no assurance that we are or will remain in compliance with diverse privacy and data security requirements in all of the jurisdictions in which we do business. Failure to comply with privacy and data security requirements could result in a variety of consequences, including civil or criminal penalties, litigation, or damage to our reputation, any of which could have a material adverse effect on our business.

We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.

Our performance, including our research and development programs and laboratory operations, largely depend on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization, including software developers, geneticists, biostatisticians, certified laboratory scientists and other scientific and technical personnel to process and interpret our genetic tests. In addition, we may need to continue to expand our sales force with qualified and experienced personnel. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future due to the competition for qualified personnel among life science and technology businesses as well as universities and public and private research institutions, particularly in the San Francisco Bay Area. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to scale our business, support our research and development efforts and our clinical laboratory. We believe that our corporate culture fosters innovation, creativity and teamwork. However, as our organization grows, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

We need to scale our infrastructure in advance of demand for our tests, and our failure to generate sufficient demand for our tests would have a negative impact on our business and our ability to attain profitability.

Our success depends in large part on our ability to extend our market position, to provide customers with high-quality test reports quickly and at a lower price than our competitors, and to achieve sufficient test volume to realize economies of scale. In order to execute our business model, we intend to continue to invest heavily in order to significantly scale our infrastructure, including our testing capacity and information systems, expand our commercial operations, customer service, billing and systems processes and enhance our internal quality assurance program. We expect that much of this growth will be in advance of demand for our tests. Our current and future expense levels are to a large extent fixed and are largely based on our investment plans and our estimates of future revenue. Because the timing and amount of revenue from our tests is difficult to forecast, when revenue does not meet our expectations, we may not be able to adjust our spending promptly or reduce our spending to levels commensurate with our revenue. Even if we are able to successfully scale our infrastructure and operations, we cannot assure you that demand for our tests will increase at levels consistent

with the growth of our infrastructure. If we fail to generate demand commensurate with this growth or if we fail to scale our infrastructure sufficiently in advance of demand to successfully meet such demand, our business, prospects, financial condition and results of operations could be adversely affected.

If we are not able to continue to generate substantial demand of our tests, our commercial success will be negatively affected.

Our business model assumes that we will be able to generate significant test volume, and we may not succeed in continuing to drive adoption of our tests to achieve sufficient volumes. Inasmuch as detailed genetic data from broad-based testing panels such as our tests have only recently become available at relatively affordable prices, the continued pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic testing that is specific to one or a few genes. Given the substantial amount of additional information available from a broad-based testing panel such as ours, there may be distrust as to the reliability of such information when compared with more limited and focused genetic tests. To generate further demand for our tests, we will need to continue to make clinicians aware of the benefits of our tests, including the price, the breadth of our testing options, and the benefits of having additional genetic data available from which to make treatment decisions. A lack of or delay in clinical acceptance of broad-based panels such as our tests would negatively impact sales and market acceptance of our tests and limit our revenue growth and potential profitability. Genetic testing is expensive and many potential customers may be sensitive to pricing. In addition, potential customers may not adopt our tests if adequate reimbursement is not available, or if we are not able to maintain low prices relative to our competitors. Also, we may not be successful in increasing demand for our tests through our direct channel, in which we facilitate the ordering of our genetic tests by consumers through an online network of physicians.

If we are not able to generate demand for our tests at sufficient volume, or if it takes significantly more time to generate this demand than we anticipate, our business, prospects, financial condition and results of operations could be materially harmed.

We have devoted a portion of our resources to the development and commercialization of STRATAFIDE, and to research and development activities related to our PCM product for cancer monitoring, including clinical and regulatory initiatives to obtain diagnostic clearance and marketing approval. The demand for these regulated products is unproven, and we may not be successful in achieving market awareness and demand for these products through our sales and marketing operations.

If ArcherDX's products and services do not perform as expected, we may not realize the expected benefits of our recent acquisition of ArcherDX.

The success of ArcherDX's products depends on the market's confidence that it can provide reliable products that enable high quality diagnostic testing with high sensitivity and specificity and short turnaround times. There is no guarantee that the accuracy and reproducibility ArcherDX has demonstrated to date will continue as its product deliveries increase and its product portfolio expands.

ArcherDX's products and services 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 ArcherDX anticipates or result in longer than expected turnaround times. In addition, labs are required to validate their processes before using ArcherDX products for clinical purposes. These validations are outside of our control. If our products do not perform, or are perceived to not have performed, as expected or favorably in we to competitive products, our consolidated operating results, reputation, and business will suffer, and ArcherDX may also be subject to legal claims arising from product limitations, errors, or inaccuracies.

In addition, we plan to match our test reports for STRATAFIDE to identified mutations with FDA-approved targeted therapies or relevant clinical trials of targeted therapies. If a patient or physician who orders a test using one of our products is unable to obtain, or be reimbursed for the use of, targeted therapies because they are not indicated in the FDA-approved label for treatment, the patient is unable to enroll in an identified clinical trial due to the enrollment criteria of the trial, or some other reason, the ordering physician may conclude the test report does not contain actionable information. If physicians do not believe our products consistently generate actionable information about their patients' disease or condition, they may be less likely to use our products.

Furthermore, we cannot provide assurance that customers will always use these products in the manner in which intended. Any intentional or unintentional misuse of these products by customers could lead to substantial civil and criminal monetary and non-monetary penalties, and could result in significant legal and investigatory fees.

The future growth of our distributed products business is partially dependent upon regulatory approval and market acceptance of our IVD products, including STRATAFIDE and PCM.

We anticipate that the future success of our distributed products business will depend in large part on our ability to effectively introduce enhanced or new offerings of IVD products, such as STRATAFIDE. The development and launch of enhanced or new products and services, whether research use only, or RUO, or IVD, require the completion of certain clinical development and commercialization activities that are complex, costly, time-intensive and uncertain, and require us to accurately anticipate patients', providers' and, if applicable, payers' attitudes and needs and emerging technology and industry trends. This process is conducted in various stages, and each stage presents the risk that ArcherDX will not achieve its goals on a timely basis, or at all.

We have limited experience commercializing IVD products. We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new products or new services and result in increased costs and the diversion of management's attention and resources from other business matters.

An important factor in our ability to commercialize our distributed products is collecting data that supports their value proposition. The data collected from any studies we complete may not be favorable or consistent with its 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 these products. This is particularly true with respect to service defects and errors. Any of the foregoing could have a negative impact on our ability to commercialize our future products, which could have a material adverse effect on our ability to realize the intended benefits of our recent acquisition of ArcherDX.

Our success will depend on our ability to use rapidly changing genetic data to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.

Our success depends on our ability to provide reliable, high-quality tests that incorporate rapidly evolving information about the role of genes and gene variants in disease and clinically relevant outcomes associated with those variants. Errors, such as failure to detect genomic variants with high accuracy, or mistakes, such as failure to identify, or incompletely or incorrectly identifying, gene variants or their significance, could have a significant adverse impact on our business.

Hundreds of genes can be implicated in some disorders, and overlapping networks of genes and symptoms can be implicated in multiple conditions. As a result, a substantial amount of judgment is required in order to interpret testing results for an individual patient and to develop an appropriate patient report. We classify

variants in accordance with published guidelines as benign, likely benign, variants of uncertain significance, likely pathogenic or pathogenic, and these guidelines are subject to change. In addition, it is our practice to offer support to clinicians and geneticists ordering our tests regarding which genes or panels to order as well as interpretation of genetic variants. We also rely on clinicians to interpret what we report and to incorporate specific information about an individual patient into the physician's treatment decision.

The marketing, sale and use of our genetic tests could subject us to liability for errors in, misunderstandings of, or inappropriate reliance on, information we provide to clinicians, geneticists or patients, and lead to claims against us if someone were to allege that a test failed to perform as it was designed, if we failed to correctly interpret the test results, if we failed to update the test results due to a reclassification of the variants according to new published guidelines, or if the ordering physician were to misinterpret test results or improperly rely on them when making a clinical decision. In addition, our entry into the reproductive health and pharmacogenetic testing markets expose us to increased liability. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain liability insurance, including for errors and omissions, we cannot assure you that such insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any liability claim, including an errors and omissions liability claim, brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could cause injury to our reputation or cause us to suspend sales of our tests. The occurrence of any of these events could have an adverse effect on our reputation and results of operations.

Our industry is subject to rapidly changing technology and new and increasing amounts of scientific data related to genes and genetic variants and their role in disease. Our failure to develop tests to keep pace with these changes could make us obsolete.

In recent years, there have been numerous advances in methods used to analyze very large amounts of genomic information and the role of genetics and gene variants in disease and treatment therapies. Our industry has and will continue to be characterized by rapid technological change, increasingly larger amounts of data, frequent new testing service introductions and evolving industry standards, all of which could make our tests obsolete. Our future success will also depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. Our tests could become obsolete and our business adversely affected unless we continually update our offerings to reflect new scientific knowledge about genes and genetic variations and their role in diseases and treatment therapies.

Our success will depend in part on our ability to generate sales using our internal sales team and through alternative marketing strategies.

We may not be able to market or sell our current tests and any future tests we may develop or acquire effectively enough to drive demand sufficient to support our planned growth. We currently sell our tests primarily through our internal sales force. Historically, our sales efforts have been focused primarily on hereditary cancer and more recently on reproductive health. Our efforts to sell our tests to clinicians and patients outside of oncology may not be successful, or may be difficult to do successfully without significant additional selling and marketing efforts and expense. In addition, following the acquisition of ArcherDX, our sales efforts have expanded to include distributed products sold to laboratories. In the past, we have increased our sales force each year in order to drive our growth, and in October 2020, we increased our sales force through the acquisition of ArcherDX. In addition to the efforts of our sales force, future sales will depend in large part on our ability to develop and substantially expand awareness of our company and our tests through alternative strategies including through education of key opinion leaders, through social media-related and

online outreach, education and marketing efforts, and through focused channel partner strategies designed to drive demand for our tests. We also plan to continue to spend on consumer advertising in connection with our direct channel to consumers, which could be costly. We have limited experience implementing these types of marketing efforts. We may not be able to drive sufficient levels of revenue using these sales and marketing methods and strategies necessary to support our planned growth, and our failure to do so could limit our revenue and potential profitability.

We also use a limited number of distributors to assist internationally with sales, logistics, education and customer support. Sales practices utilized by our distributors that are locally acceptable may not comply with sales practices standards required under U.S. laws that apply to us, which could create additional compliance risk. If our sales and marketing efforts are not successful outside the United States, we may not achieve significant market acceptance for our tests outside the United States, which could adversely impact our business.

Impairment in the value of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition.

We record goodwill and intangible assets at fair value upon the acquisition of a business. Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired. Goodwill and indefinite-lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors that impact the fair value of a reporting unit could result in an impairment of goodwill or intangible assets and, in turn, a charge to net income. Any such charges could have a material adverse effect on our results of operations or financial condition.

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

We rely on a limited number of suppliers, or, in some cases, sole suppliers, including Illumina, Inc., Integrated DNA Technologies Incorporated, Qiagen N.V., Roche Holdings Ltd. and Twist Bioscience Corporation for certain laboratory substances used in the chemical reactions incorporated into our processes, which we refer to as reagents, as well as sequencers and other equipment and materials which we use in our laboratory operations. We do not have short- or long-term agreements with most of our suppliers, and our suppliers could cease supplying these materials and equipment at any time, or fail to provide us with sufficient quantities of materials or materials that meet our specifications. Our laboratory operations could be interrupted if we encounter delays or difficulties in securing these reagents, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We rely on Illumina as the sole supplier of next generation sequencers and associated reagents and as the sole provider of maintenance and repair services for these sequencers. Any disruption in Illumina's operations could impact our supply chain and laboratory operations as well as our ability to conduct our tests, and it could take a substantial amount of time to integrate replacement equipment into our laboratory operations.

We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials provided by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in

interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot assure you that we will be able to secure alternative equipment, reagents and other materials, and bring such equipment, reagents and materials on line and revalidate them without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, we cannot assure you that replacement sequencers and associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations. If we encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and reagents we require for our tests, our business, financial condition, results of operations and reputation could be adversely affected.

Our planned STRATAFIDE and PCM products are currently being developed to use only Illumina's sequencing platform. Without access to these sequencers, we would be unable commercialize these products. In addition, any efforts to validate these distributed products on additional sequencing platforms would require significant resources, expenditures and time and attention of our 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 it will appropriately prioritize or select alternative sequencing platforms on which to focus our efforts.

If our laboratories become inoperable due to disasters, health epidemics or for any other reasons, we will be unable to perform our tests and our business will be harmed.

We perform all of our tests at our production facilities in San Francisco and Irvine, California, in Golden, Colorado and in Seattle, Washington. Our laboratories and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use. Our laboratories may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding, fire and power outages, or by health epidemics, such as the COVID-19 pandemic, which may render it difficult or impossible for us to perform our tests for some period of time. This risk of natural disaster is especially high for us since we perform the substantial majority of our tests at our San Francisco laboratory, which is located in an active seismic region, and we do not have a redundant facility to perform the same tests in the event our San Francisco laboratory is inoperable. The inability to perform our tests or the backlog that could develop if our laboratories are inoperable for even a short period of time may result in the loss of customers or harm our reputation. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

ArcherDX relies on third-party laboratories to perform portions of its service offerings.

A large portion of ArcherDX's biopharmaceutical testing services is performed by third-party laboratories while the remaining portion is performed by third-party laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, or our CLIA-certified laboratory in Colorado. The 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 it have no control over such laboratories' compliance with applicable legal and regulatory requirements. We also has no control over the timeliness of such laboratories' performance of their obligations to us, and the 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. In the event of any adverse developments with these third-party laboratories or their ability to perform their obligations in a timely manner and in accordance with the standards that we and our customers expect, our ability to service 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's attention and other resources to address and remedy such issues.

We may not have sufficient alternative backup if one or more of the third-party laboratories that we contract with are unable to satisfy their obligations to us with sufficient performance, quality and timeliness. 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 these third-party laboratories' facilities that causes a loss of capacity would heighten the risks that we face. Changes to or termination of agreements or inability to renew 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 services.

The loss of any member or change in structure of our senior management team could adversely affect our business.

Our success depends in large part upon the skills, experience and performance of members of our executive management team and others in key leadership positions. The efforts of these persons will be critical to us as we continue to develop our technologies and test processes and focus on scaling our business. If we were to lose one or more key executives, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy. All of our executives and employees are at-will, which means that either we or the executive or employee may terminate their employment at any time. We do not carry key person insurance for any of our executives or employees. In addition, we do not have a long-term retention agreement in place with our president and chief executive officer.

Development of new tests is a complex process, and we may be unable to commercialize new tests on a timely basis, or at all.

We cannot assure you that we will be able to develop and commercialize new tests on a timely basis. Before we can commercialize any new tests, we will need to expend significant funds in order to:

- conduct research and development;
- further develop and scale our laboratory processes; and
- further develop and scale our infrastructure to be able to analyze increasingly larger and more diverse amounts of data.

Our testing service development process involves risk, and development efforts may fail for many reasons, including:

- failure of any test to perform as expected;
- lack of validation or reference data; or
- failure to demonstrate utility of a test.

As we develop tests, we will have to make significant investments in development, marketing and selling resources. In addition, competitors may develop and commercialize competing tests faster than we are able to do so.

Our research and development efforts to add additional indications to our IVD products, if approved, will be hindered we are not able to contract with third parties for access to tissue samples.

Under standard clinical practice, tumor biopsies removed from patients are preserved and stored in formalin-fixed paraffin embedded, or FFPE, format, and liquid biopsies are taken with a blood draw and stored in blood collection tubes. In order to add additional indications to our IVD products, if approved, We will need to secure

access to these FFPE tumor biopsy and liquid biopsy samples, as well as information pertaining to the clinical outcomes of the patients from which they were derived for its IVD development activities. Others compete with us for access to these samples. Additionally, the process of negotiating access to samples is lengthy because it typically involves numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters. If we are unable to negotiate access to tissue samples on a timely basis or on commercially reasonable terms, or at all, or if other laboratories or competitors secure access to these samples before us, our ability to research, develop and commercialize future IVD products will be limited or delayed.

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

We depend on information technology and telecommunications systems for significant elements of our operations, including our laboratory information management system, our bioinformatics analytical software systems, our database of information relating to genetic variations and their role in disease process and drug metabolism, our clinical report optimization systems, our customer-facing web-based software, our customer reporting, and our various customer tools and platforms. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including for example, systems handling human resources, financial controls and reporting, customer relationship management, regulatory compliance and other infrastructure operations. In addition, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design, and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation, and general administrative activities, including financial reporting.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from conducting tests, preparing and providing reports to clinicians, billing payers, processing reimbursement appeals, handling physician or patient inquiries, conducting research and development activities, and managing the administrative and financial aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and results of operations.

Technical problems have arisen, and may arise in the future, in connection with our data and systems, including those that are hosted by third-party providers, which have in the past and may in the future result in interruptions in our business and operations. 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. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

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

Genetic testing has raised ethical, legal and social issues regarding privacy rights and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use

of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, genomic tests even if permissible. These and other ethical, legal and social concerns may limit market acceptance of our tests or reduce the potential markets for our tests, either of which could have an adverse effect on our business, financial condition or results of operations.

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

Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the use of our tests in various countries;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- logistics and regulations associated with shipping samples, including infrastructure conditions, customs and transportation delays;
- limits on our ability to penetrate international markets if we do not to conduct our tests locally;
- natural disasters, including the recent and ongoing outbreak and spreading of Coronavirus, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our international operations and, consequently, our revenue and results of operations.

In addition, applicable export or import laws and regulations such as prohibitions on the export of samples imposed by countries outside of the United States, or international privacy or data restrictions that are different or more stringent than those of the United States, may require that we build additional laboratories or engage in joint ventures or other business partnerships in order to offer our tests internationally in the future. Any such restrictions would impair our ability to offer our tests in such countries and could have an adverse effect on our business, financial condition and results of operations.

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

At September 30, 2020, our total gross deferred tax assets were \$204.5 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, our net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets are primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Furthermore, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, if a corporation undergoes an “ownership

change,” the corporation’s ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with completed acquisitions, or other future transactions in our stock, our ability to utilize NOLs and tax credit carryovers could be further limited by Section 382 of the Internal Revenue Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss and tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization. In addition, the Tax Cuts and Jobs Act limits the deduction for NOLs to 80% of current year taxable income and eliminates NOL carrybacks. Also, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks related to government regulation

If the FDA regulates the tests we currently offer as LDTs as medical devices, we could incur substantial costs and our business, financial condition and results of operations could be adversely affected.

We provide many of our tests as laboratory-developed tests, or LDTs. CMS and certain state agencies regulate the performance of LDTs (as authorized by the CLIA and state law, respectively).

Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency’s requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled “Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)” and “FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs),” respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. Subsequently, on January 13, 2017, the FDA published a “discussion paper” in which it outlined a substantially revised “possible approach” to the oversight of LDTs.

In March 2020, a bill titled the “Verifying Accurate Leading-edge IVCT Development Act of 2020,” or VALID Act, was officially introduced in Congress. The bill proposes a risk-based approach to regulate LDTs and creates a new in vitro clinical test, or IVCT, category of regulated products, which includes LDTs, and a regulatory structure under the FDA. As proposed, the bill grandfathered many existing tests from the proposed premarket approval, quality systems, and labeling requirements, respectively, but would require such tests to comply with other regulatory requirements (e.g., registration and listing, adverse event reporting). Later that month, Senator Paul introduced the Verified Innovative Testing in American Laboratories Act of 2020, or VITAL Act, which proposes that all aspects of “laboratory-developed testing procedures” be subject to regulation under CLIA, and that no aspects of such procedures be subject to regulation by the FDA. We cannot predict if either of these bills will be enacted in their current (or any other) form and cannot quantify the effect of these bills on our business.

In August 2020, the U.S. Department of Health and Human Services, the parent agency for FDA, announced that the FDA “will not require premarket review of LDTs absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances.” It is unclear at this time whether this policy will be retained by the Biden Administration, and if so, when the FDA might seek to begin the notice and comment rulemaking process.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals may be introduced from time-to-time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate certain LDTs as medical devices is difficult to predict at this time.

In April 2020, we completed our acquisition of Genelex Solutions, LLC, which offers certain pharmacogenetic, or PGx, tests as LDTs. Recently the FDA has taken a more active role in the oversight of PGx tests offered as LDTs. In 2019, the FDA contacted several clinical laboratories, including Genelex, to demand changes to PGx test reports and marketing materials. In February 2020, the FDA issued a statement indicating that it continues to have concerns about the claims that certain clinical laboratories make with respect to their PGx tests, and published tables that list PGx associations for which FDA has determined that the data support therapeutic management recommendations, a potential impact on safety or response, or a potential impact on pharmacokinetic properties only, respectively. To date, however, the FDA has not provided any general guidance on the type(s) of claims or other characteristics that will cause a PGx test to fall outside FDA's enforcement discretion. As such, the extent to which the FDA will allow any laboratory, including Genelex or Invitae, to offer PGx tests in their current form without meeting FDA regulatory requirements for medical devices is unclear at this time.

If the FDA ultimately regulates certain LDTs (either as medical devices or as part of a new stand-alone regulatory category for IVCTs), whether via individualized enforcement action, or more generally, as outlined in final guidance or final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements can be expensive, time-consuming and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's requirements to our tests could materially and adversely affect our business, financial condition and results of operations.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

In addition, in November 2013, the FDA issued final guidance regarding the distribution of products labeled for research use only. Certain of the reagents and other products we use in our tests are labeled as research use only products. Certain of our suppliers may cease selling research use only products to us and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

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

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers, for our tests. We have current CLIA certifications to conduct our tests at our laboratories in San Francisco and Irvine, California, Golden, Colorado, and Seattle, Washington. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories.

We are also required to maintain in-state licenses to conduct testing in California and Washington. California and Washington laws establish standards for day-to-day operation of our clinical reference laboratories in San Francisco and Irvine, and in Seattle, respectively, which include the training and skills required of personnel and quality control. (Our Colorado laboratory is not required to maintain a state clinical laboratory license.)

Several states require the licensure of out-of-state laboratories that accept specimens from those states. Our California laboratories hold the required out-of-state laboratory licenses for Maryland, New York, Pennsylvania, and Rhode Island. Our Washington laboratory holds the required out-of-state laboratory licenses in Maryland, New York, Pennsylvania, and Rhode Island (but not California). Our laboratory in Colorado holds the required out-of-state laboratory licenses for California, Maryland, Pennsylvania and Rhode Island (but not New York).

In addition to having laboratory licenses in New York, our clinical reference laboratories are approved on test-specific bases for the tests they run as LDTs by the New York State Department of Health, or NYDOH, for tests offered to patients in New York. Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of samples necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays.

In order to eventually market certain of our current or future products and services in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding quality, safety, performance and efficacy. In addition, clinical trials or clinical investigations conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory clearance, authorization or approval in one country does not guarantee regulatory clearance, authorization or approval in any other country. For example, the performance characteristics of certain of our products and services may need to be validated separately in specific ethnic and genetic populations. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking foreign regulatory clearance, authorization or approval could result in difficulties and costs for us and our collaborators and require additional preclinical studies, clinical trials or clinical investigations which could be costly and time-consuming. Regulatory requirements and ethical approval obligations can vary widely from country to country and could delay or prevent the introduction of certain of our products and services in those countries. The foreign regulatory clearance, authorization or approval process involves all of the risks and uncertainties associated with FDA clearance, authorization or approval. ArcherDX currently sells its RUO products outside the United States but has no experience in obtaining regulatory clearance, authorization or approval in international markets other than Japan. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required regulatory clearances, authorizations or approvals in international markets, or if those approvals are delayed, our target market will be reduced and our ability to realize the full market potential of our products and services will be unrealized.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, and cancellation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certifications, a state or foreign license, or accreditation,

could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

The College of American Pathologists, or CAP, maintains a clinical laboratory accreditation program. CAP asserts that its program is “designed to go well beyond regulatory compliance” and helps laboratories achieve the highest standards of excellence to positively impact patient care. While not required to operate a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. We have CAP accreditations for our laboratories. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

We may not be able to obtain regulatory clearance or approval of our IVD products, or even if approved, such products may not be approved for guideline inclusion, which could adversely affect our ability to realize the intended benefits of our recently completed acquisition of ArcherDX.

A significant portion of ArcherDX’s commercial strategy, including for STRATAFIDE and PCM, relies on receiving regulatory approvals with guideline inclusion to strengthen its position in establishing coverage and reimbursement of its IVD products with both public and private payers. If we do not receive such regulatory approvals in a timely manner or at all, or we are not successful in obtaining such guideline inclusion, it may not be able to commercialize our IVD products. Additionally, third-party payers may be unwilling to provide sufficient coverage and reimbursement for these products necessary for hospitals and other healthcare providers to adopt our solutions as part of their oncological treatment strategy. ArcherDX has also focused its efforts on the development of PCM for FDA clearance and approval as a prognostic device for predicting recurrence of a primary cancer after initial treatment, which can include surgery alone or surgery plus adjuvant therapy.

Moreover, development of the data necessary to obtain regulatory clearance and/or approval of an IVD, such as STRATAFIDE, 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 clearance and/or approval or regulatory approvals in foreign jurisdictions. Limited results from earlier-stage verification studies may not predict results from studies in larger numbers of subjects drawn from more diverse populations over longer periods of time. Unfavorable results from ongoing preclinical and clinical studies could result in delays, modifications or abandonment of ongoing analytical or future clinical studies, or abandonment of a product development program, or may delay, limit or prevent regulatory approvals or clearances or commercialization of our product candidates, any of which may materially impact our ability to realize the expected benefits of our recently completed acquisition of ArcherDX.

Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Our operations are subject to other extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among others:

- HIPAA, which establishes comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions;
- amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators and expand vicarious liability, extend enforcement authority to state attorneys general, and impose requirements for breach notification;

-
- the GDPR, which imposes strict privacy and security requirements on controllers and processors of personal data, including enhanced protections for “special categories” of personal data, including sensitive information such as health and genetic information of data subjects;
 - the CCPA, which, among other things, regulates how subject businesses may collect, use, and disclose the personal information of consumers who reside in California, affords rights to consumers that they may exercise against businesses that collect their information, and requires implementation of reasonable security measures to safeguard personal information of California consumers;
 - the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual, for the furnishing of or arrangement for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering, arranging for, or recommend purchasing, leasing or ordering, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program;
 - EKRA, which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and reaches beyond federal health care programs, to include private insurance;
 - the federal physician self-referral law, known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity unless an exception applies, and prohibits an entity from billing for designated health services furnished pursuant to a prohibited referral;
 - the federal false claims law, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
 - the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
 - the HIPAA fraud and abuse provisions, which create new federal criminal statutes that prohibit, among other things, defrauding health care benefit programs, willfully obstructing a criminal investigation of a healthcare offense and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services;
 - other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payer, including private insurers;
 - the 21st Century Cures Act information blocking prohibition, which prohibits covered actors from engaging in certain practices that are likely to interfere with the access, exchange, or use of electronic health information;
 - the Physician Payments Sunshine Act and similar state laws that require reporting of certain payments and other transfers of value made by applicable manufacturers, directly or indirectly, to or on behalf of covered recipients including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report

such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year;

- state laws that limit or prohibit the provision of certain payments and other transfers of value to certain covered healthcare providers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing clinicians for testing that they order; waiving coinsurance, copayments, deductibles and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payers; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

We have adopted policies and procedures designed to comply with these laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance may also be subject to governmental review. The growth of our business and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from participation in Federal healthcare programs, refunding of payments received by us, and curtailment or cessation of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Healthcare policy changes, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition, results of operations and cash flows.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Policy changes or implementation of new health care legislation could result in significant changes to health care systems. In the United States, this could include potential modification or repeal of all or parts of the Affordable Care Act.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA (as amended by the Further Consolidated Appropriations Act, 2020 and the Coronavirus Aid, Relief, and Economic Security Act, respectively) and its implementing regulations, clinical laboratories must report to CMS private payer rates beginning in 2017, and then in 2022 and every three years thereafter for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests and every year for advanced diagnostic laboratory tests.

We do not believe that our tests meet the definition of advanced diagnostic laboratory tests, but in the event that we seek designation for one or more of our tests as an advanced diagnostic laboratory test and the tests are determined by CMS to meet these criteria or new criteria developed by CMS, we would be required to report

private payer data for those tests annually. Otherwise, we will be required to report private payer rates for our tests on an every three years basis starting in 2022. Laboratories that fail to timely report the required payment information may be subject to substantial civil money penalties.

As set forth in the PAMA final rule, for tests furnished on or after January 1, 2018, Medicare payments for clinical diagnostic laboratory tests are paid based upon these reported private payer rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests will be assigned by the cross-walk or gap-fill methodology. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test. The payment rates calculated under PAMA went into effect starting January 1, 2018. Where applicable, reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2018 through 2020. Rates will be held at 2020 levels during 2021, and then, where applicable based upon median private payer rates reported in 2017 or 2022, reduced by up to 15% per test per year in each of 2022 through 2024 (with a second round of private payer rate reporting in 2022 to establish rates for 2023 through 2025).

PAMA also authorized the adoption of new, temporary billing codes and/or unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The CPT® Editorial Panel approved a proposal to create a new section of billing codes to facilitate implementation of this section of PAMA, but these codes would apply to our tests only if we apply for such codes.

In March 2018, CMS published a national coverage determination, or NCD, for next generation sequencing, or NGS tests for somatic (acquired) cancer testing. CMS subsequently updated this NCD in January 2020 to address coverage for NGS tests for germline (inherited) cancer testing and to clarify certain aspects of Medicare's coverage of NGS for somatic cancer testing. For somatic cancer testing, the updated NCD establishes full coverage for FDA-approved or FDA-cleared NGS-based companion diagnostic assays that report results using report templates that specify treatment options when offered for their FDA-approved or FDA-cleared use(s), ordered by the patient's treating physician for Medicare beneficiaries with advanced cancer (recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer) who have not have previously been tested with the same test using NGS for the same cancer genetic content, and have decided to seek further cancer treatment (e.g., therapeutic chemotherapy). The NCD also gives MACs the authority to establish local coverage for NGS-based somatic cancer assays that are not FDA-approved or FDA-cleared companion diagnostics when offered to patients meeting the above-referenced criteria. It appears that NGS-based somatic cancer tests provided for patients with cancer that do not meet the above-referenced criteria, e.g., patients with earlier stage cancers, are currently nationally non-covered under the NCD.

Effective January 27, 2020, the NCD also established full coverage for FDA-approved or FDA-cleared NGS-based germline tests that report results using report templates that specify treatment options when ordered by the patient's treating physician for patients with ovarian or breast cancer, a clinical indication for germline testing for hereditary breast or ovarian cancer, and a risk factor for germline breast or ovarian cancer, provided the patient has not previously been tested with the same germline test using NGS for the same germline genetic content. The NCD also gives MACs the authority to establish local coverage for NGS-based germline tests for ovarian or breast cancer that are not FDA-approved or FDA-cleared, as well as for NGS-based tests for any other cancer diagnosis (regardless of the test's FDA regulatory status) when offered to patients meeting the above-referenced criteria for germline testing. Since we already have local coverage for our germline tests for ovarian and breast cancer, we believe that the NCD will not have a material impact on which of our tests will be reimbursable by CMS for Medicare patients.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. For instance, the payment reductions imposed by the

Affordable Care Act and the expansion of the federal and state governments' role in the U.S. healthcare industry as well as changes to the reimbursement amounts paid by payers for our tests and future tests or our medical procedure volumes may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Notably, Congress enacted legislation in 2017 that eliminated the Affordable Care Act's "individual mandate" beginning in 2019, which may significantly impact the number of covered lives participating in exchange plans. The U.S. Supreme Court is currently reviewing the constitutionality of the Affordable Care Act, although it is unclear when a decision will be made. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the clinical laboratory fee schedule, which would increase our billing and collecting costs and decrease our revenue. Further, it is possible that additional governmental action be taken in response to the COVID-19 pandemic.

If we use hazardous materials in a manner that causes injury, we could be liable for resulting damages.

Our activities currently require the use of hazardous chemicals and biological material. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. In 2018, we decommissioned our laboratory in Massachusetts; however, we could be held liable for any damages resulting from our prior use of hazardous chemicals and biological materials at this facility. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

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

We are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are increasing our direct sales and operations personnel outside the United States, in which we have limited experience. We use a limited number of independent distributors to sell our tests internationally, which requires a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

Risks related to our intellectual property

One of ArcherDX's competitors has alleged that its Anchored Multiplex PCR, or AMP, chemistry and products using AMP are infringing on its intellectual property, and ArcherDX may be required to redesign the technology, obtain a license, cease using the AMP chemistry altogether and/or pay significant damages, among other consequences, any of which would have a material adverse effect on ArcherDX's business as well as our financial condition and results of operations, and the intended benefits of our recently completed acquisition of ArcherDX.

ArcherDX's AMP chemistry underlies all of its RUO products and is also the foundation of STRATAFIDE and Personalized Cancer Monitoring, or PCM. On January 27, 2020, one of ArcherDX's competitors, Natera, Inc., or Natera, filed a complaint against ArcherDX in the United States District Court for the District of Delaware, alleging that ArcherDX's products using AMP chemistry, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814. On April 15, 2020, Natera amended its complaint to allege that ArcherDX's products using AMP chemistry and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,538,814, U.S. Patent No. 10,557,172, U.S. Patent No. 10,590,482, and U.S. Patent No. 10,597,708, each of which are held by Natera. On August 6, 2020, Natera filed another complaint against ArcherDX in the United States District Court for the District of Delaware alleging that ArcherDX's products using AMP chemistry, and the manufacture, use, sale, and offer for sale of such products, infringe U.S. Patent No. 10,731,220 (together with U.S. Patent Nos. 10,538,814, 10,557,172, 10,590,482, and 10,597,708, the "Natera Asserted Patents.") Natera seeks, among other things, damages and other monetary relief, costs and attorneys' fees, and an order enjoining ArcherDX from further infringement of The Natera Asserted Patents. The litigations have now been consolidated for all purposes, are ongoing, and trial has been scheduled for May 2022.

If any of ArcherDX's products or ArcherDX's use of AMP chemistry is found to infringe any of the Natera Asserted Patents, it could be required to redesign its technology or obtain a license from Natera to continue developing, manufacturing, marketing, selling and commercializing AMP and its products. However, ArcherDX may not be successful in the redesign of its technology or able to obtain any such license on commercially reasonable terms or at all. Even if ArcherDX were able to obtain a license, it could be non-exclusive, thereby giving Natera and other third parties the right to use the same technologies licensed to ArcherDX, and it could require ArcherDX to make substantial licensing, royalty and other payments. ArcherDX also could be forced, including by court order, to permanently cease developing, manufacturing, marketing and commercializing ArcherDX's products that are found to be infringing. In addition, ArcherDX could be found liable for significant monetary damages, including treble damages and attorneys' fees, if ArcherDX is found to have willfully infringed any of the Natera Asserted Patents. Even if ArcherDX were ultimately to prevail, litigation with Natera could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We cannot reasonably estimate the final outcome, including any potential liability or any range of potential future charges associated with these litigations. However, any finding of infringement by ArcherDX of any of the Natera Asserted Patents could have a material adverse effect on the business of ArcherDX and the benefits we expected to achieve through our acquisition of ArcherDX, as well as our financial condition and results of operations.

Litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation will require us to spend significant time and money, and could in the future prevent us from selling our tests or impact our stock price.

Our commercial success will depend in part on our avoiding infringement of patents and proprietary rights of third parties, including for example the intellectual property rights of competitors. As we continue to commercialize our tests in their current or an updated form, launch different and expanded tests, and enter

new markets, competitors might claim that our tests infringe or misappropriate their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. Our activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. For example, as discussed in the preceding risk factor, we are currently engaged in litigation with a competitor of ArcherDX alleging infringement. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. We may be unaware of patents that a third party, including for example a competitor in the genetic testing market, might assert are infringed by our business. There may also be patent applications that, if issued as patents, could be asserted against us. Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales of any tests or other activities that are the subject of such suit. Defense of these claims, regardless of merit, could cause us to incur substantial expenses and be a substantial diversion of our employee resources. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our business and stock price. In the event of a successful claim of infringement against us by a third party, we may have to (1) pay substantial damages, possibly including treble damages and attorneys' fees if we are found to have willfully infringed patents; (2) obtain one or more licenses, which may not be available on commercially reasonable terms (if at all); (3) pay royalties; and/or (4) redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure, all of which could have a material adverse impact on our cash position and business and financial condition.

If licenses to third-party intellectual property rights are or become required for us to engage in our business, we may be unable to obtain them at a reasonable cost, if at all. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Moreover, we could encounter delays in the introduction of tests while we attempt to develop alternatives. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing tests, which could materially affect our ability to grow and thus adversely affect our business and financial condition.

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

Although we view current U.S. Supreme Court precedent to be aligned with our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts (such as patient genetic data) and an understanding of that fact's implications (such as a patient's risk of disease associated with certain genetic variations) should not be patentable, it is possible that subsequent determinations by the U.S. Supreme Court or other federal courts could limit, alter or potentially overrule current law. Moreover, from time to time the U.S. Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office, or USPTO, may change the standards of patentability, and any such changes could run contrary to, or otherwise be inconsistent with, our belief that naturally occurring DNA sequences and detection of natural correlations between observed facts and an understanding of that fact's implications should not be patentable, which could result in third parties newly claiming that our business practices infringe patents drawn from categories of patents which we currently view to be invalid as directed to unpatentable subject matter. For example, the U.S. Senate Judiciary Committee, Subcommittee on Intellectual Property held hearings in 2019 regarding a legislative proposal that would overrule current U.S. Supreme Court precedent concerning the scope of patentable subject matter. Our President and Chief Executive Officer, Sean George, appeared before this subcommittee. If such proposal were to be formulated as a bill and enacted into law, there could be an increase in third-party claims to patent rights over correlations between patient genetic data and its interpretation and such third parties may assert that our business practices infringe some of those resulting patent rights.

Our inability to effectively protect our proprietary technologies, including the confidentiality of our trade secrets, could harm our competitive position.

We currently rely upon trade secret protection and copyright, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, and to a limited extent patent protection, to protect our confidential and proprietary information. Although our competitors have utilized and are expected to continue utilizing similar methods and have aggregated and are expected to continue to aggregate similar databases of genetic testing information, our success will depend upon our ability to develop proprietary methods and databases and to defend any advantages afforded to us by such methods and databases relative to our competitors. If we do not protect our intellectual property adequately, competitors may be able to use our methods and databases and thereby erode any competitive advantages we may have.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. In this regard, we have applied, and we intend to continue applying, for patents covering such aspects of our technologies as we deem appropriate. However, we expect that potential patent coverage we may obtain will not be sufficient to prevent substantial competition. In this regard, we believe it is probable that others will independently develop similar or alternative technologies or design around those technologies for which we may obtain patent protection. In addition, any patent applications we file may be challenged and may not result in issued patents or may be invalidated or narrowed in scope after they are issued. Questions as to inventorship or ownership may also arise. Any finding that our patents or applications are unenforceable could harm our ability to prevent others from practicing the related technology, and a finding that others have inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, which would be expensive, and, if we lose, we may lose some of our intellectual property rights. Furthermore, these lawsuits may divert the attention of our management and technical personnel.

We expect to rely primarily upon trade secrets and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how or other confidential information. Among other things, we seek to protect our trade secrets and confidential information by entering into confidentiality agreements with employees and consultants. There can be no assurance that any confidentiality agreements that we have with our employees and consultants will provide meaningful protection for our trade secrets and confidential information or will provide adequate remedies in the event of unauthorized use or disclosure of such information. Accordingly, there also can be no assurance that our trade secrets will not otherwise become known or be independently developed by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In

addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or genetic testing, diagnostic or other healthcare companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks related to being a public company

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC and the New York Stock Exchange, or NYSE, impose a number of requirements on public companies, including with respect to corporate governance practices. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In addition, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, enacted in 2010, includes significant corporate governance and executive-compensation-related provisions. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. If these requirements divert the attention of our management and personnel from other aspects of our business concerns, they could have a material adverse effect on our business, financial condition and results of operations. Moreover, these rules and regulations applicable to public companies substantially increase our legal, accounting and financial compliance costs, require that we hire additional personnel and make some activities more time consuming and costly. It may also be more expensive for us to obtain director and officer liability insurance.

If we are unable to maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

We are required to maintain internal control 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 control over financial reporting and provide a management report on our internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We have compiled the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We need to maintain and enhance these processes and controls as we grow and we have required, and may continue to require, additional personnel and resources to do so.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal controls, our management will be unable to conclude that our internal control over financial reporting is effective. Our independent registered public accounting firm is required to issue an attestation report on the effectiveness of our internal control over financial reporting every fiscal year. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective, or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Internal control deficiencies could also result in the restatement of our financial results in the future.

Risks related to our indebtedness

The terms of our credit agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

On October 2, 2020, we entered into the credit agreement, pursuant to which we borrowed an aggregate principal amount of \$135.0 million, or the term loan. The term loan is secured by a first priority lien on all of our and our subsidiaries' assets (including our intellectual property), and is guaranteed by our subsidiaries, in each case, excluding certain subsidiaries. If the term loan is prepaid, we may be required to pay a prepayment fee of up to 6% depending on when the prepayment is made.

The credit agreement restricts our ability to pursue certain mergers, amalgamations or consolidations, other than permitted acquisitions, that we may believe to be in our best interest. In addition, the credit agreement contains financial covenants that require us to maintain a minimum cash balance and minimum quarterly revenue levels. If we default under the credit agreement, the lender will be able to declare all obligations immediately due and payable, including prepayment fees and other obligations. The lender could declare an event of default under the credit agreement upon the occurrence of any event that it interprets as a material adverse change or material adverse effect, each as defined under the credit agreement. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

In September 2019, we issued \$350.0 million aggregate principal amount of our convertible senior notes in a private placement and in October 2020 we entered into our credit agreement and borrowed \$135.0 million through the term loan under the credit agreement.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the convertible notes and term loan, 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 debt 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.

We may not have the ability to raise the funds necessary to settle conversions of the convertible senior notes in cash or to repurchase the notes upon a fundamental change, and our current credit agreement contains and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the notes.

Holders of the notes have the right to require us to repurchase all or any portion of their notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, *plus* accrued and unpaid interest, if any. In addition, upon conversion of the 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 notes being converted. However, we only have limited ability to make those cash payments under our credit agreement and, even if the credit agreement limitations are no longer in effect, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of notes surrendered therefor or notes being converted. In addition, our ability to repurchase the notes or to pay cash upon conversions of the notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the notes as required by the indenture would constitute a default under the indenture. A default under the indenture or the occurrence of the fundamental change itself could also lead to a default under our credit agreements and any agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and to repay or repurchase the notes.

The conditional conversion feature of the convertible senior notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the notes is triggered, holders of notes will be entitled to convert the notes at any time during specified periods at their option. If one or more holders elect to convert their 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 through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 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 notes, could have a material effect on our reported financial results.

In May 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)*, which has subsequently been codified as Accounting Standards Codification 470-20, *Debt with Conversion and Other Options*, or ASC 470-20. Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet at issuance, and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the notes. As a result, we are required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the notes to their face amount over the term of the notes. We will report larger net losses or lower net income in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's non-convertible coupon interest rate, which could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the notes.

In addition, under certain circumstances, convertible debt instruments (such as the notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the notes are not included in the calculation of diluted net income (loss) per share except to the extent that the conversion value of the notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. The FASB recently amended these accounting standards, effective for fiscal years beginning after December 15, 2021, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020, to eliminate the treasury stock method for convertible instruments and instead require application of the "if-converted" method. Under that method, diluted net income (loss) per share would generally be calculated assuming that all the 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 net income (or further increase our diluted net loss, as the case may be) per share.

General risk factors

Our stock price is volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

The trading price of our common stock is volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated fluctuations in our operating results;
- competition from existing tests or new tests that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;

-
- issuance of new or updated research or reports by securities analysts or changed recommendations for our stock;
 - our focus on long-term goals over short-term results;
 - the timing and magnitude of our investments in the growth of our business;
 - actual or anticipated changes in regulatory oversight of our business;
 - additions or departures of key management or other personnel;
 - disputes or other developments related to our intellectual property or other proprietary rights, including litigation;
 - changes in reimbursement by current or potential payers;
 - general economic and market conditions; and
 - issuances of significant amounts of our common stock.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, including COVID-19, may seriously affect the market price of our common stock, regardless of our actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our company and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock, change their price targets, issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, the terms of our credit agreement restrict our ability to pay dividends. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

Anti-takeover provisions in our charter documents and under Delaware law could discourage, delay or prevent a change in control and may affect the trading price of our common stock.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 20,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, our chairman of the board or our chief executive officer;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may, except as otherwise required by law, be filled only by a majority of directors then in office, even if less than a quorum; and
- require a super-majority of votes to amend certain of the above-mentioned provisions as well as to amend our bylaws generally.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. Section 203 generally prohibits us from engaging in a business combination with an interested stockholder subject to certain exceptions.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders;
- any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law; or
- any action asserting a claim against us governed by the internal affairs doctrine.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision in our certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision in our certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Securities Act or any other claim for which the federal and state courts have concurrent jurisdiction.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Our actual results for the fourth quarter of 2020 and fiscal year 2020 may be different than the preliminary estimated results included elsewhere herein.

Our preliminary estimated results for the fourth quarter of 2020 and fiscal year 2020 are unaudited and subject to change as the quarter actually ends, and we close our books and complete the quarter end closing process and prepare financial statements for the quarter. Preliminary estimated financial results are inherently subject to business, economic, regulatory, market, financial and competitive uncertainties and contingencies and other future events, as well as matters specific to our business, all of which are difficult to predict and many of which are beyond our control. The inclusion of preliminary estimated financial information herein should not be regarded as an indication that we consider such preliminary estimated financial information to be predictive of actual or future results, in particular in light of the COVID-19 pandemic. Actual results for the quarter may be materially different than the preliminary estimated results presented and our estimated preliminary results should not be relied upon as being necessarily indicative of actual results, and you are cautioned not to place undue reliance on this preliminary financial information. Furthermore, the preliminary financial results do not take into account any circumstances or events occurring after the date they were prepared.