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 (Date of earliest event reported): **January 11, 2018**

EXACT SCIENCES CORPORATION

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-35092**	**02-0478229**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

441 Charmany Drive
Madison, WI 53719
(Address of Principal Executive Offices)(Zip Code)

Registrant's telephone number, including area code: **(608) 284-5700**

Not Applicable
(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))

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. ☐

7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.1 and incorporated herein is certain information relating to Exact Sciences Corporation (the "Company") which is being disclosed in connection with the offering of notes mentioned in Item 8.01 below.

The information furnished in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

8.01 Other Events.

On January 11, 2017, the Company issued a press release announcing the commencement of a registered underwritten public offering of $500 million aggregate principal amount of convertible senior notes due 2025. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K.

9.01. Financial Statements and Exhibits.

Exhibits

The exhibits to this Current Report on Form 8-K are listed in the Exhibit Index attached hereto and incorporated herein by reference.

EXHIBIT INDEX

Exhibit No	Exhibit Description
99.1	Supplemental Regulation FD Disclosure of Exact Sciences Corporation dated January 11, 2018, furnished herewith
99.2	Press release dated January 11, 2018, furnished herewith

SIGNATURES

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

EXACT SCIENCES CORPORATION

Date: January 11, 2018

By: /s/ Jeffrey T. Elliott
Jeffrey T. Elliott
Chief Financial Officer

Exhibit 99.1

EXACT SCIENCES CORPORATION

SUPPLEMENTAL REGULATION FD DISCLOSURE

DATED JANUARY 11, 2018

This exhibit shall not constitute an offer to sell or the solicitation of an offer to buy any security and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful.

The information contained in this Supplemental Regulation FD Disclosure (this "Supplemental Disclosure") is not complete and is being furnished solely for Regulation FD compliance purposes. For additional information, readers should refer to Exact Science Corporation's Annual Report on Form 10-K for the year ended December 31, 2016 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, and its other filings with the Securities and Exchange Commission (the "SEC").

Unless otherwise indicated or required by the context, in this Supplemental Disclosure, the "Company," "we," "us" and "our" and similar terms refer to Exact Sciences Corporation and its subsidiaries. References to our "common stock" refer to the common stock of Exact Sciences Corporation.

This Supplemental Disclosure contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "could," "seek," "intend," "plan," "goal," "estimate," "anticipate" or other comparable terms. All statements other than statements of historical facts included in this Supplemental Disclosure regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results, anticipated results of our sales and marketing efforts, expectations concerning payer reimbursement and the anticipated results of our product development efforts. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: our ability to successfully and profitably market our products and services; the acceptance of our products and services by patients and healthcare providers; our ability to meet demand for our products and services; the willingness of health insurance companies and other payers to cover Cologuard and reimburse us for our performance of the Cologuard test; the amount and nature of competition from other cancer screening products and services; the effects of the adoption, modification or repeal of any healthcare reform law, rule, order, interpretation or policy; the effects of changes in healthcare pricing, coverage and reimbursement, including without limitation as a result of the Protecting Access to Medicare Act of 2014; recommendations, guidelines and quality metrics issued by various organizations such as the U.S. Preventive Services Task Force, the American Cancer Society, and the National Committee for Quality Assurance regarding cancer screening or our products and services; our ability to successfully develop new products and services; our success establishing and maintaining collaborative, licensing and supplier arrangements; our ability to maintain regulatory approvals and comply with applicable regulations; and the other risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of this Supplemental Disclosure, our most recently filed Annual Report on Form 10-K and our subsequently filed Quarterly Report(s) on Form 10-Q. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Recent Developments

We expect to report revenue between $86.9 million and $87.9 million for the fourth quarter ended December 31, 2017, an increase of 148 percent from the same quarter of 2016. We completed approximately 176,000 Cologuard tests during the fourth quarter of 2017, 115-percent growth from the same period of 2016. Higher than anticipated year-end collections had a positive impact on revenues and average revenue recognized per test.

For the full-year 2017, we anticipate reporting revenue between $265.5 million and $266.5 million, a year-over-year increase of 168 percent. Completed Cologuard test volume during 2017 was approximately 571,000 tests, a 134-percent increase from 2016.

Nearly 11,000 health care providers ordered Cologuard for the first time during the fourth quarter ended December 31, 2017. The number of providers who have ordered Cologuard since its launch increased to nearly 102,000 during 2017.

We have not yet completed preparation of our financial statements for the fourth quarter or full year of 2017. The revenue ranges presented for the quarter and year ended December 31, 2017 are preliminary and unaudited and are thus inherently uncertain and subject to change. We are in the process of completing our customary year-end close and review procedures as of and for the year ended December 31, 2017, and there can be no assurance that our final results for this period will not differ from these estimates. During the course of the preparation of our consolidated financial statements and related notes as of and for the year ended December 31, 2017, we or our independent registered public accountants may identify items that could cause our final reported results to be materially different from the preliminary financial estimates presented herein.

Our top priorities for 2018 are to (1) continue to strengthen our core Cologuard business including by increasing the size of our nationwide sales force by approximately 200 representatives, which would bring our total number of sales personnel to approximately 550, (2) prepare for future demand including by continuing to invest in people, processes, technology and systems to build capacity, and (3) expand our product pipeline by developing additional cancer diagnostic tests, which may include liver and lung cancer tests, and that we expect will result in a material increase to our research and development expenditures.

Our Company

We are a molecular diagnostics company currently focused on the early detection and prevention of some of the deadliest forms of cancer. We have developed an accurate, non-invasive, patient-friendly screening test called Cologuard for the early detection of colorectal cancer and pre-cancer, and we are currently working on the development of additional tests for other types of cancer, with the goal of becoming a leader in cancer diagnostics.

Our Cologuard® Test

Colorectal cancer is the second leading cause of cancer deaths in the United States and the leading cause of cancer deaths in the U.S. among non-smokers. Each year in the U.S. there are approximately:

- 135,000 new cases of colorectal cancer
- 50,000 deaths from colorectal cancer

Colorectal cancer treatment represents a significant, growing healthcare cost. As of 2010, $14 billion was spent annually in the U.S. on colorectal cancer treatment, and the projected annual treatment costs are expected to be $20 billion in 2020. The incidence of colorectal cancer in Medicare patients is expected to rise from 106,000 cases in 2010 to more than 180,000 cases in 2030.

It is widely accepted that colorectal cancer is among the most preventable, yet least prevented cancers. Colorectal cancer can take up to 10-15 years to progress from a pre-cancerous lesion to metastatic cancer and death. Patients who are diagnosed early in the progression of the disease—with pre-cancerous lesions or polyps or early-stage cancer—are more likely to have a complete recovery and to be treated less expensively. Accordingly, the American Cancer Society (“ACS”) recommends that all people age 50 and older undergo regular colorectal cancer screening. Of the more than 80 million people in the U.S. for whom routine colorectal cancer screening is recommended, 38 percent have not been screened according to current guidelines. Poor compliance with screening guidelines has meant that nearly two-thirds of

colorectal cancer diagnoses are made in the disease's late stages. The five-year survival rates for stages 3 and 4 are 67 percent and 12 percent, respectively. We believe the large underserved population of unscreened and inadequately screened patients represents a significant opportunity for a patient-friendly screening test.

Our Cologuard test is a non-invasive stool-based DNA ("sDNA") screening test that utilizes a multi-target approach to detect DNA and hemoglobin biomarkers associated with colorectal cancer and pre-cancer. Eleven biomarkers are targeted that have been shown to be strongly associated with colorectal cancer and pre-cancer. Methylation, mutation, and hemoglobin results are combined in the laboratory analysis through a proprietary algorithm to provide a single positive or negative reportable result.

On August 11, 2014 the U.S. Food and Drug Administration ("FDA") approved Cologuard for use as the first and only sDNA non-invasive colorectal cancer screening test. Our submission to the FDA for Cologuard included the results of our pivotal DeeP-C clinical trial that had over 10,000 patients enrolled at 90 sites in the U.S. and Canada. The results of our DeeP-C clinical trial for Cologuard were published in the New England Journal of Medicine in April 2014. The peer-reviewed study, "Multi-target Stool DNA Testing for Colorectal-Cancer Screening," highlighted the performance of Cologuard in the trial population:

- Cancer Sensitivity: 92%
- Stage I and II Cancer Sensitivity: 94%
- High-Grade Dysplasia Sensitivity: 69%
- Specificity: 87%

The competitive advantages of sDNA screening may provide a significant market opportunity. If the test were used by 40-percent of the eligible screening population at a three-year screening interval, we estimate the potential U.S. market for sDNA screening would be more than $5.5 billion, annually.

Our commercialization strategy includes three main elements focusing on physicians, patients, and payers.

Our sales team actively engages with physicians and their staffs to emphasize the need for colorectal cancer screening, educate them on the value of Cologuard, and enroll them in our physician ordering system to enable them to prescribe the test. We focus on specific physicians based on Cologuard order history and on physician groups and larger regional and national health systems.

Securing inclusion in guidelines and quality measures is a key part of our physician engagement strategy since many physicians rely on such guidelines and quality measures when making screening recommendations. In June 2016, the US Preventive Services Task Force ("USPSTF") issued an updated recommendation statement for colorectal cancer screening and gave an "A" grade to colorectal cancer screening starting at age 50 and continuing until age 75. The statement specifies seven screening methods, including FIT-DNA (which is Cologuard).

Many professional colorectal cancer screening guidelines in the U.S., including those of the ACS and the National Comprehensive Cancer Network ("NCCN"), recommend regular screening using any of a variety of methods. Since 2008, joint colorectal cancer screening guidelines endorsed by the ACS have included sDNA screening technology as a screening option for the detection of colorectal cancer in average risk, asymptomatic individuals age 50 and older. In October 2014, the ACS updated its colorectal cancer screening guidelines to specifically include Cologuard as a recommended screening test. In June 2016, the NCCN updated its Colorectal Cancer Screening Guidelines to add sDNA screening, at a once-every-three-years interval, to its list of recommended screening tests.

In October 2016, the National Committee for Quality Assurance ("NCQA") included Cologuard testing on a three-year interval in the 2017 Healthcare Effectiveness Data and Information Set ("HEDIS") measures. More than 90 percent of America's health plans measure quality based on HEDIS. In April 2017, the Centers for Medicare & Medicaid Services ("CMS") included Cologuard in its updated 2018 Medicare Advantage Star Ratings program.

A critical part of the value proposition of Cologuard is our compliance program, which involves active engagement with patients and physicians. This customer-service-oriented activity is focused on helping patients to complete Cologuard tests that have been ordered for them by their physicians and supporting physicians in their efforts to have their patients screened.

After the launch of Cologuard, we initiated a significant public relations effort to engage patients in the United States. We have conducted targeted direct-to-patient advertising campaigns through social media, print and other channels. In 2016, we began a national television advertising campaign. To date, we have focused our efforts on cable television most commonly viewed by our target patient demographic. We continue our targeted direct-to-patient advertising initiatives. During the second and third quarters of 2017 we launched new content for our television advertising campaign, highlighting the ease of use of Cologuard, which includes 30-second television spots intended to make our television advertising more cost effective. During 2018 we plan to maintain our current television advertising efforts and increase our efforts with social and digital media and engage in some national partnerships that should increase awareness for Cologuard.

The cornerstone of our payer-engagement strategy was securing coverage from CMS. Medicare covers approximately 47% of patients in the screening population for Cologuard. On October 9, 2014, CMS issued a National Coverage Determination ("NCD") for Cologuard following a parallel review process with FDA. Cologuard was the first screening test approved by FDA and covered by CMS through that process. As outlined in the NCD, Medicare Part B covers Cologuard once every three years for beneficiaries who meet all of the following criteria:

- age 50 to 85 years,
- asymptomatic (no signs or symptoms of colorectal disease including, but not limited to, lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test or fecal immunochemical test), and
- at average risk for developing colorectal cancer (e.g., no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis or hereditary non-polyposis colorectal cancer).

In the 2017 Clinical Laboratory Fee Schedule, CMS established reimbursement for Cologuard at $512.43. Payments from CMS are currently subject to sequestration. Under the Protecting Access to Medicare Act of 2014 ("PAMA"), effective January 1, 2018, the CMS reimbursement rate for Cologuard was set at $508.87, which was the volume-weighted median of private payer rates for Cologuard for the period from January 1, 2016 to June 30, 2016. We expect the CMS reimbursement rate established for 2018 to remain in place for three years, after which it would be reset based on the volume-weighted median of private payer rates for Cologuard during the data collection period between January 1, 2019 and June 30, 2019.

In addition to Medicare reimbursement, we seek to secure favorable coverage and in-network reimbursement agreements from commercial payers. Some commercial payers have issued positive coverage decisions for Cologuard and others have agreed to cover Cologuard as an in-network service. In-network agreements with payers have varying terms and conditions, including reimbursement rate, term and termination. From time to time in the ordinary course of our business, we may enter into new agreements, certain existing agreements may expire without renewal and certain other existing agreements may be terminated by us or the third-party payer. We believe that commercial payers' reimbursement of Cologuard will depend on a number of factors, including payers' determination that it is: sensitive and specific for colorectal cancer; not experimental or investigational; approved or recommended by major organizations' guidelines; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost-effective. Also, some payers may apply various medical management requirements, including a requirement that they give prior authorization for a Cologuard test before they are willing to pay for it. Other payers may perform post-payment reviews or audits, which could lead to payment recoupments. Medical management, such as prior authorizations and post-payment review or audits, may require that we, patients, or physicians provide the payer with extensive medical records and other information.

Coverage of Cologuard may also depend, in whole or in part, on whether payers determine, or courts and/or regulatory authorities determine, coverage is required under applicable federal or state laws mandating coverage of certain colorectal cancer screening services. For example, Section 2713 of the Patient Protection and Affordable Care Act ("ACA") mandates that certain health insurers cover evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of USPSTF without imposing any patient cost-sharing ("ACA Mandate"). Similarly, federal regulations require that Medicare Advantage plans cover "A" or "B" rated preventive services without patient cost-sharing. Following the June 2016 update to the USPSTF colorectal cancer screening recommendation statement, CMS issued an updated Evidence of Coverage notice for Medicare Advantage plans that affirms such plans

must include coverage of Cologuard every three years without patient cost-sharing. While we believe the ACA Mandate will require certain health insurers to cover Cologuard without patient cost-sharing (following an initial phase-in period between one and two years from the date of the updated USPSTF recommendation statement depending on the date a given plan year commences), it is possible that certain health insurers will disagree. It is also possible that the ACA Mandate will be repealed or significantly modified in the future.

Similarly, we believe the laws of approximately 30 states currently mandate coverage of Cologuard by certain health insurance plans. While some insurers have agreed with our interpretation regarding certain state mandates, other insurers have disagreed. In some cases, we have filed lawsuits in an effort to enforce state laws we believe require coverage of Cologuard, and we may file additional suits in the future. We may or may not be successful in any such lawsuit.

We are pursuing a variety of strategies to increase commercial payer coverage for Cologuard, including providing cost effectiveness data to payers to make the case for Cologuard reimbursement. We are focusing our efforts on large national and regional insurers and health plans that have affiliated health systems.

We believe quality metrics may influence payers' coverage decisions, as well as physicians' cancer screening procedures. Some government and private payers are adopting pay-for-performance programs that differentiate payments for healthcare services based on the achievement of documented quality metrics, cost efficiencies or patient outcomes. Payers may look to quality measures such as the HEDIS and CMS Star Ratings measures to assess quality of care. We believe inclusion in the HEDIS measures and Star Ratings measures may have a positive impact on payers' willingness to reimburse Cologuard, as well as on physicians' willingness to prescribe the test.

As part of our commercialization strategy, we established a state-of-the-art, highly automated lab facility that is certified pursuant to federal Clinical Laboratory Improvement Amendments ("CLIA") requirements to process Cologuard tests and provide patient results. Our commercial lab operation is housed in a 50,000 square foot facility in Madison, Wisconsin. At our lab, we currently have the capacity to process approximately one million tests per year. We are expanding our current lab facility to increase our capacity to more than two and a half million tests per year by mid-2018.

During the fourth quarter of 2017 we began construction of a new clinical laboratory facility in Madison, WI that is expected to increase our annual capacity by approximately two million tests per year. The construction is expected to be completed by mid-2019 and at that time our total capacity at both facilities should be more than four and a half million tests per year.

We also are developing a pipeline of potential future products and services. We are continuing to collaborate with MAYO Foundation for Medical Education and Research ("MAYO"), our development partner for Cologuard, on developing new tests, with the goal of becoming a leader in the early detection of cancer. We believe our proprietary technology platform provides a strong foundation for the development of additional cancer diagnostic tests. Through our collaboration with MAYO, we have identified proprietary biomarkers for several major cancers, including liver cancer and lung cancer. We have successfully performed validation studies on tissue samples for seven major cancers and on blood samples for four major cancers.

The ACS estimates that lung cancer will be diagnosed in 223,000 Americans and cause 156,000 deaths in the United States in 2017. Currently, more than half of lung cancer cases are diagnosed at an advanced stage, after symptoms appear, when the five-year survival rate is in the low single digits. We are currently developing a blood-based biomarker test to aid in the early detection of lung cancer in individuals with lung nodules discovered through a computerized tomography ("CT") or other scan. Such a test may help reduce the number of unnecessary biopsies and other follow-up procedures, and thereby reduce costs and improve health outcomes. We recently completed a multi-round study of nearly 400 patients, which demonstrated high accuracy for detecting lung cancer at all stages.

We also continue to explore opportunities for improving Cologuard, including improvements that could lower our cost of sales.

Risk Factors

Risks Related to Our Business

We may never become profitable.

We have incurred losses since we were formed and only began generating revenue from Cologuard, our only product, in 2014. From our date of inception on February 10, 1995 through September 30, 2017, we have accumulated a total deficit of approximately $838.9 million. We expect to continue investing significantly toward development and commercialization of our colorectal cancer screening technology and other products and services. If our revenue does not grow significantly, we will not be profitable. We cannot be certain that the revenue from the sale of any products or services based on our technologies will be sufficient to make us profitable.

We may need additional capital to execute our business plan.

Although we believe that we have sufficient capital to fund our operations for at least the next twelve months, we may require additional capital to fully fund our current strategic plan, which includes successfully commercializing Cologuard and developing a pipeline of future products and services. Additional financing may not be available in amounts or on terms satisfactory to us or at all. Our success in raising additional capital may be significantly affected by general market conditions, the market price of our common stock, our financial condition, uncertainty about the future commercial success of Cologuard, the development and commercial success of future products or services, regulatory developments, the status and scope of our intellectual property, any ongoing litigation, our compliance with applicable laws and regulations and other factors. If we raise additional funds through the sale of equity, convertible debt or other equity-linked securities, our stockholders' ownership will be diluted. We may issue securities that have rights, preferences and privileges senior to our common stock. If we raise additional funds through collaborations, licensing arrangements or other structured financing transactions, we may relinquish rights to certain of our technologies or products or services, grant security interests in our assets or grant licenses to third parties on terms that are unfavorable to us.

Our success depends heavily on our Cologuard colorectal cancer screening test.

For the foreseeable future, our ability to generate revenues will depend almost entirely on the commercial success of our Cologuard test. The commercial success of our Cologuard test and our ability to generate revenues will depend on a variety of factors, including the following:

- acceptance in the medical community;
- inclusion of Cologuard in healthcare guidelines and recommendations, such as those developed by ACS and USPSTF;
- inclusion of Cologuard in quality measures including the HEDIS measures and the CMS Medicare Advantage Star Ratings;
- recommendations and studies regarding Cologuard specifically or colorectal cancer screening generally that may be published by government agencies, professional organizations, academic or medical journals or other key opinion leaders;
- patient acceptance of and demand for the Cologuard test;
- patient compliance with orders for the Cologuard test by healthcare providers, and patient adherence over time to recommendations regarding periodic re-screening;
- successful sales, marketing, and educational programs, including successful direct-to-patient marketing such as television advertising and social media;
- the number of patients screened for colorectal cancer, as well as the number of patients who use Cologuard for that purpose;
- sufficient coverage and reimbursement by third-party payers, which may depend in whole or in part on multiple factors, including federal or state laws that mandate coverage for colorectal cancer screening, the extent to which those laws mandate coverage of Cologuard and the enforcement of those laws;
- the amount and nature of competition from other colorectal cancer or pre-cancer screening products and procedures;
- maintaining FDA marketing approval of Cologuard;
- the ease of use of our ordering process for physicians;
- maintaining and defending patent protection for the intellectual property relevant to Cologuard; and
- our ability to establish and maintain adequate commercial manufacturing, distribution, sales and CLIA laboratory testing capabilities.

If we are unable to develop and maintain substantial sales of our Cologuard test or if we are significantly delayed or limited in doing so, our business prospects, financial condition and results of operation would be adversely affected.

Our quarterly operating results could be subject to significant fluctuation, which could increase the volatility of our stock price and cause losses to our stockholders.

Our revenues and results of operations may fluctuate significantly, depending on a variety of factors, including the following:

- our success in marketing and selling, and changes in demand for, our Cologuard test, and the level of reimbursement and collection obtained for Cologuard;
- seasonal variations affecting physician recommendations for colorectal cancer screenings and patient compliance with physician recommendations, including without limitation holidays and weather events;
- our success in collecting payments from third-party payers, patients and collaborative partners, variation in the timing of these payments and recognition of these payments as revenues;
- the pricing of our Cologuard test, including potential changes in CMS or other reimbursement rates;
- fluctuations in the amount and timing of our selling and marketing costs and our ability to manage costs and expenses and effectively implement our business; and
- our research and development activities, including the timing of costly clinical trials.

Other companies or institutions may develop and market novel or improved methods for detecting colorectal cancer or pre-cancer, which may make our technologies less competitive or obsolete.

The market for colorectal cancer and pre-cancer screening is large, consisting of more than 80 million Americans age 50 and above for whom routine colorectal cancer screening is recommended. As a result, this market has attracted competitors, some of which possess significantly greater financial and other resources and development capabilities than we do. Some companies and institutions are developing serum-based tests and screening tests based on the detection of proteins, nucleic acids or the presence of fragments of mutated genes in the blood that are produced by colorectal cancer or pre-cancer. We are aware of at least six companies — Epigenomics AG, Applied Proteomics, Inc., Gene News, EDP Biotech Corporation, GRAIL, Inc., and Volition Diagnostics — that have developed, or are developing, blood-based tests for the detection of colorectal cancer. Epigenomics AG received FDA approval for its blood-based screening test for colorectal cancer, Epi proColon, in April 2016, and began offering the test commercially in May 2016. We believe other companies are also working on so-called "liquid biopsy" tests using next-generation sequencing or other technology, and these tests could represent significant competition for Cologuard and other tests we may develop. Our Cologuard test also faces competition from procedure-based detection technologies such as flexible sigmoidoscopy, colonoscopy and "virtual" colonoscopy (a radiological imaging approach that visualizes the inside of the bowel by use of spiral computerized axial tomography known as a CT scan) as well as traditional screening tests such as FOBT and FIT and newer screening technologies such as the PillCam COLON cleared by FDA in February 2014. Our competitors may also be working on additional methods of detecting colorectal cancer and pre-cancer that have not yet been announced.

Beyond our Cologuard test, as we seek to develop other tools to detect cancer and pre-cancer, we expect to compete with a broad range of organizations in the U.S. and other countries that are engaged in the development, production and commercialization of cancer diagnostic tools. These competitors include:

- biotechnology, diagnostic and other life science companies;
- academic and scientific institutions;
- governmental agencies; and
- public and private research organizations.

We may be unable to compete effectively against our competitors either because their products and services are superior or because they may have more expertise, experience, financial resources or stronger business relationships. Our competitors may have broader product lines and greater name recognition than we do. We have limited experience developing tests for the detection of non-colorectal cancers and we cannot guarantee that our research and development activities will be successful in developing any marketable testing products or services. Further, even if we do develop new marketable products or services, our current and future competitors may develop products and services that are

more commercially attractive than ours and they may bring those products and services to market, sooner than we are able to.

We face uncertainty related to healthcare reform, pricing, coverage and reimbursement, which could reduce our revenue.

Healthcare reform laws, including the Patient Protection and Affordable Care Act (the "ACA") and the Protecting Access to Medicare Act of 2014 ("PAMA"), are significantly affecting the U.S. healthcare and medical services industry. Existing legislation, and possible future legal and regulatory changes, including potential repeal of the ACA, elimination of penalties regarding the individual mandate for coverage, or approval of health plans that allow lower levels of coverage for preventive services, could substantially change the structure and finances of the health insurance system and the methodology for reimbursing medical services, drugs and devices, including our current and future products and services. Any change in reimbursement policy could result in a change in patient cost-sharing, which could adversely affect patient willingness and ability to use our Cologuard test and any other product or service we may develop. Healthcare reforms, which may intend to reduce healthcare costs, may have the effect of discouraging third-party payers from covering certain kinds of medical products and services, particularly newly developed technologies, such as our Cologuard test or other products or tests we may develop in the future.

The ACA requires that non-grandfathered health plans cover, without patient cost-sharing, preventive services that have in effect a grade of "A" or "B" in the current recommendations of USPSTF (the "ACA Mandate"). The requirement to cover, without cost-sharing, a newly recommended preventive service applies to each non-grandfathered health plan starting with the first plan year that begins at least one year after the date of the recommendation. In June 2016, USPSTF issued an updated colorectal screening recommendation, assigning an A grade to "screening for colorectal cancer starting at age 50 years and continuing until age 75 years." We believe the "A" grade should be interpreted to apply to the seven types of colorectal cancer tests specifically identified by USPSTF in its recommendation — including Cologuard, which was included for the first time in that recommendation — for adults ages 50 to 75 and that Cologuard should therefore be included within the ACA Mandate for colorectal cancer screening tests. However, health plans may assert that they are not required to cover Cologuard under the ACA Mandate. Enforcement of the ACA Mandate may depend, in whole or in part, on state, federal or other third party enforcement actions that we would not control. Further, a court or regulatory agency may agree with arguments that may be made by insurers and determine that the ACA Mandate does not require that they cover Cologuard or may otherwise interpret the ACA Mandate in a manner unfavorable to us. Also, Congress may modify or repeal all or part of the ACA, and any such modification or repeal may repeal or limit the ACA Mandate for preventive services. If the ACA Mandate for preventive services is repealed or modified, if the ACA Mandate is determined not to require coverage of Cologuard, if the ACA Mandate is otherwise interpreted in a manner unfavorable to us, or if we are unable to secure effective enforcement of the ACA Mandate, even if it is held to require coverage of Cologuard, our business prospects, financial condition and results of operation may be adversely affected.

Several states have laws mandating coverage for preventive services, such as colorectal cancer screening services, applicable to certain health insurers. Not all of these laws apply to Cologuard, however. Further, if the ACA is repealed or replaced, or even if it is not, states may decide to modify their laws, which may include repeal of those coverage mandates that we believe currently apply to Cologuard.

Under PAMA, effective January 1, 2018, the CMS reimbursement rate for Cologuard was set at $508.87, which was the volume-weighted median of private payer rates for Cologuard from January 1, 2016 through June 30, 2016. The CMS reimbursement rate will subsequently be reset every three years, based on the volume-weighted median of private payer rates experienced in the applicable six-month data collection period. If the CMS reimbursement rate for Cologuard is reduced pursuant to PAMA or otherwise, our revenues would likely be adversely affected. PAMA presents significant uncertainty for future CMS reimbursement rates for Cologuard. Because Medicare currently covers 47% of patients in the screening population for Cologuard, any reduction in the CMS reimbursement rates for Cologuard would negatively affect our revenues and our business prospects.

If third-party payers, including managed care organizations, do not approve and maintain reimbursement for our Cologuard test at adequate reimbursement rates, we may be unable to successfully commercialize our Cologuard test which, we expect, would limit or slow our revenue generation and likely have a material adverse effect on our business.

Successful commercialization of our Cologuard test depends, in large part, on the availability of adequate reimbursement from government insurance plans, managed care organizations and private insurance plans. Although we received a positive coverage decision and what we believe is an adequate reimbursement rate from CMS for our Cologuard test, it is also critical that other third-party payers approve and maintain reimbursement for our Cologuard test at adequate reimbursement rates. Third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new healthcare products. As a result, there is significant uncertainty surrounding whether the use of tests that incorporate new technology, such as our Cologuard test, will be eligible for coverage by third-party payers or, if eligible for coverage, what the reimbursement rates will be. Reimbursement of sDNA colorectal cancer screening by a third-party payer may depend on a number of factors, including a payer's determination that tests using our technologies are: sensitive and specific for colorectal cancer and pre-cancer; not experimental or investigational; approved or recommended by the major guidelines organizations; subject to applicable federal or state coverage mandates; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost-effective.

If we are unable to obtain positive decisions from third-party payers, including managed care organizations, approving reimbursement for our Cologuard test at adequate levels, its commercial success will be compromised and our revenues would be significantly limited. We may also experience material delays in obtaining such reimbursement decisions and payment for our Cologuard test that are beyond our control. Further, there can be no assurance that CMS and commercial payers who initially decide to cover Cologuard will continue to do so. We are pursuing a variety of strategies to increase commercial payer coverage and reimbursement of Cologuard. In certain situations, where we believe payers are obligated to cover Cologuard under federal and state laws that mandate coverage for certain colorectal cancer screening tests, we have sued to enforce coverage obligations. We may pursue similar litigation in the future. Such litigation may be costly, may divert management attention from other responsibilities, may cause payers, including those not directly involved in the litigation, to resist contracting with us, and may ultimately prove unsuccessful.

As noted above, federal and state coverage mandates may be deemed not to apply to Cologuard, may be interpreted in a manner unfavorable to us, may be difficult to enforce and are subject to repeal or modification. For example, the ACA may be repealed or materially modified, in whole or in part, or replaced with an alternative legal framework governing healthcare matters. Such repeal modification or replacement may eliminate or modify the coverage mandate for preventive services, and any such elimination or modification may have an adverse effect on our business prospects.

Moreover, coverage determinations and reimbursement rates are subject to change, and we cannot guarantee that even if we initially achieve adequate coverage and reimbursement rates, they will be applicable to our Cologuard test in the future. As noted above, under PAMA, our Medicare reimbursement rate will be subject to adjustment based on our volume-weighted median commercial reimbursement rate. A reduction in our Medicare reimbursement rate could significantly and adversely affect our business products, financial condition and results of operation.

Even where a third-party payer agrees to cover Cologuard, other factors may have a significant impact on the actual reimbursement we receive for a Cologuard test from that payer. For example, if we do not have a contract with a given payer, we may be deemed an "out-of-network" provider by that payer, which could result in a greater portion of the cost of the Cologuard test being borne by the patient. We may be unsuccessful in our efforts to enter into, or maintain, a network contract with a given payer, and we expect that our network status with a given payer may change from time to time for a variety of reasons, many of which may be outside our control. To the extent Cologuard is out of network for a given payer, physicians may be less likely to prescribe Cologuard for their patients and their patients may be less likely to comply with any such orders. Also, some payers may require that they give prior authorization for a Cologuard test before they are willing to pay for it or review claims post-service to ensure the service was medically appropriate for specific patients. Prior authorization and other medical management requirements may require that we, patients or physicians provide the payer with extensive medical records and other information. Prior authorization and other medical management requirements impose a significant additional cost on us, may be difficult to comply with given our position as a laboratory, may make physicians less likely to prescribe Cologuard for their patients, and may make patients less likely to comply with physician orders for Cologuard, all or any of which may have an adverse effect on our revenues.

If our clinical studies do not satisfy providers, payers, patients and others as to the reliability, effectiveness and superiority of our Cologuard test or any future test we may develop and seek to commercialize , we may experience reluctance or refusal on the part of physicians to order, and third-party payers to pay for, such test.

Although we have received FDA approval for our Cologuard test, if the results of our research and clinical studies and our sales and marketing activities relating to communication of these results, do not convince guidelines organizations, physicians and other healthcare providers, third-party payers and patients that our Cologuard test is reliable, effective and superior to alternative screening methods, we may experience reluctance or refusal on the part of physicians to order, and third-party payers to pay for, our Cologuard test, which could adversely affect our business prospects. Likewise, if the results of our research and clinical studies and our sales and marketing activities relating to communication of these results, do not convince guidelines organizations, physicians and other healthcare providers, third-party payers and patients that other tests we may develop and seek to commercialize in the future are reliable, effective and superior to alternative tests, we may experience reluctance or refusal on the part of physicians to order, and third-party payers to pay for, those tests, which could adversely affect our business prospects.

We have finite selling and marketing resources and only limited sales, marketing, customer support, manufacturing, distribution and commercial laboratory experience, which may restrict our success in commercializing Cologuard and other products we may develop and we may be unsuccessful in entering into or maintaining third-party arrangements to support our internal efforts .

To grow our business as planned, we must expand our sales, marketing and customer support capabilities, which will involve developing and administering our commercial infrastructure and/or collaborative commercial arrangements and partnerships. We must also maintain satisfactory arrangements for the manufacture and distribution of our Cologuard test. Also, in connection with the launch of Cologuard in late 2014, we began operating a CLIA certified lab facility to process Cologuard tests and provide patient results. We have limited experience managing a sales force, customer support operation and operating a manufacturing operation and clinical lab facility and we may encounter difficulties retaining and managing the specialized workforce these activities require. We may seek to partner with others to assist us with any or all of these functions. However, we may be unable to find appropriate third parties with whom to enter into these arrangements. Furthermore, if we do enter into these arrangements, these third parties may not perform as expected or the arrangements may otherwise prove to be detrimental to our short- and long-term results. For example, certain third-party arrangements may cause us to forego or defer the development or acquisition of internal capabilities. If a third-party arrangement fails to perform as expected or if it is terminated prematurely for any reason, our business may be harmed not only by such failure or termination itself, but also by the opportunity cost associated with our not timely developing or acquiring necessary or useful capabilities internally.

If we are unable to deploy and maintain effective sales and marketing capabilities, we will have difficulty achieving market awareness and selling our products and services.

To achieve commercial success for our Cologuard test and our future products and services, we must continue to develop and grow our sales and marketing organization and our sales and marketing organization must effectively explain to healthcare providers the reliability, effectiveness and benefits of Cologuard and our future products and services as compared to alternatives. We may not be able to successfully manage our dispersed or inside sales forces or our sales force may not be effective. Because of the competition for their services, we may be unable to partner with or retain additional qualified sales representatives, either as our employees or independent contractors or through independent sales organizations. We may not be able to enter into agreements with sales representatives on commercially reasonable terms, if at all. Further, market competition for commercial and marketing talent is significant, and we may not be able to hire or retain such talent on commercially reasonable terms, if at all.

Establishing and maintaining sales and marketing capabilities will be expensive and time-consuming. Our expenses associated with maintaining our sales force may be disproportional compared to the revenues we may be able to generate on sales of the Cologuard test or any future products or services.

The success of our Cologuard test depends on the degree of market acceptance by physicians, patients, healthcare payers and others in the medical community.

Our Cologuard test may not gain market acceptance by physicians, healthcare payers and others in the medical community. The degree of market acceptance of our Cologuard test will depend on a number of factors, including:

- its demonstrated sensitivity and specificity for detecting colorectal cancer and pre-cancer;
- its price;
- the availability and attractiveness of alternative screening methods;
- the willingness of physicians to prescribe Cologuard;
- the ease of use of our ordering process for physicians; and
- adequate third-party coverage or reimbursement.

Despite the availability of current colorectal cancer screening methods as well as the recommendations of the ACS and others that all average-risk Americans be screened for colorectal cancer beginning at age 50, 38 percent of these individuals are not screened according to current guidelines. Use of a stool-based DNA colorectal cancer screening test requires people to collect a stool sample, which some people may be reluctant to do. If our Cologuard test does not achieve an adequate level of acceptance, we may not generate the substantial revenues we need to generate to become profitable.

Our assumptions regarding the market opportunity for Cologuard may not prove true. We estimate the potential market opportunity for Cologuard assuming, among other things, the size of the screening population, a 40-percent test adoption rate in the screening population and a three-year screening interval. Although ACS guidelines and others recommend a three-year screening interval for Cologuard and CMS has determined that Medicare will cover the test at this interval, physicians, healthcare payers, the FDA and other regulators and opinion leaders could recommend a different testing schedule. Further, patients may not adhere to the recommended testing interval.

Recommendations, guidelines and quality metrics issued by various organizations, including the U.S. Preventative Services Task Force, the American Cancer Society and the National Committee for Quality Assurance, may significantly affect payers' willingness to cover, and physicians' willingness to prescribe, our products.

Securing influential recommendations, inclusion in healthcare guidelines and inclusion in quality measures are keys to our physician and payer engagement strategies. These guidelines, recommendations and quality metrics may shape payers' coverage decisions and physicians' cancer screening procedures.

The U.S. Preventive Services Task Force ("USPSTF"), a panel of primary care physicians and epidemiologists and other national experts funded by the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality, makes influential recommendations on clinical preventative services. In June 2016, the USPSTF issued an updated recommendation statement for colorectal cancer screening, and gave an "A" grade to colorectal cancer screening starting at age 50 and continuing until age 75. The statement specifies seven screening methods, including FIT-DNA (which is Cologuard). The updated USPSTF recommendation statement may have certain potentially significant implications. For example, the ACA mandates that certain non-grandfathered health insurers cover evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of USPSTF without imposing any patient cost-sharing. Similarly, federal regulations require that Medicare Advantage plans cover "A" or "B" graded preventive services without patient cost-sharing. Following the updated USPSTF recommendation statement, the Centers for Medicare & Medicaid Services ("CMS") issued an updated Evidence of Coverage notice for Medicare Advantage plans that affirms such plans must include coverage of Cologuard every three years without patient cost-sharing. While we believe the ACA Mandate will require certain health insurers to cover Cologuard without patient cost-sharing (following an initial phase in period between one and two years), it is possible that certain health insurers will disagree, in which case courts and/or government agencies may need to resolve the issue. Enforcement of the ACA Mandate may be difficult and may depend, in whole or in part, on state, federal or other third party enforcement actions that we would not control. Further, a court or regulatory agency may agree with arguments that may be made by insurers and determine that the ACA Mandate does not require that they cover Cologuard or may otherwise interpret the ACA Mandate in a manner unfavorable to us. Also, Congress may modify or repeal all or part of the ACA, and any such modification or repeal may repeal or limit the ACA Mandate for preventive services. If the ACA Mandate for preventive services is repealed or modified, if the ACA Mandate is determined not to require coverage of Cologuard, if the ACA Mandate is otherwise interpreted in a manner unfavorable to us, or if we are unable to secure effective

enforcement of the ACA Mandate, even if it is held to require coverage of Cologuard, our business prospects may be adversely affected.

In addition, the healthcare industry in the United States has experienced a trend toward cost containment and value-based purchasing of healthcare services. Some government and private payers are adopting pay-for-performance programs that differentiate payments for healthcare services based on the achievement of documented quality metrics, cost efficiencies or patient outcomes. Payers may look to quality measures such as the National Committee for Quality Assurance ("NCQA"), Healthcare Effectiveness Data and Information Set ("HEDIS") and the CMS Medicare Advantage Star Ratings to assess quality of care. These measures are intended to provide incentives to service providers to deliver the same or better results while consuming fewer resources. In October 2016, the NCQA included Cologuard testing on a three-year interval in the final published 2017 HEDIS measures. In April 2017, CMS released final details for the 2018 Medicare Advantage Star Ratings program and included Cologuard. If for some reason Cologuard was removed from, or not included in, HEDIS, the Star Ratings or other quality metrics, payers may be less inclined to reimburse our Cologuard test at adequate levels, if at all, which could adversely impact our business. Additionally, if Cologuard was removed from, or not included in, HEDIS, the Star Ratings or other quality metrics, physicians may not earn quality credit for prescribing Cologuard and therefore may be less inclined to do so.

We expect to make significant investments to research and develop new cancer diagnostic tools, which may not be successful.

In addition to commercializing our Cologuard test, we are seeking to develop a pipeline for future products and services, including screening and diagnostic tests for lung, liver and other types of cancers. We expect to incur significant expenses on these development efforts but they may not be successful.

Developing new cancer diagnostic tools is a speculative and risky endeavor. Candidate products and services that may initially show promise may fail to achieve the desired results in larger clinical studies or may not achieve acceptable levels of clinical accuracy. We may need to explore a number of different marker combinations, alter our candidate products or platform technologies and repeat clinical studies before we identify a potentially successful candidate. We may need to acquire, whether through purchase, license or otherwise, technologies owned by third parties, and we may not be able to acquire such technologies on commercially reasonable terms, or at all. Product development is expensive, may take years to complete and can have uncertain outcomes. Failure can occur at any stage of the development. If, after development, a candidate product or service appears successful, we may, depending on the nature of the product or service, still need to obtain FDA and other regulatory clearances or approvals before we can market it. The FDA's clearance or approval pathways are likely to involve significant time, as well as additional research, development and clinical study expenditures. There can be no guarantee that the FDA would clear or approve any future product we may develop. Even if the FDA clears or approves a new product we develop, we would need to commit substantial resources to commercialize, sell and market the product before it could be profitable, and the product may never be commercially viable. Additionally, development of any product may be disrupted or made less viable by the development of competing products.

If we determine that any of our current or future development programs is unlikely to succeed, we may abandon it without any return on our investment into the program. Given our current levels of cash and resources, and our planned expenditures to support Cologuard commercialization, we expect that we may need to raise significant additional capital to bring any new products to market, which may not be available on acceptable terms, if at all.

We may not be able to successfully establish and maintain strategic collaborative and licensing arrangements with third parties, which could adversely affect our ability to commercialize our Cologuard test and to develop and commercialize other products and services.

The commercialization of our Cologuard test and the development and commercialization of other products and services rely, directly or indirectly, upon strategic collaborations and licensing agreements with third parties. We currently have a collaborative and licensing arrangement with MAYO Foundation for Medical Education and Research. In addition, we have licensing agreements with Hologic and MDx Health. Such arrangements provide us with intellectual property crucial to our product development and commercialization, including technology that we have incorporated into our Cologuard test. Our dependence on licensing, collaboration and other similar agreements with third parties may subject us to a number of risks. There can be no assurance that any current contractual arrangements between us and third parties or between our strategic partners and other third parties will be continued on materially

similar terms and will not be breached or terminated early. Any failure to obtain or retain the rights to necessary technologies on acceptable commercial terms could require us to re-configure our products and services, which could negatively impact their commercial sale or increase the associated costs, either of which could materially harm our business and adversely affect our future revenues.

As we commercialize and market our Cologuard test and seek to develop new products and services, we expect to continue and expand our reliance on collaborative and licensing arrangements. Establishing new strategic collaborations and licensing arrangements is difficult and time-consuming. Discussions with potential collaborators or licensors may not lead to the establishment of collaborations on favorable terms, if at all. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be limited. Potential collaborators or licensors may reject collaborations with us based upon their assessment of our financial, regulatory or intellectual property position. Even if we successfully establish new collaborations, these relationships may never result in the successful commercialization of any product or service.

If we fail to meet any applicable requirements of CLIA or similar state laws, that failure could adversely affect any future payer consideration of our technologies, prevent their approval entirely, and/or interrupt the commercial sale and/or marketing of any products and services and otherwise cause us to incur significant expense.

We are subject to federal and state laws and regulations regarding the operation of clinical laboratories. Federal Clinical Laboratory Improvement Amendments ("CLIA") requirements and laws of certain states impose certification requirements for clinical laboratories, establish standards for quality assurance and quality control, among other things. Some state laws restrict laboratory marketing activities, which may adversely affect our ability to market our laboratory services. Clinical laboratories are subject to inspection by regulators, and to sanctions for failing to comply with applicable requirements. Sanctions available under CLIA include prohibiting a laboratory from running tests, requiring a laboratory to implement a corrective plan, and imposing civil monetary penalties. If we fail to meet any applicable requirements of CLIA or state law, that failure could adversely affect any future payer consideration of our technologies, prevent their approval entirely, and/or interrupt the commercial sale and/or marketing of any products and services and otherwise cause us to incur significant expense.

We must maintain FDA approval for Cologuard and of our Madison, Wisconsin facilities; failure to maintain compliance with FDA requirements may prevent or delay the marketing or manufacture of our Cologuard test.

As a condition of the FDA approval of our Cologuard test, we are required to conduct a post-approval study. We anticipate that the post-approval study will require significant funding and resources to reach its conclusion. There is a risk that the FDA may modify or withdraw the approval of Cologuard if the results of this post-approval study are not satisfactory or are inconsistent with previous studies. We rely on third parties, such as contract research organizations, medical institutions and clinical investigators to conduct the post-approval study. We have limited control over the activities of these third parties and the post-approval study may be delayed or halted prior to its completion for reasons outside our control.

Additionally, our Madison, Wisconsin facilities are periodically subject to inspection by the FDA and other governmental agencies to ensure they meet production and quality standards. Operations at these facilities could be interrupted or halted if the FDA or other governmental agency deems the findings of such inspections unsatisfactory. Failure to comply with FDA or other regulatory requirements could result in fines, unanticipated compliance expenditures, recall or seizures of our products, total or partial suspension of production or distribution, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution. In addition, circumstance may arise that cause us to recall products or equipment used in connection with our Cologuard test, and such recalls could have an adverse effect on our ability to provide the Cologuard test, which in turn would adversely affect our financial condition.

Our inability to obtain without delay any necessary regulatory clearances or approvals for new diagnostic products or services, or improvements to our current offerings, could materially encumber future product commercialization.

We may develop new diagnostic test candidates that are regulated by the FDA as medical devices. Unless otherwise exempted, medical devices must receive from the FDA either "510(k) clearance" or premarket approval ("PMA") before marketing them in the United States. The FDA determines whether a medical device will require either 510(k) clearance or the PMA process based on statutory criteria that include the risk associated with the device and

whether the device is similar to an existing, legally marketed product. The process to obtain either 510(k) clearance or PMA will likely be costly, time-consuming and uncertain. However, we believe the PMA process is generally more challenging. Even if we design a product that we expect to be eligible for the 510(k) clearance process, the FDA may require that the product undergo the PMA process. There can be no assurance that the FDA will ever permit us to market any new product or service that we develop. Even if regulatory approval is granted, such approval may include significant limitations on indicated uses, which could materially and adversely affect the prospects of any new product or service.

FDA regulatory approval or clearance is not just required for new products and services we develop, but would also be required for certain enhancements we may seek to make to our Cologuard test.

Delays in receipt of, or failure to obtain, clearances or approvals could materially delay or prevent us from commercializing our products and services or result in substantial additional costs that could decrease our profitability. In addition, even if we receive FDA clearance or approval for a new or enhanced product or service, the FDA may condition, withdraw or materially modify its clearance or approval.

In the future, we may develop tests that could be regulated as laboratory developed tests ("LDTs"). If the FDA proceeds with its plans to actively regulate LDTs or continues to regulate LDTs with enforcement discretion, we may need to obtain additional FDA or other regulatory approvals, which may delay, encumber or block us from commercializing these diagnostic tests.

We may develop products or services that would be regulated as LDTs under CLIA. LDTs are clinical laboratory tests that are developed, validated and manufactured by a laboratory for its own use. Historically, LDTs have been regulated under CLIA while the FDA has exercised enforcement discretion and not required approvals or clearances for most LDTs performed by CLIA-certified laboratories. The FDA has historically chosen not to exercise its authority to regulate LDTs because LDTs were limited in number, were relatively simple tests, and typically were used to diagnose rare disease and uncommon conditions.

In October 2014, the FDA published two draft guidance documents describing a proposed risk-based framework under which it might regulate LDTs. The FDA's draft framework proposed, among other things, premarket review for higher-risk LDTs, such as those that have the same intended use as FDA-approved or cleared diagnostics currently on the market. In November 2015, the FDA issued a report citing evidence for the need for additional regulation of LDTs and stated the FDA is continuing to work to finalize premarket review requirements for LDTs. In January 2017, FDA confirmed it would not finalize guidance on the regulation of LDTs to allow more time for public discussion and time for the congressional authorizing committees to develop a legislative solution. We cannot predict the timing, content or form of any legislation, regulation or guidance, or the potential effect on our existing molecular diagnostic tests or our tests in development, or the potential impact of such guidance or regulation on our business, financial condition or results of operation.

The FDA's guidance documents, if and when finalized, or if FDA exercises enforcement discretion may materially impact our development of LDTs and may require us to change our business model in order to maintain compliance with these regulations. New laws and regulations may significantly slow the time it takes us to bring LDTs to market, may materially increase the costs of developing, and decrease the profitability of providing, LDTs, and may prevent us from commercializing certain products or services. We cannot provide any assurance that FDA regulation will not be required in the future for any of our tests, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation adopted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer molecular diagnostic tests or to develop and introduce new tests. Moreover, if pre-market review is required by the FDA or if we decide to voluntarily pursue the FDA's pre-market review for any of our tests, there can be no assurance that our diagnostic tests will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our tests. If pre-market review is required, our business could be negatively impacted as a result of commercial delay that may be caused by any new requirements.

We currently manufacture our Cologuard test predominantly in one facility and perform our Cologuard test in one laboratory facility. As demand for our Cologuard test grows, we may lack adequate facility space and capabilities to meet increased processing requirements. Moreover, if these or any future facilities or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.

We currently perform our Cologuard test in a single laboratory facility in Madison, Wisconsin. Our headquarters and manufacturing facilities are also located in Madison, Wisconsin.

As we expand the commercialization of Cologuard and increase the number of tests processed by our laboratory facility, we believe it will be necessary to both expand our existing laboratory facility and to add a new laboratory facility in order to increase our processing capacity to meet anticipated demand. We are currently in the process of seeking to expand the capacity at our existing laboratory facility to more than two and a half million tests per year. We expect to complete that expansion by mid-2018. Also, during the fourth quarter of 2017, we purchased real property in Madison, Wisconsin and began construction of a new clinical laboratory facility on it. The new laboratory facility is expected to increase our annual capacity by approximately two million tests per year. Construction of the new facility is expected to be completed by mid-2019. Failure to complete, or timely complete, these expansion projects, may significantly delay our processing times and capabilities, which may adversely affect our business, financial condition and results of operation. In addition, our financial condition may be adversely affected if we are unable to complete these expansion projects on budget and otherwise on terms and conditions acceptable to us. Finally, our financial condition will be adversely affected if demand for our laboratory services does not materialize in line with our current expectations and if, as a result, we end up building excess capacity that does not yield a reasonable return on our investment.

If our present, or any future facilities, were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, storms, tornadoes, other inclement weather events or natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, our business could be severely disrupted. If our present and/or future Madison, Wisconsin, laboratory is disrupted, we may not be able to perform our Cologuard test or generate test reports as promptly as patients and healthcare providers require or expect, or possibly not at all. If we are unable to perform our Cologuard test or generate test reports within a timeframe that meets patient and healthcare provider expectations, our business, financial results and reputation could be materially harmed.

We currently maintain insurance against damage to our property and equipment and against business interruption, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

We rely upon certain single-source suppliers and loss or interruption of supply from single-source suppliers could have a disruptive effect on our business.

We purchase certain supplies from third-party suppliers and manufacturers. In some cases, due to the unique attributes of products that are incorporated into our Cologuard test, we maintain a single-source supplier relationship. These third parties are independent entities subject to their own unique operational and financial risks that are outside our control. These third parties may not perform their obligations in a timely and cost-effective manner and they may be unwilling to increase production capacity commensurate with demand for our Cologuard test or future products or services. Moreover, we may become dependent on other single-source suppliers as we expand and develop our product pipeline. The loss of a single-source supplier, the failure to perform by a single-source supplier, the deterioration of our relationship with a single-source supplier or any unilateral modification to the contractual terms under which we are supplied materials by a single-source supplier could have a disruptive effect on our business, and could adversely affect our results of operations.

Failure in our information technology, storage systems or our clinical laboratory equipment could significantly disrupt our operations and our research and development efforts, which could adversely impact our revenues, as well as our research, development and commercialization efforts.

Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our information technology, or IT, systems, which support our operations, including at our clinical laboratory, and our

research and development efforts. We are substantially dependent on our IT systems to receive and process Cologuard test orders, securely store patient health records and deliver the results of our Cologuard tests. The integrity and protection of our own data, and that of our customers and employees, is critical to our business. The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve. IT 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 IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data, and in particular to operate our clinical laboratory, could adversely affect our ability to operate our business. Any interruption in the operation of IT systems could have an adverse effect on our operations. Furthermore, any breach in our IT systems could lead to the unauthorized access, disclosure and use of non-public information, including protected health information, which is protected by HIPAA and other laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and damage to our reputation.

We rely on courier delivery services to transport Cologuard collection kits to patients and samples back to laboratory facilities for analysis. If these delivery services are disrupted or become prohibitively expensive, customer satisfaction and our business could be negatively impacted.

In most cases, we ship Cologuard collection kits to patients, and patients ship samples to our Madison, Wisconsin, laboratory facility for analysis, by air and ground express courier delivery service. Disruptions in delivery service, whether due to bad weather, natural disaster, terrorist acts or threats, or for other reasons, can adversely affect customer satisfaction, specimen quality and our ability to provide our services on a timely basis. If the courier delivery services that transport Cologuard collection kits institute significant price increases, our profitability would be negatively affected and we may need to identify alternative delivery methods, if possible, modify our service model, or attempt to raise our pricing, which may not be possible with regard to Medicare claims or commercially practicable with regard to commercial claims.

Due to billing complexities in the diagnostic and laboratory service industry, we may not be able to collect payment for the Cologuard tests we perform.

Billing for diagnostic and laboratory services is a complex process. Laboratories bill many different payers including patients, private insurance companies, Medicare, Medicaid, and employer groups, all of which have different billing requirements. We are continuing to work with third-party payers to cover and reimburse Cologuard tests. If we are unsuccessful, we may not receive payment for Cologuard tests we perform for patients on a timely basis, if at all, and we may not be able to provide services for patients with certain healthcare plans. We may have to litigate to enforce coverage obligations under Medicare laws and laws that mandate coverage for certain colorectal cancer screening tests or to enforce contractual coverage obligations. Such litigation may be costly, may divert management attention from other responsibilities, may cause payers, including those not directly involved in the litigation, to resist contracting with us, and may ultimately prove unsuccessful. We may face write-offs of doubtful accounts, disputes with payers and patients, and long collection cycles. We may face patient dissatisfaction, complaints or lawsuits to the extent Cologuard tests are not fully covered by insurers and patients become responsible for all or part of the price of the test. As a result, patient demand for Cologuard could be adversely affected. To the extent patients express dissatisfaction with our billing practices to their physicians, those physicians may be less likely to prescribe Cologuard for other patients, and our business would be adversely affected.

Even if payers do agree to cover Cologuard, our billing and collections process may be complicated by the following and other factors, which may be beyond our control:

- disputes among payers as to which payer is responsible for payment;
- disparity in coverage among various payers or among various healthcare plans offered by a single payer;
- payer medical management requirements, including prior authorization requirements;
- differing information and billing requirements among payers; and
- failure by patients or physicians to provide complete and correct billing information.

Sometimes, when we have a contract with a commercial payer to cover Cologuard, we are not permitted to bill patients insured by that payer for amounts beyond deductibles, co-payments and co-insurance as prescribed in the coverage agreement between the payer and the patients. Therefore, when such contracted payers do not pay us our full, contracted rate for a Cologuard test, for example, for failure to satisfy prior-authorization or other payer medical management requirements, we may not be permitted to collect the balance from the patient and our business is adversely impacted.

The uncertainty of receiving payment for our Cologuard test and complex laboratory billing processes could negatively affect our business and our operating results.

We may be subject to substantial costs and liability, or be prevented from using technologies incorporated in our Cologuard test, as a result of litigation or other proceedings relating to patent or other intellectual property rights.

Third parties may assert infringement or other intellectual property claims against our licensors, our licensees, our suppliers, our strategic partners or us. We pursue a patent strategy that we believe provides us with a competitive advantage in the non-invasive early detection of colorectal cancer and pre-cancer and is designed to maximize our patent protection against third parties. We have filed patent applications that we believe cover the methods we have designed and use in our Cologuard test to detect colorectal cancer and pre-cancer. In order to protect or enforce our patent and other intellectual property rights, we may have to initiate actions against third parties. Any actions regarding patents could be costly and time-consuming and divert the attention of our management and key personnel from our business. Additionally, such actions could result in challenges to the validity or applicability of our patents. Because the U.S. Patent & Trademark Office maintains patent applications in secrecy until a patent application publishes or the patent is issued, we have no way of knowing if others may have filed patent applications covering technologies used by us or our partners. Additionally, there may be third-party patents, patent applications and other intellectual property relevant to our technologies that may block or compete with our technologies. From time to time we have received correspondence from third parties alleging to hold intellectual property rights that could block our development or commercialization of products. While none of these inquiries to date have had any material effect on us, we may receive inquiries in the future that could have a material effect on our business. Even if third-party claims are without merit, defending a lawsuit may result in substantial expense to us and may divert the attention of management and key personnel. In addition, we cannot provide assurance that we would prevail in any such suits to the extent necessary to conduct our business according to our strategic plan or that the damages or other remedies, if any, awarded against us would not be substantial. Claims of intellectual property infringement may require that we, or our strategic partners, enter into royalty or license agreements with third parties that may only be available on unacceptable terms, if at all. These claims may also result in injunctions against the further development and commercial sale of services or products containing our technologies, which would have a material adverse effect on our business, financial condition and results of operations.

Also, patents and patent applications owned by us may become the subject of interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial cost to us as well as a possible adverse decision as to the priority of invention of the patent or patent application involved. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application subject to such a proceeding.

If we are unable to protect our intellectual property effectively, we may be unable to prevent third parties from using our intellectual property, which would impair any competitive advantage we may otherwise have.

We rely on patent protection as well as a combination of trademark, copyright and trade secret protection and other contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property, which may not be entirely successful, if at all. Additionally, certain of our patents began to expire in 2017. This loss of patent protection may permit third parties to use certain intellectual property assets previously exclusively reserved for our use.

We cannot assure you that any of our currently pending or future patent applications will result in issued patents, and we cannot predict how long it will take for any such patents to be issued. Further, we cannot assure you that other parties will not challenge any patents issued to us or that courts or regulatory agencies will hold our patents to be valid or enforceable. We have been in the past, and may be in the future, the subject of opposition proceedings relating to our patents. We cannot guarantee you that we will be successful in defending challenges made against our patents and patent

applications. Any successful third-party challenge to our patents could result in co-ownership of such patents with the third party or the unenforceability or invalidity of such patents. Furthermore, in the life sciences field, courts frequently render opinions that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of isolated DNA and/or methods for analyzing or comparing DNA. Such decisions may adversely impact our ability to obtain new patents and facilitate third-party challenges to our existing patents.

Even where we have valid patents, third parties may be able to successfully design their products and services around those patents, such that their products and services do not infringe our patents. To the extent third parties are able to develop or commercialize competing products and services that do not infringe our patents, our business will be adversely impacted.

Our business is subject to various complex laws and regulations. We could be subject to significant fines and penalties if we or our partners fail to comply with these laws and regulations.

As a provider of clinical diagnostic products and services, we and our partners are subject to extensive and frequently changing federal, state and local laws and regulations governing various aspects of our business. In particular, the clinical laboratory industry is subject to significant governmental certification and licensing regulations, as well as federal and state laws regarding:

- test ordering and billing practices;
- marketing, sales and pricing practices;
- health information privacy and security, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and comparable state laws;
- insurance;
- anti-markup legislation; and
- consumer protection.

We are also required to comply with FDA regulations, including with respect to our labeling and promotion activities. In addition, advertising of our tests is subject to regulation by the Federal Trade Commission, or FTC, and advertising of laboratory services is regulated by certain state laws. Violation of any FDA requirement could result in enforcement actions, such as seizures, injunctions, civil penalties and criminal prosecutions, and violation of any FTC or state law requirement could result in injunctions and other associated remedies, all of which could have a material adverse effect on our business. Most states also have similar regulatory and enforcement authority for devices. Additionally, most foreign countries have authorities comparable to the FDA and processes for obtaining marketing approvals. Obtaining and maintaining these approvals, and complying with all laws and regulations, may subject us to similar risks and delays as those we could experience under FDA, FTC and state regulation. We incur various costs in complying and overseeing compliance with these laws and regulations.

Healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments and healthcare laws and regulations are subject to change. Development of the existing commercialization strategy for our Cologuard test and planned development of products in our pipeline has been based on existing healthcare policies. We cannot predict what additional changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations.

If we or our partners, including independent sales representatives to the extent we engage them, fail to comply with these laws and regulations, we could incur significant fines and penalties and our reputation and prospects could suffer. Additionally, any such partners could be forced to cease offering our products and services in certain jurisdictions, which could materially disrupt our business.

Some of our activities may subject us to risks under federal and state laws prohibiting 'kickbacks' and false or fraudulent claims.

In addition to FDA marketing restrictions, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the healthcare product and service industry and to regulate billing practices and financial relationships with physicians, hospitals and other healthcare providers. These laws include a federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar

state laws, which prohibit payments intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. While the federal law applies only to referrals, products or services for which payment may be made by a federal healthcare program, state laws often apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices and providers of laboratory services by limiting the kinds of financial arrangements, including sales programs, that may be used with hospitals, physicians, laboratories and other potential purchasers or prescribers of medical devices and laboratory services. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, or are for items or services that were not provided as claimed. Additionally, to avoid liability under federal false claims laws, we must carefully and accurately code claims for reimbursement, proactively monitor the accuracy and appropriateness of Medicare claims and payments received, diligently investigate any credible information indicating that we may have received an overpayment, and promptly return any overpayments. Medicare payments are subject to audit, including through the Comprehensive Error Rate Testing (CERT) program, and payments may be recouped by CMS if it is determined that they were improperly made. Currently, a significant percentage of our revenues are generated by payments from Medicare. The federal anti-kickback statute and certain false claims laws prescribe civil and criminal penalties (including fines) for noncompliance that can be substantial. While we continually strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing and billing practices are constantly evolving and even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could harm our business and prospects. Our failure to comply with applicable laws could result in various adverse consequences that could have a material adverse effect upon our business, including the exclusion of our products and services from government programs and the imposition of civil or criminal sanctions.

Compliance with the HIPAA security, privacy and breach notification regulations may increase our costs.

The HIPAA privacy, security and breach notification regulations, including the expanded requirements under HITECH, establish comprehensive federal standards with respect to the uses and disclosures of protected health information ("PHI") by health plans, healthcare providers and healthcare clearinghouses, in addition to setting standards to protect the confidentiality, integrity and security of PHI. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payments for our services, and our healthcare operations activities;
- a patient's rights to access, amend and receive an accounting of certain disclosures of PHI;
- requirements to notify individuals if there is a breach of their PHI;
- the contents of notices of privacy practices for PHI;
- administrative, technical and physical safeguards required of entities that use or receive PHI; and
- the protection of computing systems maintaining electronic PHI.

We have implemented practices to meet the requirements of the HIPAA privacy, security and breach notification regulations, as required by law. We are required to comply with federal privacy, security and breach notification regulations as well as varying state privacy, security and breach notification laws and regulations, which may be more stringent than federal HIPAA requirements. In addition, for healthcare data transfers from other countries relating to citizens of those countries, we must comply with the laws of those countries. The federal privacy regulations restrict our ability to use or disclose patient identifiable data, without patient authorization, for purposes other than payment, treatment, healthcare operations and certain other specified disclosures such as public health and governmental oversight of the healthcare industry.

HIPAA provides for significant fines and other penalties for wrongful use or disclosure of PHI, including potential civil and criminal fines and penalties. Computer networks are always vulnerable to breach and unauthorized persons may in the future be able to exploit weaknesses in the security systems of our computer networks and gain access to PHI. Additionally, we share PHI with third-party contractors who are contractually obligated to safeguard and maintain the confidentiality of PHI. Unauthorized persons may be able to gain access to PHI stored in such third-party contractors' computer networks. Any wrongful use or disclosure of PHI by us or our third-party contractors, including disclosure due to data theft or unauthorized access to our or our third-party contractors' computer networks, could subject us to fines or penalties that could adversely affect our business and results of operations. Although the HIPAA statute and regulations

do not expressly provide for a private right of damages, we could also incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

The success of our business is substantially dependent upon the efforts of our senior management team.

Our success depends largely on the skills, experience and performance of key members of our senior management team including Kevin Conroy, our Chairman, President and Chief Executive Officer, Maneesh Arora, our Senior Vice President and Chief Operating Officer, Dr. Graham Lidgard, our Senior Vice President and Chief Science Officer, and Jeff Elliott, our Chief Financial Officer. These executives are critical to directing and managing our growth and development in the future. Our success is substantially dependent upon our senior management's ability to lead our company, implement successful corporate strategies and initiatives, develop key relationships, including relationships with collaborators and business partners, and successfully commercialize products and services. While our management team has significant experience in securing FDA approvals for diagnostic products, we have considerably less experience in commercializing products or services. The efforts of our management team will be critical to us as we develop our technologies and seek to commercialize our Cologuard test and other products and services.

Our success depends on our ability to retain our managerial personnel and to attract additional personnel.

Our success depends in large part on our ability to attract and retain managerial personnel. If we were to lose any of our senior management team, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies. Competition for desirable personnel is intense, and there can be no assurance that we will be able to attract and retain the necessary staff. The failure to maintain management or to attract sales and marketing personnel as we commercialize our Cologuard test could materially adversely affect our business, financial condition and results of operations.

Our management has broad discretion over the use of our available cash and marketable securities and might not spend available cash and marketable securities in ways that increase the value of your investment.

As of September 30, 2017, we had $462.5 million in combined cash and marketable securities. Our management currently expects to deploy these resources primarily to expand our Cologuard operation and commercialization activities, to fund our product development efforts and for general corporate and working capital purposes. However, our management has broad discretion to pursue other objectives and we may use these funds for other purposes. Our management might not effectively deploy our cash and marketable securities which could have an adverse effect on our business.

Our business and reputation will suffer if we are unable to establish and comply with, stringent quality standards to assure that the highest level of quality is observed in the performance our Cologuard test.

Inherent risks are involved in providing and marketing cancer diagnostic tests, such as our Cologuard test, and related services. Patients and healthcare providers rely on us to provide accurate clinical and diagnostic information that may be used to make critical healthcare decisions. As such, users of our Cologuard test may have a greater sensitivity to errors than users of some other types of products and services.

We must maintain top service standards and FDA-mandated and other quality controls. Performance defects, incomplete or improper process controls, excessively slow turnaround times, unanticipated uses of Cologuard or mishandling of stool samples or Cologuard test results (whether by us, patients, healthcare providers, courier delivery services or others) can lead to adverse outcomes for patients and interruptions to our services. These events could lead to voluntary or legally mandated safety alerts relating to Cologuard or our laboratory facility and could result in the removal of Cologuard from the market or the suspension of our laboratory's operations. Insufficient quality controls and any resulting negative outcomes, could result in significant costs and litigation, as well as negative publicity that could reduce demand for Cologuard and payers' willingness to cover our Cologuard test. Even if we maintain adequate controls and procedures, damaging and costly errors may occur.

Product and professional liability suits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.

The sale and use of our Cologuard test could lead to product or professional liability claims based on, among other things, allegations that it contained a design or manufacturing defect or our laboratory was negligent in processing test results, which resulted in the failure to detect the condition for which it was designed or an unnecessary procedure which caused harm. A product or professional liability claim could result in substantial damages, be costly and time consuming to defend, and cause material harm to our business, reputation or financial condition. We cannot assure you that our liability insurance would protect our assets from the financial impact of defending a product or professional liability claim. Any claim brought against us, with or without merit, could increase our liability insurance rates or prevent us from securing insurance coverage in the future.

We expect to rely on third parties to conduct any future studies of our technologies that may be required by the FDA or other US or foreign regulatory bodies, and those third parties may not perform satisfactorily.

We do not have the ability to independently conduct the clinical or other studies that will be required to obtain FDA or other regulatory approvals for future products we may develop or the approval of foreign regulatory bodies that may be required for such future products or for our Cologuard test to the extent we seek to market products internationally. Accordingly, we expect to rely on third parties such as contract research organizations, medical institutions and clinical investigators to conduct any such studies, including the post-approval study required by the FDA for our Cologuard test. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third-party contractors may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. Our reliance on third parties that we do not control will not relieve us of our requirement to prepare, and ensure our compliance with, various procedures required under good clinical practices, even though third-party contract research organizations may prepare and comply with their own, comparable procedures. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain a required regulatory approval.

Our inability to manage growth could harm our business.

In connection with the commercialization of our Cologuard test, we have added, and expect to continue to add, additional personnel in the areas of sales and marketing, laboratory operations, billing and collections, quality assurance and compliance. Our number of full time employees has increased from 677, as of December 31, 2015, to 736, as of December 31, 2016, and to 1,268, as of December 31, 2017. Further, as we build our commercialization efforts and expand research and development activities for new products and services, the scope and complexity of our operations is increasing significantly. As a result of our growth, our operating expenses and capital requirements have also increased, and we expect that they will continue to increase, significantly. Our ability to manage our growth effectively requires us to expend funds to improve our operational, financial and management controls, reporting systems and procedures. As we move forward in commercializing our Cologuard test, we will also need to effectively manage our growing manufacturing, laboratory operations and sales and marketing needs. We are presently seeking to add facilities to support anticipated demand for our Cologuard test and anticipated associated growth in our personnel. We are expanding the capacity of our existing clinical laboratory, and have started construction of a second clinical laboratory, both in Madison, Wisconsin. We are also planning to add new manufacturing, warehouse and office facilities. We face various risks in managing these expansion efforts, including financing, construction delays, budget management, quality control, design efficiency, and transition execution. If we are unable to manage our anticipated growth effectively, our business could be harmed.

International operations could subject us to risks and expenses that could adversely impact the business and results of operations.

To date, we have not undertaken substantial commercial activities outside the United States. We evaluated the commercialization of Cologuard in several European, Middle Eastern and Asian countries. After undertaking preliminary preparatory activities, we determined to cease those efforts and we do not have present plans to expand Cologuard internationally. If we seek to expand Cologuard internationally, or launch other products or services

internationally, in the future, those efforts would expose us to risks from the failure to comply with foreign laws and regulations that differ from those under which we operate in the U.S., as well as U.S. rules and regulations that govern foreign activities such as the U.S. Foreign Corrupt Practices Act. In addition, we could be adversely affected by other risks associated with operating in foreign countries. Economic uncertainty in some of the geographic regions in which we might operate, including developing regions, could result in the disruption of commerce and negatively impact cash flows from our operations in those areas. Also, if we choose to pursue international expansion efforts, it may be necessary or desirable to contract with third parties, such as laboratories, distributors or others. We may not be able to enter into such agreements on commercially acceptable terms, or at all, such arrangements may not perform to our expectations, we may be exposed to various risks as a result of the activities of our partners, and we may be exposed to contractual or other liabilities to our partners if the arrangements prove non-beneficial for them or if we seek to terminate them early.

These and other factors may have a material adverse effect on any international operations we may seek to undertake and, consequently, on our financial condition and results of operations.

Delaware law, our charter documents and rights agreement could impede or discourage a takeover or change of control that stockholders may consider favorable.

As a Delaware corporation, we are subject to certain anti-takeover provisions. Under Delaware law, a corporation may not engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Accordingly, our board of directors could rely on Delaware law to prevent or delay an acquisition of our company. In addition, certain provisions of our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. These provisions include the following:

- Our board of directors is divided into three classes serving staggered three-year terms.
- Only our board of directors can fill vacancies on the board.
- Our stockholders may not act by written consent.
- There are various limitations on persons authorized to call a special meeting of stockholders and advance notice requirements for stockholders to make nominations of candidates for election as directors or to bring matters before an annual meeting of stockholders.
- Our board of directors may issue, without stockholder approval, shares of undesignated preferred stock.

These types of provisions could make it more difficult for a third party to acquire control of us, even if the acquisition would be beneficial to our stockholders.

In addition, we have adopted a rights agreement that provides that in the event of (i) an acquisition of 15% or more of our outstanding common stock or (ii) an announcement of an intention to make a tender offer or exchange offer for 15% or more of our outstanding common stock, our stockholders, other than the potential acquiror, shall be granted rights enabling them to purchase additional shares of our common stock at a substantial discount to the then prevailing market price. The rights agreement could significantly dilute such acquiror's ownership position in our shares, thereby making a takeover prohibitively expensive and encouraging such acquiror to negotiate with our board of directors. Therefore, the rights agreement could make it more difficult for a third party to acquire control of us without the approval of our board of directors.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders and reduce our financial resources.

We have recently undertaken certain acquisition activities. In 2017, we acquired the stock of Sampleminded, Inc. and we acquired certain assets from Armune Bioscience, Inc. We could incur losses resulting from yet undiscovered liabilities of these acquired business that are not covered by any indemnification or other contractual remedies. In addition, we may not be able to successfully integrate these businesses into our existing operations in an effective, timely and non-disruptive manner.

In the future, we may enter into transactions to acquire other businesses, products, services or technologies. Because we have only made a limited number of small acquisitions to date, our ability to do so successfully is unproven. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms or at all. Any

acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by investors, healthcare providers, patients and others. We may decide to incur debt in connection with an acquisition or issue our common stock or other securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by any indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2016, we had federal and state net operating loss carryforwards ("NOLs") of approximately $725.1 million and $291.9 million, respectively. In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. An ownership change is generally defined as a greater than 50% change in equity ownership by value over a specified time period (generally three years). Given the Code's broad definition, an ownership change could be the unintended consequence of otherwise normal market trading in our stock that is outside our control. An ownership change under Section 382 of the Code could also be triggered by certain strategic transactions. The Tax Cuts and Jobs Act (H.R. 1) was signed into law on December 22, 2017 (the "Act"). The Act contains significant changes to corporate taxation and modifies several existing laws around federal NOLs, including a limitation on the deduction for NOLs to 80% of current year taxable income as well as an indefinite carryover period for federal NOLs. Both provisions are applicable for losses arising in tax years beginning after December 31, 2017. For these reasons, even if we attain profitability our ability to utilize our NOLs may be limited, potentially significantly so. Our deferred tax asset related to our NOLs will likely be reduced, due to the decrease in the federal corporate tax rate outlined in the Act. Notwithstanding these changes to United States federal income tax law and the other changes enacted by the Act, we do not believe that the Act will have a material adverse effect on our financial reporting, cash flows or tax liabilities.

Our stock price has fluctuated widely and is likely to continue to be volatile.

The market price for our common stock varied between a high of $63.60 and a low of $13.05 in the twelve-month period ended December 31, 2017. Our stock price is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market and other factors, including those listed in this "Risk Factors" section and other, unknown factors. Our stock price also may be affected by:

- comments by securities analysts regarding our business or prospects;
- our issuance of common stock or other securities;
- our inability to accurately forecast future performance;
- our inability to meet analysts' expectations;
- our entering into merger, acquisition or other similar transactions;
- general fluctuations in the stock market or in the stock prices of companies in the life sciences or healthcare diagnostics industries; and
- general conditions and publicity regarding the life sciences or healthcare diagnostics industries.

Consequently, the current market price of our common stock may not be indicative of future market prices, and we may be unable to sustain or increase the value of an investment in our common stock. Further, sharp drops in the market price of our common stock, such as we experienced at certain times in our history, may expose us to securities class-action litigation. Such litigation could result in substantial expenses and diversion of management's attention and corporate resources, which would seriously harm our business, financial condition, and results of operations.

We have never paid cash dividends and do not intend to do so.

We have never declared or paid cash dividends on our common stock. We currently plan to retain any earnings to finance the growth of our business rather than to pay cash dividends. Payments of any cash dividends in the future will depend on our financial condition, results of operations and capital requirements, as well as other factors deemed relevant by our board of directors.

Risks Related to Our Indebtedness and the Notes

The notes are our unsecured senior obligations and will be effectively junior to all of our existing and future secured indebtedness and other secured obligations, to the extent of the value of the assets securing that indebtedness, and be structurally subordinated to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

The notes are our senior unsecured obligations and will effectively rank junior in right of payment to any of our secured indebtedness and other secured obligations to the extent of the value of the assets securing such indebtedness and be structurally subordinated to all indebtedness and other liabilities (including trade payables, but excluding intercompany obligations) of our subsidiaries. In the event of our bankruptcy, liquidation, reorganization or other winding up, our assets that secure indebtedness or other obligations effectively ranking senior in right of payment to the notes will be available to pay obligations on the notes only after the secured indebtedness or other secured obligations has been repaid in full from these assets. There may not be sufficient assets remaining to pay amounts due on any or all of the notes then outstanding. The indenture governing the notes will not prohibit us from incurring additional indebtedness in the future, including senior secured indebtedness, and such indebtedness may be substantial, nor will the indenture prohibit our subsidiaries from incurring additional indebtedness or other liabilities. See "Description of the Notes—Ranking."

As of September 30, 2017, our total consolidated indebtedness was approximately $4.7 million, all of which was secured. As of September 30, 2017, our subsidiaries had approximately $3.5 million of indebtedness and other liabilities (including trade payables). After giving effect to the issuance of the notes (assuming no exercise of the underwriter's option to purchase additional notes), our total consolidated indebtedness would have been approximately $504.7 million as of September 30, 2017. In December 2017, we entered into (i) a revolving loan agreement, which provides us with a 24-month secured revolving credit facility of up to $15.0 million and (ii) a construction loan agreement, which provides us with a non-revolving secured construction loan of $25.6 million. As of December 31, 2017, we had not drawn any funds from these two agreements.

Our increased indebtedness could adversely affect our business, financial condition and results of operations and our ability to meet our payment obligations under such indebtedness.

As of September 30, 2017, we had approximately $4.7 million of long-term indebtedness outstanding. After giving effect to this offering of notes, our long-term indebtedness will increase by $500 million (or $575 million if the underwriter exercises its option to purchase additional notes in full) (which amount, with respect to the notes, reflects the face amount of the notes). The indenture governing the notes will not restrict our ability to incur additional indebtedness. This level of debt could have significant consequences on our future operations, including:

- increasing our vulnerability to adverse economic and industry conditions;
- making it more difficult for us to meet our payment and other obligations under the notes offered hereby;
- making it more difficult to obtain any necessary future financing for working capital, capital expenditures, debt service requirements or other purposes;
- requiring the dedication of a substantial portion of any cash flow from operations to service our indebtedness, thereby reducing the amount of cash flow available for other purposes, including capital expenditures;
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital than we have; and
- limiting our flexibility in planning for, or reacting to, changes in our business and the markets in which we compete.

Any of the above-listed factors could have an adverse effect on our business, financial condition and results of operations and our ability to meet our payment obligations under the notes.

Our ability to meet our payment and other obligations under the notes depends on our ability to generate significant cash flow in the future. This, to some extent, is subject to general economic, financial, competitive, legislative and regulatory factors as well as other factors that are beyond our control. We cannot assure you that our business will generate cash flow from operations, or that future borrowings will be available to us, in an amount sufficient to enable us to meet our payment obligations under the notes and to fund other liquidity needs. If we are not able to generate sufficient cash flow to service our debt obligations, we may need to refinance or restructure our debt, including the notes, sell assets, reduce or delay capital investments, or seek to raise additional capital. If we are unable to implement one or more of these alternatives, we may not be able to meet our payment obligations under the notes, and this default could cause us to be in default on any other currently existing or future outstanding indebtedness.

We may incur substantially more debt or take other actions which would intensify the risks discussed above.

We and our subsidiaries may be able to incur substantial additional debt in the future, some of which may be secured debt. We and our subsidiaries will not be restricted under the terms of the indenture governing the notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing the notes that could have the effect of diminishing our ability to make payments on the notes when due.

Servicing our debt will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay amounts due under our indebtedness, including the notes.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt, including the notes, 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.

The terms of the notes will not contain restrictive covenants and provide only limited protection in the event of a change of control.

The indenture under which the notes will be issued will not contain restrictive covenants that would protect you from several kinds of transactions that may adversely affect you. In particular, the indenture will not contain covenants that will limit our ability to pay dividends or make distributions on or redeem our capital stock or limit our ability to incur additional indebtedness and, therefore, may not protect you in the event of a fundamental transaction, a highly leveraged transaction or other similar transaction. The requirement that we offer to repurchase the notes upon a change of control is limited to the transactions specified in the definition of a "fundamental change" under "Description of the Notes— Fundamental Change Put." Similarly, the circumstances under which we are required to adjust the conversion rate upon the occurrence of a "make-whole fundamental change" are limited to circumstances where a note is converted in connection with such a transaction as set forth under "Description of the Notes—Conversion Rights—Adjustment to Conversion Rate Upon a Make-Whole Fundamental Change."

Accordingly, subject to restrictions contained in any future debt agreements, we could enter into certain transactions, such as acquisitions, refinancings or recapitalizations that could affect our capital structure and the value of the notes and common stock but would not constitute a fundamental change under the notes.

Some significant restructuring transactions may not constitute a fundamental change, in which case we would not be obligated to offer to repurchase the notes.

Upon the occurrence of a fundamental change, you have the right to require us to repurchase your notes. However, the fundamental change provisions will not afford protection to holders of the notes in the event of certain transactions. For example, transactions such as leveraged recapitalizations, refinancings, restructurings or acquisitions initiated by us may not constitute a fundamental change requiring us to repurchase the notes. In the event of any such transaction, the holders would not have the right to require us to repurchase the notes, even though each of these transactions could increase the amount of our indebtedness, or otherwise adversely affect our capital structure or any credit ratings, thereby adversely affecting the holders of the notes.

We may not have the ability to raise the funds necessary to settle conversions of the notes or to repurchase the notes for cash when required by the holders upon a fundamental change.

Holders of the notes have the right to require us to repurchase the notes upon the occurrence of a fundamental change prior to maturity as described under "Description of the Notes—Fundamental Change Put." In addition, unless we elect to deliver solely shares of our common stock, we will be required to make cash payments in respect of the notes being converted as described under "Description of the Notes—Conversion Rights—Settlement Upon Conversion." However, we may not have enough available cash or be able to obtain financing at the time we are required to make purchases of notes surrendered therefor or notes being converted. In addition, our ability to repurchase the notes or to pay cash upon conversion of the notes may be limited by law, by regulatory authority or by agreements that will govern our future indebtedness. Our failure to repurchase the notes at a time when the repurchase is required by the indenture that will govern the notes or to pay cash payable on future conversions of the notes as required by such indenture would constitute a default under such indenture. A default under the indenture that will govern the notes or the fundamental change itself could also lead to a default under 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 repurchase the notes or make cash payments upon conversions thereof.

Holders of the notes may not be able to determine when a fundamental change giving rise to their right to have the notes repurchased has occurred following a sale of "substantially all" of our assets.

One of the circumstances under which a fundamental change may occur is upon the sale or disposition of "all or substantially all" of our assets. There is no precise, established definition of the phrase "substantially all" under applicable law and the interpretation of that phrase will likely depend upon particular facts and circumstances. Accordingly, the ability of a holder of notes to require us to repurchase its notes as a result of a sale of less than all our assets to another person may be uncertain.

The adjustment to the conversion rate upon the occurrence of a make-whole fundamental change may not adequately compensate you for the lost option time value of your notes as a result of such transaction.

If a make-whole fundamental change occurs prior to maturity and a holder elects to convert in connection with such transaction, we will increase the conversion rate under certain circumstances. The number of additional shares by which the conversion rate will be increased will be determined based on the date on which the make-whole fundamental change becomes effective and the price paid (or deemed paid) per share of our common stock in the make-whole fundamental change, as described under "Description of the Notes—Conversion Rights— Adjustment to Conversion Rate Upon a Make-Whole Fundamental Change." Although this adjustment is designed to compensate you for the lost option value of your notes as a result of a make-whole fundamental change, the adjustment may not adequately compensate you for such loss. In addition, if the price paid per share of our common stock in the make-whole fundamental change is less than $ or greater than $ (in each case, subject to adjustment), there will be no such adjustment.

Our obligation to increase the conversion rate as described above could also be considered a penalty, in which case its enforceability would be subject to general principles of reasonableness and equitable remedies.

The conditional conversion feature of the notes could result in your receiving less than the value of the common stock into which a note would otherwise be convertible.

Prior to the close of business on the business day immediately preceding July 15, 2024, the notes are convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election, only if specified conditions are met. If these specified conditions are not met, you will not be able to convert your notes prior to July 15, 2024, and you may not be able to receive the value of the consideration into which the notes would otherwise be convertible. Therefore, you may not be able to realize the appreciation, if any, in the value of our common stock after the issuance of the notes in this offering and prior to such date. In addition, the inability to freely convert may also adversely affect the trading price of the notes and your ability to resell the notes.

If you convert your notes on or after the final regular record date preceding the maturity date and we elect physical settlement, you will have to wait until at least the maturity date before receiving amounts due upon conversion.

Under the notes, a converting holder will be exposed to fluctuations in the value of the amounts due upon conversion during the period from the date on which such holder converts its notes until the date we settle our conversion obligation. If you convert your notes on or after the final regular record date preceding the maturity date and

we elect physical settlement, we will deliver the consideration due in respect of conversion on the maturity date. Accordingly, you may have to wait a period of time before receiving amounts due upon conversion of the notes, and if the price of our common stock decreases during this period, the value of the consideration that you receive will be adversely affected and would be less than the conversion value of the notes on the conversion date. See "Description of the Notes—Conversion Rights—Settlement Upon Conversion."

Upon conversion of the notes, you may receive less valuable consideration than expected because the value of our common stock may decline after you exercise your conversion right.

Under the notes, a converting holder will be exposed to fluctuations in the value of our common stock during the period from the date such holder surrenders notes for conversion until the date we settle our conversion obligation.

The amount of consideration that you will receive upon conversion will be based upon the volume weighted average price ("VWAP") of our common stock for each of the 30 VWAP trading days during the relevant observation period. Accordingly, if the price of our common stock decreases during this period, the value of the consideration you receive will be adversely affected. In addition, if the market price of our common stock at the end of such period is below the average of the VWAP of our common stock during such period, the value of any shares of our common stock that you receive in satisfaction of our conversion obligation will be less than the value used to determine the number of shares that you will receive.

Further, if holders elect to convert notes after the final regular record date preceding the maturity date and we elect physical settlement, delivery of the shares would not occur until the maturity date and you will be exposed to the fluctuations in the value of our common stock between the date you elect such conversation and delivery of the shares.

Upon conversion of the notes, we may pay cash in lieu of issuing shares of our common stock with respect to all or a portion of the converted notes. Therefore, holders of the notes may receive no shares of our common stock or will receive fewer shares than the number underlying their notes.

Upon conversion, we may pay cash in lieu of issuing shares of our common stock with respect to all or a portion of converted notes. See "Description of the Notes—Conversion Rights—Settlement Upon Conversion." Accordingly, upon conversion of notes, holders may not receive any shares of our common stock. Further, our liquidity may be reduced upon conversion of the notes.

The conversion rate of the notes may not be adjusted for all dilutive events that may adversely affect the trading price of the notes or the common stock issuable upon conversion of the notes.

The conversion rate of the notes is subject to adjustment upon certain events, including the issuance of stock dividends on our common stock, the issuance of certain rights, options or warrants, subdivisions, combinations, distributions of capital stock, indebtedness or assets, cash dividends exceeding a specified threshold and issuer tender or exchange offers as described under "Description of the Notes—Conversion Rights—Conversion Rate Adjustments." However, the conversion rate will not be adjusted for certain other events, such as issuances of our common stock for cash or issuances of our common stock in connection with acquisitions or third-party tender offers, that may adversely affect the trading price of the notes or our common stock. An event that adversely affects the value of the notes may occur, and that event may not result in an adjustment to the conversion rate.

Future sales or other dilution of our equity could depress the market price of our common stock.

Sales of our common stock in the public market, or the perception that such sales could occur, could negatively impact the market price of our common stock. We also have several institutional stockholders that own significant blocks of our common stock. If one or more of these stockholders were to sell large portions of their holdings in a relatively short time, for liquidity or other reasons, the prevailing market price of our common stock could be negatively affected. We are not restricted from issuing additional shares of common stock during the life of the notes. If we issue additional shares of common stock, the price of our common stock, and in turn, the price of the notes may decline.

Under certain circumstances, shares of our common stock could be issued upon conversion of the notes, which would dilute the ownership interest of our existing stockholders. In addition, the issuance of additional common stock, or issuances of securities convertible into or exercisable for our common stock or other equity linked securities, including preferred stock or warrants, would dilute the ownership interest of our common stockholders and could

depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

Provisions of the notes could discourage an acquisition of us by a third party.

Certain provisions of the notes could make it more difficult or more expensive for a third party to acquire us. Upon the occurrence of certain transactions constituting a fundamental change, holders of the notes will have the right, at their option, to require us to repurchase all of their notes or any portion of the principal amount of such notes in integral multiples of $1,000. We may also be required to increase the conversion rate in the event of a make-whole fundamental change. In addition, the indenture and the notes will prohibit us from engaging in certain mergers or acquisitions unless, among other things, the surviving entity assumes our obligations under the notes and the indenture. These and other provisions in the indenture could deter or prevent a third party from acquiring us even when the acquisition may be favorable to you.

The accounting method for convertible debt securities, such as the notes, could have a material adverse effect on our reported financial results.

Under Financial Accounting Standards Board Accounting Standards Codification 470-20, *Debt with Conversion and Other Options* ("ASC 470-20"), an entity must separately account for the liability and equity components of 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. ASC 470-20 requires the value of the conversion option of the notes, representing the equity component, to be recorded as additional paid-in- capital within shareholders' equity in our consolidated balance sheet and as a discount to the notes, which reduces their initial carrying value. The carrying value of the notes, net of the discount recorded, will be accreted up to the principal amount of the notes from the issuance date until maturity, which will result in non-cash charges to interest expense in our consolidated statement of operations. Accordingly, we will report lower net income in our financial results because ASC 470-20 will require interest to include both the current period's accretion of the debt discount (non-cash interest) and the instrument's cash interest, which could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the notes.

Recent and future regulatory actions and other events may adversely affect the trading price and liquidity of the notes.

Recent and future regulatory actions and other events may adversely affect the trading price and liquidity of the notes. We expect that many investors in, and potential purchasers of, the notes will employ, or seek to employ, a convertible arbitrage strategy with respect to the notes. Investors would typically implement such a strategy by selling short the common stock underlying the notes and dynamically adjusting their short position while continuing to hold the notes. Investors may also implement this type of strategy by entering into swaps on the common stock in lieu of or in addition to short selling the common stock. As a result, any specific rules regulating equity swaps or short selling of securities or other governmental action that interferes with the ability of market participants to effect short sales or equity swaps with respect to our common stock could adversely affect the ability of investors in, or potential purchasers of, the notes to conduct the convertible arbitrage strategy that we believe they will employ, or seek to employ, with respect to the notes. This could, in turn, adversely affect the trading price and liquidity of the notes.

The SEC and other regulatory and self-regulatory authorities have implemented various rules and taken certain actions, and may in the future adopt additional rules and take other actions, that may impact those engaging in short selling activity involving equity securities (including our common stock). Such rules and actions include Rule 201 of SEC Regulation SHO, the adoption by the Financial Industry Regulatory Authority, Inc. and the national securities exchanges of a "Limit Up-Limit Down" program, the imposition of market-wide circuit breakers that halt trading of securities for certain periods following specific market declines, and the implementation of certain regulatory reforms required by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 ("Dodd-Frank"). Any governmental or regulatory action that restricts the ability of investors in, or potential purchasers of, the notes to effect short sales of the common stock, borrow the common stock or enter into swaps on the common stock could adversely affect the trading price and the liquidity of the notes. In addition, Dodd-Frank and implementing regulations prohibit banking entities and their affiliates from engaging in proprietary trading in financial instruments, or the so-called "Volcker Rule." These restrictions will limit the ability of banking entities and their affiliates to invest in or purchase the notes and could, in turn, adversely affect the trading price and liquidity of the notes.

As a holder of notes, you will not be entitled to any rights with respect to our common stock, but you will be subject to all changes made with respect to our common stock.

If you hold notes, you will not be entitled to any rights with respect to our common stock (including, without limitation, voting rights and rights to receive any dividends or other distributions on our common stock), but you will be subject to all changes affecting our common stock. If you elect to convert your notes at the close of business on the conversion date, you will have the rights with respect to (and will be the record holder of) our common stock (if we have elected to settle the relevant conversion by delivering shares of our common stock). For example, in the event that an amendment is proposed to our certificate of incorporation or bylaws requiring stockholder approval and the record date for determining the stockholders of record entitled to vote on the amendment occurs prior to the date you are deemed the record owner of the shares of our common stock due upon conversion, you will not be entitled to vote on the amendment, although you will nevertheless be subject to any changes in the powers, preferences or special rights of our common stock.

There is currently no public market for the notes, and an active trading market may not develop for the notes. The failure of a market to develop for the notes could adversely affect the liquidity and value of your notes.

The notes are a new issue of securities, and there is no existing market for the notes. We do not intend to apply for listing of the notes on any securities exchange or for quotation of the notes on any automated dealer quotation system. We have been advised by the underwriter that it presently intends to make a market in the notes after completion of the offering. However, it is under no obligation to do so and may discontinue any market-making activities at any time without notice. An active trading market may not develop for the notes, and there can be no assurance as to the liquidity of any market that may develop for the notes. If an active, liquid market does not develop for the notes, the market price and liquidity of the notes may be adversely affected. If any of the notes are traded after their initial issuance, they may trade at a discount from their initial offering price.

The liquidity of the trading market, if any, and future trading prices of the notes will depend on many factors, including, among other things, the market price of our common stock, prevailing interest rates, our operating results, financial performance and prospects, the market for similar securities and the overall securities market, and may be adversely affected by unfavorable changes in these factors. Historically, the market for convertible debt has been subject to disruptions that have caused volatility in prices. It is possible that the market for the notes will be subject to disruptions which may have a negative effect on the holders of the notes, regardless of our operating results, financial performance or prospects.

An adverse rating of the notes may cause their trading price to fall.

We do not intend to seek a rating for the notes, but if a rating agency rates the notes, it may assign a rating that is lower than expected by investors. Ratings agencies also may lower ratings on the notes in the future. If rating agencies assign a lower-than-expected rating or reduce, or indicate that they may reduce, their ratings in the future, the trading price of the notes could significantly decline.

Our board of directors and management will have broad discretion over the use of the proceeds we receive in this offering and might not apply the proceeds in ways that increase the value of your investment.

Our board of directors and management will have broad discretion to use the net proceeds from this offering, and you will be relying on the judgment of our board of directors and management regarding the application of these proceeds. We expect to use the net proceeds from this offering for general corporate and working capital purposes. Our board of directors and management might not apply the net proceeds from the offering in ways that increase the value of your investment and might not yield a significant return, if any, on any investment of such net proceeds. You will not have the opportunity to influence our decisions on how to use such proceeds.

You may be subject to tax if we make or fail to make certain adjustments to the conversion rate of the notes even though you do not receive a corresponding cash distribution.

The conversion rate of the notes is subject to adjustment in certain circumstances, including the payment of cash dividends. If the conversion rate is adjusted as a result of a distribution that is taxable to our common stockholders, such as a cash dividend, you may be deemed to have received a dividend subject to U.S. federal income tax without the receipt of any cash. In addition, a failure to adjust (or to adjust adequately) the conversion rate after an event that increases your proportionate interest in us could be treated as a deemed taxable dividend to you. If a make-whole

fundamental change occurs prior to the maturity date, under some circumstances, we will increase the conversion rate for notes converted in connection with the make-whole fundamental change. Such increase may also be treated as a distribution subject to U.S. federal income tax as a dividend. See "Material U.S. Federal Income Tax Considerations." If you are a non-U.S. holder (as defined in "Material U.S. Federal Income Tax Considerations"), any deemed dividend generally would be subject to U.S. federal withholding tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty, which may be set off against subsequent payments on the notes. See "Material U.S. Federal Income Tax Considerations."

There is a risk that the notes will be issued with original issue discount.

We may not know the issue price of the notes at the time of the first sales of the notes to holders other than the underwriter. If the price at which a substantial amount of the notes is first sold to holders other than the underwriter is less than the stated principal amount by more than a de minimis amount, then the notes will have original issue discount under applicable tax rules which may require a holder to recognize taxable interest income in advance of the receipt of cash attributable to that income. For a fuller discussion see "Material U.S. Federal Income Tax Considerations—U.S. Holders—Issue Price and Basis in the Notes."

There is a risk that the Internal Revenue Service ("IRS") could challenge the issue price of the notes as determined by us, or that it could challenge our position that all of the notes are part of a single issue and will be fungible under applicable tax rules, in which case the notes may be issued with, or with a greater amount of, original issue discount.

We will sell the notes to the underwriter in this offering for a fixed price but with no limitation on the price at which such underwriter can resell the notes to investors and there is the potential that such sales could occur over time. If the IRS were to successfully challenge our determination of the issue price for the notes, certain U.S. federal income tax consequences could result for investors. For example, the notes may be considered to have original issue discount (or a greater amount of original issue discount) which generally would require a holder to recognize taxable interest income in advance of the receipt of cash attributable to that income and may therefore affect the market value of the notes. U.S. holders should consult their own tax advisors as to the U.S. federal income tax consequences to them of such a successful challenge under the circumstances of this offering. For a fuller discussion of these tax risks, see "Material U.S. Federal Income Tax Considerations—U.S. Holders—Issue Price and Basis in the Notes."

The Tax Cuts and Jobs Act could have a negative effect on us or holders of the notes.

On December 20, 2017, the U.S. Congress passed the Tax Cuts and Jobs Act, and on December 22, 2017, President Trump signed the Tax Cuts and Jobs Act into law. The Tax Cuts and Jobs Act makes significant changes to the U.S. federal income tax rules applicable to both individuals and entities, including corporations. There remains uncertainty as to the impact of the Tax Cuts and Jobs Act on us or on an investment in the notes. You should consult with your tax advisor with respect to U.S. tax reform and its potential effect on your investment in the notes.

The market price of our common stock, which may fluctuate significantly, will directly affect the market price for the notes.

We expect that the market price of our common stock will affect the market price of the notes. In addition, the trading price of our common stock has been, and is likely to continue to be, highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. This may result in greater volatility in the market price of the notes than would be expected for non-convertible notes. The market price of our common stock will likely fluctuate in response to a number of factors, including our financial condition, operating results and prospects, as well as economic, financial and other factors, reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, or changes in our industry and competitors and government regulations, many of which are beyond our control. For more information regarding such factors, see "Risk Factors." Holders who receive common stock upon conversion of the notes will therefore be subject to the risk of volatility and depressed prices of our common stock.

In addition, we expect that the market price of the notes will be influenced by yield and interest rates in the capital markets, our creditworthiness and the occurrence of certain events affecting us that do not require an adjustment to the conversion rate. Fluctuations in yield rates in particular may give rise to arbitrage opportunities based upon changes in the relative values of the notes and our common stock. Any such arbitrage could, in turn, affect the market prices of our common stock and the notes.

The market price of our common stock could also be affected by, among other factors:

- investors' anticipation of the potential resale in the market of a substantial number of additional shares of our common stock received upon conversion of the notes;

- possible sales of our common stock by investors who view the notes as a more attractive means of equity participation in us than owning shares of our common stock; and

- hedging or arbitrage trading activity that may develop involving our common stock. This trading activity could, in turn, affect the trading prices of the notes.

Conversions of the notes may adversely affect our financial condition.

If one or more holders elect to convert their notes, unless we elect to satisfy our conversion obligation by delivering solely common stock (other than cash in lieu of 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 notes will initially be held in book-entry form and, therefore, holders must rely on the procedures and the relevant clearing systems to exercise their rights and remedies.

Unless and until certificated notes are issued in exchange for book-entry interests in the notes, owners of the book-entry interests will not be considered owners or holders of the notes. Instead, DTC, or its nominee, will be the sole holder of the notes. Payments of principal, interest (including any additional interest), amounts due upon conversion, and other amounts owing on or in respect of the notes in global form will be made to the paying agent, which will make the payments to DTC. Thereafter, such payments will be credited to DTC participants' accounts that hold book-entry interests in the notes in global form and credited by such participants to indirect participants. Unlike holders of the notes themselves, owners of book-entry interests will not have the direct right to upon our solicitations for consents or requests for waivers or other actions from holders of the notes. Instead, if a holder owns a book-entry interest, such holder will be permitted to act only to the extent such holder has received appropriate proxies to do so from DTC or, if applicable, a participant. We cannot assure holders that to procedures for the granting of such proxies will be sufficient to enable holders to vote on any requests actions on a timely basis.

Exhibit 99.2

Exact Sciences Announces Offering of $500 Million Convertible Senior Notes Due 2025

MADISON, Wis. January 11, 2018— Exact Sciences Corporation (NASDAQ: EXAS) today announced an underwritten public offering of $500 million aggregate principal amount of convertible senior notes due 2025 (the "Notes") pursuant to an effective shelf registration statement filed with the Securities and Exchange Commission (the "SEC") on Form S-3. The Company has also granted the underwriter a 30-day option to purchase up to an additional $75 million aggregate principal amount of Notes. The Company intends to use the net proceeds of this offering for general corporate and working capital purposes. The Notes will be convertible into cash, shares of the Company's common stock (plus, if applicable, cash in lieu of any fractional share), or a combination thereof, at the Company's election.

BofA Merrill Lynch is acting as sole book-running manager for the offering. An automatically effective shelf registration statement relating to these securities was filed with the SEC on June 6, 2017. A copy of the prospectus supplement and prospectus relating to the offering may be obtained free of charge on the SEC's website at http://www.sec.gov or by sending a request to BofA Merrill Lynch, NC1-004-03-43, 200 North College Street, 3rd Floor, Charlotte, NC 28255-0001, Attention: Prospectus Department (or by e-mail at dg.prospectus_requests@baml.com).

This press release shall not constitute an offer to sell or a solicitation of an offer to buy nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state. The offering of these securities will be made only by means of the prospectus and related prospectus supplement.

About Exact Sciences Corp.

Exact Sciences Corp. is a molecular diagnostics company focused on the early detection and prevention of the deadliest forms of cancer. The company has exclusive intellectual property protecting its non-invasive, molecular screening technology for the detection of colorectal cancer.

Certain statements made in this news release contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe the Company's future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "could," "seek," "intend," "plan," "estimate," "anticipate," or other comparable terms. Forward-looking statements in this news release may address the following subjects among others: the terms and size of the offering and the use of proceeds from the offering. Forward-looking statements involve inherent risks and uncertainties that could cause actual results to differ materially from those in the forward-looking statements as a result of various factors including those risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of the Company's most recently filed Annual Report on Form 10-K and the Company's subsequently filed Quarterly Reports on Form 10-Q. The Company urges you to consider those risks and uncertainties in evaluating the Company's forward-looking statements. The Company cautions readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, the Company disclaims any obligation or undertaking to publicly release any updates or

revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in the Company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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