

EXACT SCIENCES CORP  
Form 40-APP  
January 31, 2018  
SEC File No. 812 \_\_\_\_\_

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

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APPLICATION FOR AN ORDER PURSUANT TO  
SECTION 3(b)(2) OF THE INVESTMENT COMPANY ACT OF 1940  
DECLARING THAT EXACT SCIENCES CORPORATION IS NOT  
AN INVESTMENT COMPANY UNDER THE 1940 ACT

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IN THE MATTER OF  
EXACT SCIENCES CORPORATION

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UNITED STATES OF AMERICA  
BEFORE THE  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

In the Matter of ) APPLICATION FOR AN ORDER  
) PURSUANT TO SECTION 3(b)(2)  
) OF THE INVESTMENT COMPANY  
EXACT SCIENCES ) ACT OF 1940 DECLARING THAT  
CORPORATION ) EXACT SCIENCES CORPORATION IS  
) NOT AN INVESTMENT COMPANY  
) UNDER THE ACT  
)

File No. [\_\_\_\_\_]

I. SUMMARY OF RELIEF REQUESTED

Exact Sciences Corporation (“Exact Sciences” or the “Company”) hereby applies for an order of the U.S. Securities and Exchange Commission (the “Commission,” or the “SEC”) pursuant to Section 3(b)(2) of the Investment Company Act of 1940 (15 U.S.C. §§80a-1 et seq.), as amended (the “1940 Act”), declaring that Exact Sciences is primarily engaged in a business or businesses other than that of investing, reinvesting, owning, holding, or trading in securities, and therefore is not an “investment company,” as defined in the 1940 Act. An order from the SEC would confirm the status of Exact Sciences as an operating company whose business is currently focused on producing and developing screening and diagnostic tests for the early detection and prevention of some of the deadliest forms of cancer. Consistent with this operating business, Exact Sciences manufactures a non-invasive, patient-friendly screening test called Cologuard®, and provides it to patients on a prescription-only basis through its clinical laboratory. Cologuard® screens for the early detection of colorectal cancer and pre-cancer. The Company is currently working on the development of additional tests for other types of cancer, consistent with its strategic mission of becoming a leader in cancer diagnostics.

Exact Sciences is filing this application pursuant to Section 3(b)(2) of the 1940 Act (the “Application”) to confirm its clear status as an operating company and not as an “investment company.” Section 3(a)(1) of the 1940 Act sets forth a three-prong definition that broadly defines an “investment company,” as any issuer that:

(A) is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting, or trading in securities (the “Business Test”);

(B) is engaged or proposes to engage in the business of issuing face-amount certificates of the installment type, or has been

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engaged in such business and has any such certificate outstanding; or (C) is engaged or proposes to engage in the business of investing, reinvesting, owning, holding, or trading in securities, and owns or proposes to acquire investment securities having a value exceeding 40 per centum of the value of such issuer's total assets (exclusive of Government securities and cash items) on an unconsolidated basis (the "Asset Test").

Notably, Exact Sciences does not issue, has never issued, and does not propose to issue face-amount certificates of the installment type. Therefore, Exact Sciences would not be an investment company on that basis, and this Application does not address this aspect of the definition of "investment company." The Application does address the Business Test and the Asset Test, as applied to the Company's historical and intended operations.

Briefly, Exact Sciences holds on its balance sheet "investment securities," as defined in the 1940 Act as "all securities except (A) Government securities, (B) securities issued by employees' securities companies, and (C) securities issued by majority-owned subsidiaries of the owner which (i) are not investment companies, and (ii) are not relying on the exception from the definition of investment company in paragraph (1) or (7) of subsection (c)" of Section 3 of the 1940 Act.<sup>2</sup> As of its recently reported quarter end of September 30, 2017, the value of Exact Sciences' investment securities constituted approximately 65% of the value of the Company's total assets on an unconsolidated basis (exclusive of cash items and Government securities).<sup>3</sup> These securities holdings, however, are necessary to finance the Company's research and development ("R&D") and operating business.

In light of its securities holdings, Exact Sciences triggers the technical application of the Asset Test to suggest the Company is an investment company. However, the Company's history, operations, public pronouncements, and sources of revenues clearly show that it is not. Because of the technical application of the Asset Test to Exact Sciences, the Company has relied on exclusions from the definition of investment company in not registering with the SEC under the 1940 Act or otherwise re-ordering its asset holdings. Exact Sciences is seeking an order from the Commission pursuant to Section 3(b)(2) because reliance on these exclusions has become uncertain and may become unavailable over the long term. The Company believes the requested order is warranted because it is primarily engaged, and will continue to be primarily engaged, in a business other than a business of investing, reinvesting, owning, holding, or trading in

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<sup>1</sup> 15 U.S.C. §80a-3(a)(1).

<sup>2</sup> 15 U.S.C. §80a-3(a)(2).

All assets have been valued for the purpose of these determinations in accordance with Section 2(a)(41) of the 1940 Act. Section 2(a)(41) defines "value" to mean (i) with respect to securities owned at the end of the last preceding fiscal quarter for which market quotations are available, the market value at the end of such quarter; (ii) with respect to other securities and assets owned at the end of the last preceding fiscal quarter, fair value at the end of such quarter, as determined in good faith by the board of directors; and (iii) with respect to securities and other assets acquired after the end of the last preceding fiscal quarter, the cost of the securities and other assets.

securities within the meaning of Section 3(b)(2), as interpreted by *In re Tonopah Mining Co.*, 26 S.E.C. 426 (1947) (“Tonopah Mining”), the formative case distinguishing operating companies from investment companies for purposes of the 1940 Act.

## II. STATEMENT OF FACTS

### A. Overview of Exact Sciences’ Business and Operations

Founded in 1995, Exact Sciences is a Delaware corporation headquartered in Madison, Wisconsin at 441 Charmany Drive. The Company employs approximately 1,235 full time employees and conducts business at leased and owned offices, laboratories, and other facilities in the Madison area (as well as a small office in Salt Lake City, Utah). These offices and labs give the Company approximately 407,000 square feet to devote to R&D, clinical testing and processing, product manufacturing, and general company operations.

In 2001, the Company made its first public offering of common stock. It has since raised capital in subsequent public offerings for purposes of financing its operations. It is a public reporting company with the SEC and its shares are listed and traded on the Nasdaq Stock Market LLC (“Nasdaq”) under the ticker symbol “EXAS”.

As of October 27, 2017, Exact Sciences had market capitalization of approximately \$6.1 billion and 119,730,401 shares of common stock outstanding. The Company has nine wholly-owned subsidiaries: Exact Sciences Laboratories, LLC, a Delaware limited liability company; Exact Sciences Finance Corporation, a Delaware corporation; Exact Sciences Europe Ltd, a private limited company organized under the laws of England and Wales; Exact Sciences Development Company, LLC, a Delaware limited liability company; Beijing Exact Sciences Medical Technology Company Ltd., a company organized under the laws of the People’s Republic of China; CG Growth LLC, a Wisconsin limited liability company; Sampleminded, Inc., a corporation organized under the laws of the State of Utah; Data in Motion LLC, a Utah limited liability company; and Cimarron Medical Software, Inc., a corporation organized under the laws of the State of Utah.

The current operating subsidiaries conduct business that is integrally related to the business of Exact Sciences. For example, Exact Sciences Development Company, LLC conducts the Company’s R&D. Exact Sciences Laboratories, LLC operates the clinical lab that processes Cologuard® testing to the public. The Company is using CG Growth LLC as the entity through which it is acquiring real property for the expansion of its business. Two subsidiaries -- Beijing Exact Sciences Medical Technology Company Ltd. and Cimarron Medical Software, Inc. -- are non-operational and are in the process of dissolution.

None of the subsidiaries owns “investment securities.” A copy of the Company’s most recent quarterly report on Form 10-Q, dated as of September 30, 2017, is attached hereto in Exhibit A.

## 1. Corporate Governance

The Company is managed by a ten-member Board of Directors (“Board”). The executive management team consists of professionals who are leaders in business, medicine, biotechnology/life sciences, and government.

### a. Board Members

Set forth below are biographies of the ten-member Board. Seven Board members have extensive experience in the healthcare industry, all have extensive business and/or executive experience, and one has extensive experience in government.

Maneesh K. Arora, Senior Vice President, Chief Operating Officer and Director, has served as Chief Operating Officer of the Company since February 2012 and as a Senior Vice President since April 2009 when he joined Exact Sciences. Mr. Arora also served as Chief Financial Officer of the Company from April 2009 to August 2013. Like Mr. Conroy, Mr. Arora was associated with TWT prior to joining Exact Sciences. During his tenure at TWT, Mr. Arora served as Chief Financial Officer and also undertook business strategy and commercial operations responsibilities. Mr. Arora began his career at Kraft Foods as a financial analyst and held several positions of increasing responsibility during his nine years at Kraft.

Thomas D. Carey has served as a Director since April 2013. Mr. Carey is the founder and Managing Director of Perspective Group, LLC, a human capital and executive search firm serving the healthcare industry. Previous to his position with Perspective Group, Mr. Carey was associated with Spencer Stuart, a global executive search firm, from 2010 through 2015, where he was responsible for leading the firm’s global efforts in providing board services to companies within all segments of the healthcare market. Prior to his tenure with Spencer Stuart, Mr. Carey was associated with Russell Reynolds Associates from 2001 to 2010 where he served as a Partner and Co-Head of the firm’s Global Life Sciences Practice. Mr. Carey also has served as an investment banker and Chief Financial Officer for private and public healthcare and information technology companies.

Eli Casdin has served as a Director since October 2017. Mr. Casdin founded Casdin Capital, LLC, a life sciences and healthcare investment company, in 2011 and has served as Chief Investment Officer and Managing Partner since its founding. Prior to founding Casdin Capital, Mr. Casdin was Vice President at Alliance Bernstein from 2007 to 2011 where he researched investment implications of new technologies for the life sciences and healthcare sectors. Prior to that, Mr. Casdin served as a research analyst at Bear Stearns and Cooper Hill Partners, specializing in healthcare investments in life sciences tools, diagnostics and medical devices.

Kevin T. Conroy, Chief Executive Officer and Chairman of the Board, has served as President and Chief Executive Officer of the Company since April 2009, as a Director since March 2009, and as Chairman of the Board since March 2014. Prior to joining Exact Sciences, Mr. Conroy was associated with Third Wave Technologies, Inc. (“TWT”), a molecular diagnostics company, where he served in several capacities, including as President and Chief Executive Officer (December 2005 to July 2008) and General Counsel. Prior to joining TWT,

Mr. Conroy served as intellectual property counsel at GE Healthcare, a medical imaging and diagnostics company and a division of General Electric Company. Before joining GE Healthcare, Mr. Conroy was Chief Operating Officer of two early-stage venture-backed technology companies. Mr. Conroy's professional career also includes experience as an intellectual property litigator for McDermott Will & Emery and Pattishall, McAuliffe, Newbury, Hilliard and Geraldson.

James E. Doyle has served as a Director since July, 2014 and was previously a two-term governor of the State of Wisconsin from 2003 to 2011, the state's 44th governor. Gov. Doyle is currently Of Counsel at Foley & Lardner LLP, an international law firm, as well as partner of Doyle & Boyce Strategies, a consulting firm to several national foundations. Prior to his gubernatorial service, Gov. Doyle served three terms as Wisconsin Attorney General from January 1991 to January 2003, during which time he also served as President of the National Association of Attorneys General (1997 to 1998). His government service also included a position as the District Attorney of Dane County, Wisconsin.

John A. Fallon, M.D. has served as a Director since January 2016. Dr. Fallon has previously served as Senior Vice President and Chief Physician Executive at Blue Cross Blue Shield of Massachusetts ("Blue Cross") from 2004 through 2015. Prior to his role at Blue Cross, Dr. Fallon served as Chief Executive Officer for clinical affairs at the State University of New York Downstate Medical Center. His professional experience also includes the Partners Healthcare System, where he was chairman of the physician network. Dr. Fallon was also the founder and Chief Executive Officer of North Shore Health System, a large physician-hospital organization in Massachusetts. Dr. Fallon serves on the Boards of Directors of several public and not-for-profit companies and various professional organizations. Dr. Fallon has practiced internal medicine for more than 20 years.

Daniel J. Levangie has served as a Director since July 2010. Mr. Levangie, an executive with operating experience in the field of medical devices and in vitro diagnostics, is co-founder and manager of ATON Partners, a private investment and management consulting firm. Mr. Levangie also served as President of Insulet Delivery Solutions. Prior to co-founding ATON Partners, Mr. Levangie was Chief Executive Officer of Dune Medical Devices, Inc. and co-founder and managing partner of Constitution Medical Investors, Inc., a Boston-based private investment and product development firm acquired by Roche Diagnostics Corporation in July 2013. Mr. Levangie has held a variety of executive management positions at Cytoc Corporation, Cytoc Health Corporation, and Cytoc Surgical Products Division. He has also held a number of sales, marketing, and management positions with Abbott Laboratories. Mr. Levangie is currently a Director of CereVasc, LLC and Dune Medical, Inc., and has previously served as a Director of several public diagnostic, medical device, and surgical products companies.

David A. Thompson has served as a Director since July 2010 and as lead independent Director since March 2014. Previously, Mr. Thompson was the Chairman and lead independent Director of TWT. Mr. Thompson was a 30-year veteran of Abbott Laboratories where he retired from in 1995. Mr. Thompson held several corporate officer positions at Abbott Laboratories, including Senior Vice President and President diagnostic division, Vice President Human Resources, Vice President corporate materials management and Vice President operations. He has also served as lead Director of St. Jude Medical, Inc., a medical technology and services



company, and as a Director of each of Hycor Biomedical, Inc., a medical diagnostic products company, LifeCell Corporation, a biological products company, NABI, a biopharmaceutical company, and TriPath Imaging, Inc., an automated imaging company.

Michael S. Wyzga, has served as a Director since February, 2015. Previously, from December 2011 to November 2013, Mr. Wyzga has served as the President and Chief Executive Officer and a Director of Radius Health, Inc., a biopharmaceutical company. Prior to that, Mr. Wyzga served in various senior management positions at Genzyme Corporation, a global biotechnology company. Mr. Wyzga is an independent healthcare consultant and currently serves as Chairman of the Board of Directors of Gensight Biologics S.A., a clinical-stage biologics company, a director of Akebia Therapeutics, Inc., a pharmaceutical company, and Oncomed Pharmaceuticals, Inc., a pharmaceutical company. He also has previously served as a Director of various public biotechnology and pharmaceutical companies.

Katherine S. Zanotti has served as a Director since April 2009. Ms. Zanotti is the Chief Executive Officer of Arbonne International. Ms. Zanotti has also served the Chairman of Natural Products Group (the holding company of Arbonne, Natures Gate, and Levlad). From July 2002 to March 2006, Ms. Zanotti was a member of management of several well-known public companies, such as McDonald's Corporation and the Proctor & Gamble Company. Ms. Zanotti currently serves on the Board of Trustees of Xavier University and Director of the following companies: Hill-Rom Holdings, Inc., a worldwide manufacturer and provider of medical technologies and related services, Mentor Corporation, a medical device company, Alberto Culver Company, a personal care products company, and TWT.

b. Executive Management Team

Set forth below are the biographies of the Company's executive management team.

Kevin T. Conroy - See above.

Maneesh K. Arora - See above.

Graham P. Lidgard, Ph.D. has served as Exact Sciences' Senior Vice President and Chief Science Officer since joining the Company in August 2009. Dr. Lidgard joined Exact Sciences from Nanogen Inc., a medical diagnostics products company, where he was Senior Vice President of research and development from 2003 to 2009. Prior to joining Nanogen, Dr. Lidgard led the research and development organization at Gen-Probe Inc., a molecular diagnostics company. Prior to joining Gen-Probe in 1995, Dr. Lidgard was co-founder and Vice President of product development of Matritech Inc., a developer of diagnostic products for the early detection of bladder cancer. Before he co-founded Matritech, Dr. Lidgard held senior positions at Ciba Corning Diagnostics Corp.'s worldwide diagnostics group.

Jeffrey T. Elliott joined Exact Sciences in June 2016 and has served as Chief Financial Officer since November 2016. Prior to his appointment as Chief Financial Officer, Mr. Elliott served as the Company's Vice President, Business Development and Strategy, from June 2016 to November 2016. Prior to joining the Company, Mr. Elliott was with Robert W. Baird & Co., where he was a senior research analyst covering diagnostics and life-science tools companies.

Earlier in his career, Mr. Elliott worked in a supply chain role for Walgreens and as a consultant at Cap Gemini Ernst & Young.

D. Scott Coward has served as Exact Sciences' Senior Vice President, General Counsel and Secretary since joining the Company in January 2015. He was previously with K&L Gates LLP, an international law firm, where he practiced corporate and securities law and served as managing partner of the Raleigh, NC office. Prior to his tenure at K&L Gates, Mr. Coward served as General Counsel of Blue Rhino Corporation, a leading supplier of consumer propane-related products. Previous to that, Mr. Coward served as an Associate General Counsel at GE Medical Systems in Milwaukee, WI, and as a partner at the Raleigh, NC law firm Smith Anderson Blount Dorsett Mitchell & Jernigan LLP.

## 2. State of the Market for Exact Sciences' Business

Exact Sciences operates in the healthcare sector, a market with a capitalization of approximately \$4.8 trillion. This market is comprised of several industries (or subsectors), including, among others, the biotechnology and life-sciences industries,<sup>4</sup> and generally includes companies involved in R&D, production, and marketing of pharmaceuticals, diagnostic and biotechnology products. Exact Sciences has historically focused its business activities on cancer screening, with a view to becoming a leading cancer screening and diagnostics company. The Company has disclosed that the market for colorectal cancer and pre-cancer screening is large, consisting of more than 85 million Americans age 50 and above. Given the potential for significant market demand, Exact Sciences pursued strategic opportunities to develop a screening test for colorectal cancer and pre-cancer. These efforts culminated in the development of Cologuard®, a patient-friendly, non-invasive stool-based DNA screening test for colorectal cancer and pre-cancer, which received approval by the U.S. Food and Drug Administration ("FDA") and Medicare coverage in 2014. The Company is currently commercializing Cologuard®.

The healthcare sector is highly competitive and heavily regulated. Companies competing in this sector generally need significant liquid capital to finance their operations and meet high production, commercialization, and regulatory costs. Part of these high costs is attributable to R&D. Successful healthcare companies often spend a significant proportion of their revenues on R&D in order to bring a product to market. The FDA, the primary regulator of the biotechnology industry, establishes strict protocols and quality controls for medical products under its jurisdiction. The process and time commitment to bring products through the FDA's strict approval process also contribute to high costs.

What's more, healthcare companies can experience low success rates due to a wide variety of factors, including: failure of a development program to yield a product that achieves its desired clinical objectives, high costs of development, failure of a product to obtain required regulatory approval or clearance, failure of a product to obtain reimbursement necessary to

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According to the Global Industry Classification Standard ("GICS"), the biotechnology industry, which is a subsector of the healthcare sector, includes companies primarily engaged in R&D, manufacturing and/or marketing of products<sup>4</sup> based on genetic analysis and genetic engineering. The biotechnology industry's total market capitalization is approximately \$1.03 trillion.

support its commercialization, and failure of a product to generate the necessary physician or patient demand or acceptance. Statistically, biotechnology companies can experience significant odds against successful launch and commercialization as they shepherd a product through all the required clinical trial stages before production and marketing may commence. Therefore, the Company's success in this market depends on a number of factors, including the success and efficiency of its R&D program, its ability to secure and maintain intellectual property, its operating capacity and efficiency, and its marketing efforts for a completed product, all of which require working capital and the astute management of its balance sheet through business cycles to meet operating and regulatory costs. To meet these challenges, Exact Sciences maintains substantial current assets (\$513.7 million as of September 30, 2017) to finance its operations. The Company has experienced an accumulated deficit of more than \$838 million since its founding as it has worked to develop and commercialize a non-invasive colorectal screening test. Although the commercial launch of Cologuard® has been highly successful,<sup>5</sup> the Company is still not profitable and still does not generate positive cash flow. Accordingly, it still depends on raised capital to finance current operations and continued growth. The Company has successfully raised capital through various public securities offerings and has financed its R&D, operations, and commercialization of Cologuard®, in large part, with the proceeds from these offerings. As the Company prepares to deploy its capital to commercialize Cologuard® and develop future products, the Company also makes targeted, conservative investments in, among other things, capital preserving financial instruments, such as government securities,<sup>6</sup> investment-grade corporate debt, investment-grade asset-backed securities, commercial paper, certificates of deposits ("CDs"), and various cash items (collectively, "Capital Preservation Assets"). The Company's strategy with regard to such investments emphasizes liquidity and preservation of capital to ensure that funds are available -- and available when needed -- to support its business operations.

### 3. Current and Future Product Lines

#### a. Cologuard®

As noted above, the Company currently produces, and has prioritized the commercialization of, Cologuard®. According to the Company's annual report, colorectal cancer is the second leading cause of cancer deaths in the United States and the leading cause of cancer deaths in the United States among non-smokers. Colorectal cancer treatment represents a significant, growing healthcare cost, with projected annual treatment costs of \$20 billion by

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<sup>5</sup> The Company's revenues have grown rapidly from \$39 million in 2015, to \$99 million in 2016, and to \$179 million through the third quarter of 2017.

The Company invests in the securities of government-sponsored enterprises or "GSEs." The Commission staff has issued a series of no-action letters that confirmed that the securities of GSEs are government securities. See, e.g.,  
<sup>6</sup> Federal National Mortgage Association, SEC No-Action Letter (pub. avail. May 6, 1971) ("Fannie Mae" securities are government securities); Federal Home Loan Mortgage Corporation, SEC No-Action Letter (pub. avail. July 24, 1971) ("Freddie Mac" securities are government securities). See also Investment Company Act Release No. 10666 (April 18, 1979) ("Ginnie Mae" securities are government securities).

2020. Cologuard® is intended to address incidence of colorectal cancer by providing an accurate, non-invasive, patient-friendly screening test for the early detection of colorectal cancer and pre-cancer.

On August 11, 2014, the FDA approved Cologuard® for use as the first and only stool-based DNA non-invasive colorectal cancer screening test. Since the 2014 launch of Cologuard®, the Company expanded sales, marketing, and customer service capabilities to support the newly approved product. In particular, Exact Sciences hired a large field and inside sales force and initiated a significant public relations effort to promote the product to patients in the United States by targeted direct-to-patient campaigns on social media, print, and other means. Additionally, the Company began a national television advertising campaign on cable television networks. The Company expects to continue its advertising and marketing campaigns for Cologuard® over the long term. In no instance during this marketing campaign is there any inference or indication that the Company is an investment company. The marketing of Cologuard® has increased the Company's overall, annual non-R&D expenses by 219% for the fiscal year ended 2016 compared to the fiscal year ended 2014 when Cologuard® obtained FDA approval. The Company's rise in media advertising costs alone went from \$5.3 million for 2014 year-end, to \$10.8 million for 2015 year-end, and to \$38.1 million for 2016 year-end. For the first nine months of 2017, ended September 30, sales and marketing of Cologuard® had already accounted for \$113.3 million. The effect of these increased promotional expenses has been to reduce R&D expenses in proportion to overall expenses, while R&D expenses in absolute dollar terms have generally increased or remained steady. The Company expects to increase funding for R&D for other products, while also funding the active commercialization of Cologuard®.

Also in support of Cologuard®, the Company expanded its customer-service infrastructure by leasing a state-of-the-art, automated lab facility. The facility, which is certified pursuant to the Clinical Laboratory Improvement Amendments ("CLIA"), contains approximately 50,000 square feet of laboratory use for processing and providing patient test results. The Company estimates that this facility is able to support one million cancer-screening tests annually, with capabilities to expand the number of processed tests in the future as the users of Cologuard® increase. The lab is subject to production and quality standards and FDA periodic examinations to ensure satisfaction of quality-control standards. The Company also is planning a second laboratory, having closed in November on the acquisition of property for redevelopment in order to construct a second lab, and other operational facilities. Thus, the current operation and anticipated operation of these facilities add to the Company's overall, non-R&D expenses. The Company expects to continue funding the expansion of its facilities to keep pace with the rapidly growing demand for Cologuard®, as well as to support future products and services.

#### b. Product Pipeline

The Company also expects to increase funding of its R&D program, insofar as it is seeking strategic opportunities and other product-development initiatives, with a particular focus on lung cancer. According to the American Cancer Society ("ACS"), approximately 223,000 Americans this year will be diagnosed with lung cancer, and 156,000 cases will prove fatal. The Company believes it can successfully leverage its existing Cologuard® technology platform to develop additional cancer diagnostic test, and expects to make significant investments in R&D to

expand diagnostic testing capabilities for several major cancers. The Company's continued collaboration with the MAYO Foundation for Medical Education and Research ("MAYO") also is a key component of this strategic business plan.<sup>7</sup> In the near term, Exact Sciences seeks to leverage its relationship with MAYO to develop new screening and diagnostic tests, with a goal of becoming a leader in cancer diagnostics. Already, the strategic work with MAYO has identified markers for several major cancers, and the Company recently has performed validation studies on tissue and blood samples for several major cancers. The Company also recently completed a 400 patient study as part of its efforts to develop a new cancer diagnostic test.

Exact Sciences' ongoing investment in its product pipeline demonstrates that the business of Exact Sciences has fundamentally remained the same since its founding in 1995; it is an operating company, with robust R&D capabilities. Even though overall expenses related to the commercialization of Cologuard® has increased to reduce the ratio of R&D expenses to the Company's overall expenses, the Company's strategic plan is to continue developing and commercializing state-of-the-art screening and diagnostic cancer tests.

Stated differently, although R&D expenses of the Company have generally increased or remained steady over time in absolute dollars, the Company's overall expenses have increased disproportionately as the Company becomes a seasoned producer of an established product. Thus, the Company expects to commit substantial resources to R&D, but does not expect R&D expenses to increase disproportionately in relation to overall expenses, as was the case in the past, because of the existence of increased expenses necessary for commercialization. As Cologuard® continues its development toward becoming a cash-flow positive product, the Company expects to increase its R&D expenditures in absolute terms. Because the operating expenses for Cologuard® are significant, the ratio of R&D expenses to the Company's overall expense, however, may not increase significantly over time.

#### 4. Regulation of Exact Sciences' Business

The Company's activities are subject to regulation and oversight consistent with other companies active in the healthcare sector. For instance, the Federal Food, Drug, and Cosmetic Act and rules regulate the development, marketing, labeling, promotion, manufacturing, and export of products, such as Cologuard®. Moreover, as a condition of the FDA's approval of Cologuard®, FDA regulations require manufacturing facility registration, product listing with the FDA, compliance with labeling requirements, maintenance of a satisfactory quality management system, and satisfaction of post-market surveillance requirements.

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Exact Sciences Development Company, LLC is party to a licensing agreement with MAYO that grants it an exclusive worldwide license to specified MAYO intellectual property and a non-exclusive worldwide license to <sup>7</sup>specified MAYO know-how, which covers any screening, surveillance, or diagnostic test or tool for use with any form of cancer, pre-cancer, disease, or condition. MAYO has agreed to make professionals available for purposes of supporting R&D through 2020.

The Centers for Medicare & Medicaid Services (“CMS”) oversee the Company’s Madison testing lab pursuant to the CLIA. The Company’s lab is also subject to state law oversight. The CLIA and laws of certain of the states (i) impose certification requirements for clinical laboratories, (ii) establish standards for quality assurance and quality control, and (iii) grant inspection authority of the lab to government regulators. Furthermore, the operation of the lab can implicate the Health Insurance Portability and Accounting Act of 1996 (“HIPAA”) to the extent the Company provides clinical laboratory testing services to, and enters into specified relationships with, companies deemed “covered entities” for purposes of HIPAA (i.e., health plans, healthcare clearinghouses, and healthcare providers). Very generally under HIPAA, “covered entities” and their “business associates” must establish protocols to protect against the misuse of individually identifiable health information.

The Company’s business is subject to (i) other privacy laws on the state and international level that regulate access to, and use and disclosure of, health information, and (ii) various antifraud and anti-corruption laws, such as the Federal False Claims Act and federal Anti-Kickback Statute.

#### B. Financing of Exact Sciences’ Business

The Company requires significant liquid capital primarily to: (i) advance commercialization of a product; (ii) make capital expenditures in keeping with the growth of the Company’s operating business; and (iii) fund R&D for new products. Exact Sciences has offered common stock and convertible notes, and incurred bank debt, to meet those three needs and to finance the expansion of its business.

Additionally, the Company’s success depends on its ability to generate revenues from the commercialization of Cologuard®. The Company is already reaping benefits in substantially increased revenues from its strategic marketing plan and capital expenditures to market Cologuard®. This success has depended on the following:

Acceptance of Cologuard® in the medical community;

Inclusion of Cologuard® in healthcare guidelines, such as those developed by ACS and U.S. Preventive Services Task Force;

Inclusion of Cologuard® in quality measures including the Healthcare Effectiveness Data and Information Set measures and CMS 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 and effectively keeping pace with product demand;

Successful sales, marketing, and educational programs, including successful direct-to-patient marketing such as television advertising;

The number of patients tested for colorectal cancer, as well as the number of patients who use Cologuard® for testing purposes;

Sufficient coverage and reimbursement by third-party payors, such as Medicare and Medicaid, which may depend in whole or in part on multiple factors,

including federal or state laws that mandate coverage for colorectal cancer screening and the extent to which those laws mandate coverage of Cologuard®;

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 the Company's ordering process for physicians;

Maintaining and defending patent protection for the intellectual property relevant to Cologuard®; and

The ability to establish and maintain adequate commercial manufacturing, distribution, sales and CLIA laboratory testing capabilities.

The Company experiences significant capital outlays to bring a product to market and maintain it once it successfully passes the R&D, clinical trial, FDA approval, and commercialization phases. The table below highlights expenditures for fiscal years 2012 through 2016 and for the nine-month period ended September 30, 2017:

	Cash-Based Operating Expenditures (\$ in millions)	Change From Prior Year	Cash-Based Operating Expenditures as % of Beginning Cash and Short-Term Investments
2012	\$50.3	76%	54%
2013	\$41.7	(17)%	39%
2014	\$87.1	109%	65%
2015	\$172.7	98%	61%
2016	\$233.2	35%	76%
Three Fiscal Quarters Ended 9/30/17	\$239.8	41%	77%

#### 1. R&D

Exact Sciences' business depends on its ability to successfully develop and market new and timely products and technologies. Exact Sciences believes it must continue to make

\* "Cash-Based Operating Expenditures" means (I) the sum of (a) cost of sales and (b) operating expenses (including research and development, sales and marketing, and general and administrative expenses), less (II) the sum of (a) stock-based compensation and (b) depreciation and amortization of fixed assets and intangible assets, all as disclosed on Exact Sciences' consolidated statements of operations and consolidated statements of cash flows.

\*\* "Beginning Cash and Short-Term Investments" means the sum of cash and cash equivalents and marketable securities, as disclosed on Exact Sciences' consolidated balance sheet as of the end of the immediately preceding calendar year end.

\*\*\* Comparison is made to the three fiscal quarters ended September 30, 2016.

substantial investments in R&D and in its marketing efforts. Over the past five years, the Company devoted nearly \$166 million to its R&D efforts, which on average for that same five-year period accounted for approximately 41% of the Company's overall expenses<sup>8</sup>. The table below depicts the R&D expenses<sup>9</sup> for fiscal years 2012 through 2016, and for the nine month-period ended September 30, 2017, the Company's total expenses over the same period and the change in R&D expenses from year to year.

Fiscal Year	R&D Expenses	Change From Prior Year	R&D Expense as % of Total Expenses	R&D Expense as % Beginning Cash and Short-Term Investments
2012	\$ 42.1MM	91%	74%	45%
2013	\$ 27.7MM	(34)%	54%	26%
2014	\$ 28.7MM	4%	28%	22%
2015	\$ 33.9MM	18%	17%	12%
2016	\$ 33.5MM	(1)%	12%	11%
Three Fiscal Quarters Ended 9/30/17	\$29.5MM	12%***	11%	9%

Exact Sciences' investments in R&D allowed it develop Cologuard® and will allow it to develop additional tests for other types of cancer, with the goal of becoming a leader in cancer screening and diagnostics. The Company will continue its R&D to develop, test, and obtain FDA approval consistent with the Company's business strategy and mission.

Exact Sciences expects that its R&D expenditures will continue to cycle up and down over the period required to take a product from a concept to commercialization. The Company

<sup>8</sup> To protect its R&D investments and competitive advantage, Exact Sciences has obtained a number of patents in the United States. In addition to patents, Exact Sciences also possesses other proprietary intellectual property, including trademarks, know-how, trade secrets, and copyrights.

<sup>9</sup> R&D expenses are research and development expenses as defined in Statement of Financial Accounting Standards No. 2.

\* "Total Expenses" means the sum of cost of sales and operating expenses (including research and development, general and administrative, and sales and marketing expenses), all as disclosed on Exact Sciences' consolidated statements of operations.

\*\* "Beginning Cash and Short-Term Investments" means the sum of cash and cash equivalents and marketable securities, as disclosed on Exact Sciences' consolidated balance sheet as of the end of the immediately preceding calendar year end.

\*\*\* Comparison is made to the three fiscal quarters ended September 30, 2016.



anticipates that R&D expenses will be especially high at certain points in the development cycle, including when the Company is conducting clinical trials, and will be lower at other points, including when the Company is concentrating on commercializing a recently launched screening or diagnostic test. The entire cycle, however, is capital intensive.

## 2. Sales and Marketing

The successful commercialization of Cologuard® depends on a robust sales and marketing program. In this connection the Company increased its sales and marketing and general administrative expenses by \$49.6 million during 2016, while its R&D expenses have remained relatively steady, decreasing slightly by approximately \$400,000. The Company expects to continue devoting significant expenditures to its Cologuard® sales and marketing.

## 3. Capital Expenditures

Exact Sciences made substantial capital expenditures in connection with its operating business. The table outlines forth purchases of capital assets (net of retirements) used to support Exact Sciences' long-term growth during fiscal years 2012 through 2016, and the nine-month period ended September 30, 2017:

Fiscal Year	Net Capital Expenditures (in millions)	Change From Prior Year	Net Capital Expenditures as % of Beginning Cash and Short Term Investments
2012	\$1	67%	1%
2013	\$9	1229%	9%
2014	\$12	29%	9%
2015	\$20	68%	7%
2016	\$15	-26%	5%
Three Fiscal Quarters Ended 9/30/17	\$24	100%**	8%

These capital expenditures included the acquisition of a new R&D building for approximately \$4.8 million in 2015. As previously noted, the Company recently closed on the acquisition of property for redevelopment and construction of a second clinical lab and other operational facilities. These recent expenditures in 2017 were necessary to keep pace with the demand for Cologuard® and the growth of the Company.

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\* "Beginning Cash and Short-Term Investments" means the sum of cash and cash equivalents and marketable securities, as disclosed on Exact Sciences' consolidated balance sheet as of the end of the immediately preceding fiscal year.

\*\* Comparison is made to the three fiscal quarters ended September 30, 2016.

#### 4. Other Cash Outlays

The Company has made other recent significant operating expenditures that support its business, such as a small acquisition of an information technology company and an acquisition of previously-licensed intellectual property. It anticipates it could make other strategic investments that would be closely related to the Company's business. Lastly, as noted, the Company has experienced substantial expenditures in television advertising of Cologuard® and has invested a significant amount of capital in the growth of its sales force.

#### C. The Life-Sciences/Biotech Industries Are Highly Cyclical

In addition to being capital intensive and regulated, the life-sciences and biotech industries are subject to business cycles, the timing, length and volatility of which are difficult for the Company to predict. This generally relates to the cycle of development, clinical testing, approval, and launch. In each stage, the Company will need sufficient cash to finance a product through the different cycles.

#### D. Exact Sciences' Cash Management Guidelines

As noted, Exact Sciences has financed operations primarily through offerings of its debt and equity securities, but ultimately seeks to generate cash from operations to support its business. To the extent that it makes investments, it does so to preserve capital necessary to fund R&D and operations. The Company believes it makes prudent investments for these purposes and to this end, the Company's investment strategy is to preserve capital and maintain liquidity, pending the use of capital for its current and future operations, while achieving a reasonable rate of return that is expected to be greater than the return obtainable by investing exclusively in cash and government obligations. When it makes securities investments, Exact Sciences invests in fixed-income securities that are rated investment grade.<sup>10</sup> Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates the designation as of each balance sheet date. Debt securities carried at amortized cost are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Marketable debt securities not classified as held-to-maturity are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive income. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the straight-line method. Such amortization is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in investment income. The cost of securities sold is based on the specific identification method.

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The Company's securities investments are considered "capital preservation investments," as defined in Rule 3a-8, meaning "an investment that is made to conserve capital and liquidity until funds are used in the issuer's primary business or businesses." One of the conditions to reliance on Rule 3a-8 requires investments in securities be "capital preservation investments," with limited de minimis other investments. 17 C.F.R. §270.3a-8(a)(4). The Company may make de minimis strategic investments consistent with Rule 3a-8, meaning that no more than 10% of investments can be in "other investments" that are not capital preservation investments. 17 C.F.R. §270.3a-8(a)(4)(i).

Interest and dividends on securities classified as available-for-sale are included in investment income.

As of September 30, 2017 and year-end at December 31, 2016, all of the Company's marketable securities were deemed available-for-sale. The objectives of the Company's investment strategy are to provide liquidity and safety of principal while striving to achieve the highest rate of return consistent with these two objectives. The Company's investment policies provide for investments in which the Company has the ability and intent, if necessary, to liquidate for purposes of financing the Company's current operations. For these reasons, and consistent with its historical reliance on Rule 3a-8 under the 1940 Act, the Company does not invest more than 10% of its assets in securities other than in Capital Preservation Assets.

The Company primarily recognizes revenues from performing screening services using the Cologuard® test. As of September 30, 2017, the Company's revenues were \$178.6 million, which represents a substantial increase from the \$64.1 million it recognized during the same nine-month period in 2016. For the nine-month period, ended September 30, 2017, the Company recognized investment income of \$2.6 million from its Capital Preservation Assets, an approximately \$1.2 million increase for the same nine-month period in 2016. The increase in investment income was due to an increase in the average cash and marketable securities held on the Company's balance sheet, as well as an increase in the average rate of return. Regardless of this increase, investment income nevertheless continued to be less than 1% of revenues and was also less than 1% of expenses attributable to the Company's R&D!<sup>11</sup> The Company expects investment to decline as a percentage of revenues as the market for Cologuard® expands.

### III. REASON FOR REQUESTING RELIEF

As the evidence above bears out, Exact Sciences since inception has actively engaged in the business of developing and distributing cancer screening and testing technologies. In order to compete successfully in its market sector, the Company requires capital to finance its R&D, secure intellectual property, conduct marketing, and commercialize its products and services. To this end, the Company holds "investment securities" on its balance sheet, which historically, and currently, exceed 40% of the Company's total assets on an unconsolidated basis, as prescribed by the Asset Test. Because of the nature of the Company's business and investments, it has historically relied on Rule 3a-8 under the 1940 Act in not registering with the Commission as an investment company. Rule 3a-8 prescribes an exclusion from the definition of "investment company" in recognition that R&D companies may not technically qualify as operating companies outside of the Asset Test because of their need to invest a significant portion of their capital in securities for purposes of financing their R&D and operational activities. Rule 3a-8 sets forth seven conditions for reliance. These conditions require that: (i) R&D expenses be "substantial"<sup>12</sup> in

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<sup>11</sup> The relation of investment income to R&D expenses complies with Rule 3a-8. Rule 3a-8 requires that net income derived from investments in securities not exceed twice the amount of a company's R&D expenses. 17 C.F.R. §270.3a-8(a)(2).

<sup>12</sup> In the adopting release to Rule 3a-8, the Commission left the term "substantial," unquantified, noting that a majority of expenses devoted to R&D certainly would be "substantial" and, under the facts and circumstances, less than a majority could be "substantial." for purposes of the rule. See Investment

comparison to overall expenses for the previous four quarters combined; (ii) net income from securities investments not exceed twice the amount of R&D expenses over the same period; (iii) expenses for investment management activities, investment research and custody, for the last four fiscal quarters, combined, not exceed 5% of a company's total expenses for the same period; (iv) any securities investments be predominantly in "capital preservation investments" based on prescribed characteristics denoting preservation versus speculation; (v) a company not hold itself out as being in the business of investing, reinvesting, and trading in securities; (vi) historical and current business of a company reflect activities other than investing, reinvesting, owning, holding, and trading in securities; and (vii) a company's Board of Directors adopt a policy reflecting the capital preservation nature of a company's securities investments.

The Company believes it complies with all the conditions of Rule 3a-8, but has raised concerns whether condition (i) above continues to be practical in light of changes to the Company's overall expenses in connection with the commercialization of Cologuard®, and whether, given the cyclical nature of R&D, the Company's R&D expenses, although substantial in absolute terms, may not be "substantial" as a ratio of overall expenses, particularly as overall expenses increase with the commercialization of completed products or down cycles for R&D.

Since the FDA's approval of Cologuard®, the Company has devoted more resources to sales and marketing, thus causing a decline in the ratio of R&D expenses to overall expenses. For example, R&D expenses, as a ratio of total expenses, has declined from a high of 74% of total expenses in 2012 to approximately 12% of total expenses for year-end 2016, and approximately 11% for the nine-month period ended September 30, 2017. In absolute terms, however, R&D expenses are substantial and have increased or remained steady, even as Cologuard® progressed through the R&D lifecycle to an FDA-approved product currently subject to a sales and marketing program.

Inasmuch as Rule 3a-8 does not prescribe a specific "bright-line" to determine when R&D expenses are "substantial," the Commission staff has agreed that a 20% threshold would be substantial for purposes of the rule,<sup>13</sup> thus potentially raising the implication that R&D expenses at a lower rate may not be substantial, and thus outside of the rule.

Because of this possible implication, continued reliance on Rule 3a-8 has become uncertain. Although the Company believes it complies with Rule 3a-8, it has taken a "belts-and-suspenders" approach and decided over the past six months to secondarily rely on Rule 3a-2 under the 1940 Act in an abundance of caution.<sup>14</sup> The Company acknowledges that its reliance

Company Act Release 26077 (June 16, 2003) (adopting Rule 3a-8). A little more than four years after adopting Rule 3a-8, the Commission staff granted no-action relief to a company relying on Rule 3a-8 where its R&D expenses were 20% of overall expenses. See Cooley Godward Kronish LLP, SEC No-Action Letter (pub. avail. July 12, 2007). This 20% benchmark serves generally as an industry "bright line," with the implication that R&D expenses below the 20% threshold may not be substantial. See, *infra*, notes 25 and 26 and accompanying text (orders for R&D companies whose R&D expenses are less than 20% of overall expenses).

<sup>13</sup> See, *supra*, note 12.

Rule 3a-2 under the 1940 Act prescribes an exclusion for "transient" investment companies whose assets exceed the

<sup>14</sup> 40% threshold in the Asset Test, provided that a company operate outside of the Asset Test on a temporary basis (no more than one year) and the company's Board issues a resolution to make bona fide attempts to be in compliance with the Asset Test within one year. A company may permissibly rely on

on Rule 3a-2 is temporary because of the one-year sunset provision in the rule. It seeks to rely secondarily on Rule 3a-2 while it seeks an order from the Commission under Section 3(b)(2) of the 1940 Act declaring that Exact Sciences is an operating company, and not an “investment company,” or is otherwise seeking alternative formal guidance from the Commission or its staff that Exact Sciences is not an investment company. The requested order, if granted, would provide much needed certainty for Exact Sciences and permit it to continue managing its balance sheet consistent with prudent investment guidelines for purposes of preserving capital to finance future R&D programs and the successful commercialization of Cologuard® and future products, all of which are consistent with the Company’s strategic mission of becoming a leader in cancer screening and diagnostics.

As the discussion below bears out, Exact Sciences has never been, is not now, and does not propose to be primarily engaged in the business of “investing, reinvesting, owning, holding, or trading in securities” within the meaning of the Business Test and the Asset Test. Therefore, Exact Sciences submits this Application for an order pursuant to Section 3(b)(2) of the 1940 Act to confirm that Exact Sciences is not an “investment company” and to resolve any uncertainty as to the Company’s continued and clear status as an operating company.

#### IV. DISCUSSION

##### A. Introduction

Section 3(b)(2) of the 1940 Act authorizes the Commission to grant an order declaring that an issuer is primarily engaged in a business other than that of investing, reinvesting, owning, holding, or trading in securities, either directly or through majority-owned subsidiaries or through controlled companies conducting similar types of business.

The Company qualifies for such an order because its business consists of developing, testing, and marketing cancer and pre-cancer diagnostic screening tests. That is the Company’s sole business. The Company’s need for liquid capital to conduct its business means that it, in part, makes investments in certain securities exceeding 40% of the Company’s total assets (exclusive of government securities and cash items) on an unconsolidated basis. Pursuant to Section 3(a)(1)(C) of the 1940 Act, the Company technically satisfies the Asset Test as an “investment company” absent an exclusion or exemption.

Because of the extent of the Company’s securities holdings, it has historically relied on the exclusion from the definition of “investment company” in Rule 3a-8 under the 1940 Act, and continues to rely on it, although with less certainty in light of significantly increased sales and marketing expenses, as well as expenses necessary to keep pace with market demand for Cologuard®. That is, the ratio of R&D expenses to overall expenses has fluctuated more recently as Cologuard® has exited the R&D phase to the commercialization phase; however, the Company’s business has not fundamentally changed. It continues to be primarily engaged in business as an operating company focused on developing and commercializing screening and diagnostic tests for the early detection and prevention of cancer. It is not a company whose

Rule 3a-2 once in a three-year period. The Company does not rely on Rule 3a-1 under the 1940 Act because it expects to hold securities in excess of the 45% test under Rule 3a-1.

business is primarily engaged in investing, reinvesting, owning, holding, and trading in securities.

**B. Definition of Investment Company**

A company is an “investment company” and required to register with the Commission if it is an “issuer” and (i) “is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting, or trading in securities,”<sup>16</sup> or (ii) “it is engaged or proposes to engage in the business of investing, reinvesting, owning, holding or trading in securities, and it owns or proposes to acquire investment securities having a value exceeding 40 per centum of the value of such issuer’s total assets (exclusive of Government securities and cash items) on an unconsolidated basis.”<sup>17</sup>

Section 3(a)(2) defines “investment securities” as “all securities except (A) Government securities, (B) securities issued by employees’ securities companies, and (C) securities issued by majority-owned subsidiaries of the owner which (i) are not investment companies, and (ii) are not relying on the exception from the definition of investment company in [Sections 3(c)(1) or 3(c)(7) of the 1940 Act].” Section 2(a)(16) defines “government securities” as those securities issued or guaranteed by the United States or its authorized instrumentality.<sup>18</sup> The 1940 Act does not define the term “cash items,” although the Commission staff has interpreted cash items to include shares of registered money market funds qualified under Rule 2a-7 under the 1940 Act that seek to maintain a stable net asset value equal to \$1.00 per share.<sup>19</sup> The Company’s cash items are held in bank deposits or shares of money market funds qualified under Rule 2a-7; therefore, those holdings are subtracted from the Asset Test calculation.

Notwithstanding the application of the Asset Test, an issuer may nevertheless be excluded from the definition of “investment company” if it is “primarily engaged, directly or through a wholly-owned subsidiary or subsidiaries, in a business or businesses other than that of investing, reinvesting, owning, holding, or trading in securities;”<sup>20</sup> or if the Commission grants an order pursuant to Section 3(b)(2). The 1940 Act does not define or otherwise establish clear benchmarks depicting the meaning of “primarily engaged,” leaving the meaning to the Commission to determine on a case-by-case basis pursuant to Section 3(b)(2). By its terms Section 3(b)(2) relates to the activities of both the parent and its majority-owned subsidiaries.<sup>21</sup> Although Section 3(b)(2) prescribes an exemption only from the Asset Test, the operative “primarily engaged” language of Section 3(b)(2) has been interpreted consistently with the

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Section 2(a)(22) of the 1940 Act defines “issuer” for these purposes to mean any natural person or company that “issues or proposes to issue any security, or has outstanding any security which is issued. 15 U.S.C. §80a-2(a)(22).<sup>15</sup> Exact Sciences is an issuer because, as of October 27, 2017 it had 119,730,401 shares of common stock outstanding.

<sup>16</sup> 15 U.S.C. §80a-3(a)(1)(A).

<sup>17</sup> 15 U.S.C. §80a-3(a)(1)(C).

<sup>18</sup> 15 U.S.C. §80a-2(a)(16). See, supra, note 6 regarding status of GSE securities as government securities.

<sup>19</sup> Willkie Farr & Gallagher, SEC No-Action Letter (Oct. 23, 2000).

<sup>20</sup> 15 U.S.C. §80a-3(b)(1).

<sup>21</sup> See *Tonopah Mining*, at 26 S.E.C. 426 (1947).

similar language of the Business Test.<sup>22</sup> Accordingly, a Section 3(b)(2) order by its terms would declare that a company is not an “investment company” for both the Business Test and the Asset Test.

Thus, the primary inquiry, under either the Business Test or the Asset Test, is whether the Company’s business as an operating company, including the financing of its business, constitutes primarily engaging in investing, reinvesting, owning, holding, or trading in securities, rendering it an “investment company” within the meaning of the 1940 Act. The factors enumerated in Tonopah Mining are key to differentiating operating companies from investment companies. The five-factor Tonopah Mining test looks to: (i) a company’s historical development; (ii) its public representations of policy; (iii) the activity of its officers and directors; (iv) the nature of its present assets; and (v) the sources of its present income. As is evident in the discussion below, the application of the Tonopah Mining factors compels the conclusion that Exact Sciences is not an investment company.

### C. Application of the Tonopah Mining Test

#### 1. Historical Development of Exact Sciences

Beginning in 1995, when the Company was founded, to the present, Exact Sciences has operated in the healthcare sector to develop state-of-the-art cancer screening and diagnostic tests. Below is a brief compilation of the Company’s historical development:

In 1995, Exact Sciences was founded.

In February 2001, Exact Sciences conducted an initial public offering of its common stock.

From 1995 to 2008, the Company developed and commercialized a first-generation, non-invasive colorectal screening test.

In March 2009, Exact Sciences “rebooted” with a new executive team, relocated from Massachusetts to Wisconsin, and began its R&D for a second-generation colorectal screening test.

In July 2010, the Company made a presentation at the American Association for Clinical Chemistry which demonstrated that its new methylation detection technology achieved 100% sensitivity and specificity in colorectal cancer tissue. In October 2010, results of Exact Sciences validation study were released at the American Association for Cancer Research meeting.

In July 2011, the Company in July continued its R&D work in the production of Cologuard® by beginning enrollment for the DeeP-C Study at a pivotal clinical trial stage; and in November the Company presented data from a second validation study at the Association for Molecular Pathology annual meeting.

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<sup>22</sup> The Commission has recognized that “a determination under Section 3(b)(2) . . . that an issuer primarily is engaged in a noninvestment business also means that it is not an investment company under Section 3(a)(1)(A).” Investment Company Act Release No. 19566 (July 15, 1993) (proposing Rule 3a-8 under the 1940 Act). Rule 3a-8 expressly extends its exclusion to both Section 3(a)(1)(A) and Section 3(a)(1)(C). 17 C.F.R. §270.3a-8(a).

In 2012, Exact Sciences presented its finding on colorectal cancer and pre-cancer detection rates at the American Association for Cancer Research Frontiers in Cancer Prevention meeting. The Company also completed enrollment of the DeeP-C clinical trial, which was the largest privately funded study of its kind for colorectal cancer screening, with an enrollment of more than 12,700 subjects. At the end of 2012, Exact Sciences submitted the first module of the premarket approval application to the FDA for its colorectal cancer screening test.

In April 2013, Exact Sciences announced DeeP-C clinical trial preliminary top-line results.

In March and April of 2014, results from the DeeP-C pivotal clinical study were published online in the New England Journal of Medicine. Also in March 2014, the FDA Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee determined by a unanimous vote of ten to zero that Exact Sciences demonstrated safety, effectiveness and a favorable risk benefit profile of Cologuard®. The FDA then approved Cologuard® in August 2014.

In October 2014, CMS issued a decision effecting national coverage for Cologuard®.

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®).

In October 2016, the National Committee for Quality Assurance included Cologuard® testing on a three-year interval in the 2017 Healthcare Effectiveness Data and Information Set (HEDIS) measures. More than 90% of America’s health plans measure quality based on HEDIS.

In April 2017, CMS included Cologuard® in its updated 2018 Medicare Advantage Star Ratings program. Medicare Advantage plans are eligible to receive quality credit under the Star Ratings program for Cologuard® tests completed in 2014 or later.

Since 2001, the Company has made a number of separate securities offerings, and in each, the offering disclosure was clear that the Company was an operating company focused on developing cancer screening tests.

The Company’s historical progression clearly shows that it primarily engages in the development and commercialization of cancer-screening tests, not in the business of investing, reinvesting, owning, holding, and trading in securities.

## 2. Exact Sciences’ Public Presentation of Policy

Exact Sciences has never held, and does not now hold, itself out as an investment company within the meaning of the 1940 Act. In its annual reports, stockholder letters, prospectuses, Commission filings, press releases, marketing materials, and on its web site ([www.exactsciences.com](http://www.exactsciences.com)), the Company’s public presentations consistently state its mission to eradicate colorectal cancer, with a goal of becoming a leader in cancer screening and diagnostics. The Company has never held itself out in any advertisement or otherwise as an investment



company or any company primarily engaged in a business of deriving value and performance from the successful management of a portfolio of securities.

Virtually all of the Company's press releases are for the purpose of announcing new products, strategic alliances or acquisitions, customer-related matters, quarterly financial results, or changes in executive management, all pertaining to the Company's relevance as a cancer screening and diagnostics company. Exact Sciences has never represented any activities other than developing and commercializing cancer screening technologies. Additionally, Exact Sciences emphasizes operating results, not its investment income, the possibility of returns primarily from the implementation of investment strategies, or performance returns as a material factor in its business or future growth. Indeed, the only public representations that Exact Sciences makes regarding its investment securities are those required to be disclosed in public filings with the Commission. For example, in its most recent Form 10-Q, the Company discloses its "marketable securities" and its "investment income" as part of its quarterly financial presentation, not as a marketing initiative, but as a regulatory matter as a public reporting company subject to periodic disclosures pursuant to the Securities Exchange Act of 1934.

Accordingly, it is clear from the Company's public Commission filings and its other public presentations that shareholders invest in the Company's securities with an expectation of realizing gains from the Company's development and commercialization of cancer-screening and diagnostic technologies, and not from returns on an investment portfolio.

### 3. Activities of Exact Sciences' Officers and Directors

Exact Sciences' directors and officers spend substantially all of their time managing the Company's operating business. As the biographies above clarify, the Company's management and corporate governance structure is comprised of professionals who have been leaders, or gained expertise, in technology, science, medicine, life science/biotechnology, and government. These professionals are devoted to the operating business of the Company. None of the members of management or the Board has spent or proposes to devote more than 1% of his or her time, even if that, to any securities investment activities on behalf of the Company. They, along with the approximately 1,235 full-time employees, are dedicated to the production and commercialization of Cologuard®, and the development of new cancer screening and diagnostic products.

The Company outsources certain of its treasury functions related to managing investments, and has retained a national bank to manage its Capital Preservation Assets. It, therefore, has no officers, directors, or employees who spend any time managing portfolio assets. The cost of asset management and related services for 2016 was \$395,088, which accounts for less than 2% of all expenses for the Company. The Company does not expect this figure to increase materially over the long term. Not surprisingly, securities investment expenses are miniscule in comparison to the Company's overall expenses because of the Company's fundamental nature as an operating company.

#### 4. Nature of Exact Sciences' Assets

The Company's consolidated balance sheet discloses fixed and current assets consistent with an operating business. As of September 30, 2017, these assets include property and equipment (valued at cost), as follows: computer equipment and software of \$27.3 million; laboratory equipment of \$20.4 million; leasehold improvements of \$14.2 million; assets under construction of \$20.9 million; buildings, including office and laboratory space of \$4.8 million; furniture and fixtures, \$3.2 million; and other long-term assets of \$17.8 million. With the recent capital expenditures on a new lab and redevelopment and acquisition of a new headquarters, these assets are expected to increase. Certain current assets, valued as of September 30, 2017, include accounts receivable of \$24.6 million in connection with the Company's commercialization of Cologuard®, inventory of \$18.1 million also consistent with those efforts, and pre-paid expenses and other assets of \$8.6 million. These operating assets (less depreciation of \$35 million for property and equipment) totaled approximately \$159.9 million collectively.

The Company's remaining assets are consistent with an R&D company that must retain liquid assets to finance its business. As the Commission is aware, the asset composition of R&D companies does not precisely reflect their operating aspects because significant investments in R&D are made for extended periods during which the company may have limited or no income. The Commission acknowledged that these companies depend on securities investments, in part, to finance operations.<sup>23</sup> In recognition of their unique nature, particularly that R&D expenses and related "intellectual capital" are not recognized as permissible assets for purposes of the 1940 Act, the Commission believed a different asset test should apply to R&D companies. The alternative asset test for R&D companies looks at (i) the use of investment securities to finance R&D and operations, (ii) the significance of R&D expenses and the insignificance of investment expenses, and (iii) the nature of the company's investments for capital preservation purposes.<sup>24</sup>

The asset mix of Exact Sciences is no different than a typical R&D company. The Company maintains robust cash management assets, including marketable securities, in order to fund its R&D and operations. These assets, as of September 30, 2017, include cash and cash equivalents of \$50.8 million and marketable securities of \$411.7 million, all comprised of Capital Preservation Assets. The Company's investment guidelines for capital preservation require marketable securities to carry investment-grade credit ratings. Based on these guidelines, the Company holds corporate bonds, asset-backed securities, government securities, commercial paper, CDs and shares in money market funds. For the nine-month period, ended September 30, 2017, of the \$411.7 million of marketable securities, approximately \$65.0 million are invested in government securities. Government securities, along with the Companies holdings of cash and cash items, would be excluded from the Asset Test, thus giving the Company investment securities accounting for approximately 65% of its total assets in accordance with the calculation methodology of the Asset Test. Consistent with R&D companies, Exact Sciences uses current assets, including its

<sup>23</sup> See Investment Company Act Release No. 26077 (June 16, 2003), adopting Rule 3a-8 under the 1940 Act.

Investment Company Act Release Nos. 19274 (Feb. 18, 1993) (notice); and 19334 (Mar. 16, 1993) (March 22, 1993) (order) (the "ICOS Order"). The Commission granted the ICOS Order to a company that recognized investment revenues constituting 50-67% of its overall revenues and investment securities accounting for 67% of the company's total assets. The Commission ultimately codified the principles of the ICOS Order in Rule 3a-8.

investments in marketable securities, to finance its continued R&D program and operations in connection with the commercialization of Cologuard®. The Company's investment policies in this regard are clearly and consistently disclosed in public filings with the Commission and are implemented in compliance with Rule 3a-8.

Even with the increased focus on distributing Cologuard®, Exact Sciences will continue to devote substantial resources to R&D creating R&D expenses that, although expected to increase in absolute dollars in the future, are not expected to increase as a ratio of overall expenses. As revealed above, R&D expenses in dollar terms have increased or remained relatively steady, even after the FDA approved Cologuard® in 2014; \$28.7 million in 2014; \$33.9 million in 2015, and \$33.5 million in 2016. The costs of commercializing Cologuard®, however, have risen sharply over the same period, \$38.9 million in 2014, \$82.1 million in 2015, and \$112.8 million in 2016. For the nine-month period ended September 30, 2017, the Company has already incurred sales and marketing expenditures of \$113.3 million, which accounts for more than half of the Company's overall expenses for that period. R&D, by the same token, has remained steady at \$29.5 million for the same period, but decreased to approximately 11% of overall expenses for the nine months ended September 30, 2017 and 12% for the previous year end. The Company, however, has not fundamentally changed, and its changed expense structure is not due to incurring transaction costs in connection with the investment, reinvestment, and trading in a portfolio of securities or otherwise in connection with hiring investment management professionals to manage a portfolio of securities. The changed expense structure is directly attributable to the Company's successful R&D for Cologuard® and the current priority of successfully bringing Cologuard® to market.

Further, investment income remains an insubstantial metric by which the Company is measured. Although investment income has increased over the past year, it still accounts for less than 1% of the bottom line, compared with R&D expenses and revenues recognized from the commercialization of Cologuard®. The Company's investment income is merely reflective of R&D companies that carry securities investments on their balance sheets to finance R&D and current operations, a principle the Commission has recognized by adopting Rule 3a-8 and by granting Section 3(b)(2) orders to others whose R&D expenses have experienced similar cyclical declines as a proportion of overall expenses similar to Exact Sciences.

For example, the Commission granted an order in *In the Matter of RealNetworks, Inc.*<sup>25</sup> to RealNetworks, Inc., a digital media and software company, excluding it from the 1940 Act. Notably, RealNetworks proposed to own investment securities accounting for as much as 79% of its total assets, while at the same time arguing for status as an R&D company in which it had R&D expenses that accounted for 18% of its total expenses in its most recent year end prior to seeking a Commission order. Furthermore, RealNetworks proposed to hold as much as 10% of its investment securities portfolio in securities that were not considered to be "capital preservation investments." In contrast, Exact Sciences has always invested solely in Capital Preservation Assets, although it may make strategic investments in the future in "other investments" consistent with Rule 3a-8.

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<sup>25</sup> RealNetworks, Inc., Investment Company Act Release No. 27888 (July 24, 2007) (Order); and Investment Company Act Release No. 27877 (June 28, 2007) (Notice).

In another similar case, also having precedential value to the matter at hand, the Commission granted an order in *In the Matter of Applied Materials, Inc.*<sup>26</sup> to Applied Materials, Inc., a supplier of integrated circuit fabrication equipment and services, excluding it from the 1940 Act. Applied Materials failed the Asset Test by owning investment securities constituting approximately 50% of its total assets, while devoting a significant portion of its expenses to R&D, with 16% of its total expenses attributable to R&D in the fiscal year most recent to the Commission's Section 3(b)(2) order. Like RealNetworks and Applied Materials, the Company experiences fluctuations in its R&D expenses given the cyclical nature of its business. Like those predecessors, those fluctuations do not change the fundamental nature of the Company's primary business. Indeed, this Application does not raise any novel issues in its request for relief and is consistent with other orders granted pursuant to Section 3(b)(2) to companies having substantial investment securities assets, but whose businesses clearly are operating businesses not to be confused with an investment company.<sup>27</sup>

#### 5. Exact Sciences' Sources of Income and Nature of Exact Sciences' Revenues

Exact Sciences earns revenues from the performance of Cologuard® testing at its clinical laboratory. For the year ended December 31, 2016, the Company earned approximately \$99.4 million attributable to Cologuard®, and for the nine-month period ended September 30, 2017, Cologuard® revenues were \$178.6 million, which reflect sharp increases in revenue due to the success of the product. The nature of the Company's revenues is clearly evidence of a strategy of successful expenditures on R&D, sales, and marketing of a screening test that has successfully completed the rigors of the R&D phase. Investment income is substantially smaller. The Company earned \$2 million in investment income in 2016, and has earned \$2.6 million for the nine-month period ended September 30, 2017. In each case, these figures are insignificant compared to the upward trend in the revenues generated from the commercialization of Cologuard® and the potential earnings from other cancer screening and diagnostics tests that the Company is seeking to develop.

These numbers alone are compelling testimony of the Company's focus as an operating company. Namely, the Company is experiencing sharp increases in its earnings potential now that it has completed the primary R&D process for Cologuard®.

<sup>26</sup> Applied Materials, Inc., Investment Company Act Release No. 27114 (Oct. 12, 2005) (Order); and Investment Company Act Release No. 27064 (Sep. 13, 2005) (Notice).

See, e.g. *In the Matter of Corvis Corporation*, Investment Company Act Rel. No. 25804 (Nov. 18, 2002) (order); and Investment Company Act Rel. No. 25774 (Oct. 21, 2002) (notice); *In the Matter of Russian Telecommunications Development Corp.*, Investment Company Act Rel. No. 25298 (Nov. 26, 2001) (order); and Investment Company Act Rel. No. 25249 (Oct. 31, 2001) (notice); *In the Matter of Yahoo!, Inc.*, Investment Company Act Rel. No. 24494 (June 13, 2000) (notice); *In the Matter of Air Touch Communications, Inc.*,

<sup>27</sup> Investment Company Act Rel. No. 24294 (Feb. 23, 2000) (order); and Investment Company Act Rel. No. 24271 (Jan. 28, 2000) (notice); *In the Matter of Global TeleSystems Group, Inc.*, Investment Company Act Rel. No. 23895 (July 7, 1999) (order); and Investment Company Act Rel. No. 23864 (June 9, 1999) (notice); *In the Matter of VIH Latin America, Inc.*, Investment Company Act Rel. No. 23399 (Aug. 25, 1998) (order); and Investment Company Act Rel. No. 23367 (notice); and *In the Matter of Microsoft Corporation*, Investment Company Act Rel. No. 16467 (July 5, 1988) (order); and Investment Company Act Rel. No. 16430 (June 10, 1988) (notice).

D. Subjecting Exact Sciences to the 1940 Act Serves No Public Policy

The Company is regulated consistent with its current operations in the healthcare sector, and applying the regulatory regime of the 1940 Act to the Company would not be consistent with the functional operation of a biotechnology/life sciences company. Rather, the Company is more suitably regulated by the FDA and CMS. Consistent with its core business, the FDA establishes stringent protocols to bring a product to market and imposes continuing quality control standards on the production and distribution of the Company's products. The CMS through CLIA sets standards for the operation of the Company's labs, and subjects them to periodic examination. As a public reporting company, Exact Sciences is subject to continuing public disclosure and financial reporting with the Commission. It is subject to Nasdaq listing standards. The 1940 Act's registration and governance requirements do not appear to qualitatively add to the regulatory oversight of the Company's operations. Indeed, registration and regulatory oversight by the 1940 Act would be mismatched to the Company's primary business of developing and commercializing cancer screening and diagnostic tests, and certain of the 1940 Act's provisions could severely hinder the Company's successful operations by impeding access to financing, restricting the payment of incentives to attract and hire quality professionals, or prohibiting potential business strategies with affiliates or potential joint ventures.

Moreover, Exact Sciences is similarly situated to RealNetworks and Applied Materials, each of which obtained orders pursuant to Section 3(b)(2), declaring that they were not investment companies. Similar to those companies, Exact Sciences maintains investment securities in excess of the 40% benchmark prescribed by the Asset Test, but clearly conducts a business that would not be confused with the business of an investment company where shareholders seek profits from the investment and trading in a portfolio of securities. Rather, the value to be derived from an investment in the Company depends on its continued R&D program to bring new products to the market, as well as its continued commercialization of Cologuard®. Therefore, shareholder value is not derived from the performance of a portfolio of securities. Similarly, like RealNetworks and Applied Materials, the decline in the Company's R&D expenses is due to the cyclical nature of the Company's operating business and not attributable to a fundamental change in the Company's strategic mission.

Because the Company relies on its holdings of Capital Preservation Assets, in part, to finance its R&D and operations, application of the Asset Test on its holdings would be a misleading indicator of the Company's true mission and its priority to become a leader in cancer screening and diagnostics. A requirement to change the Company's balance sheet is unnecessary and would be a burdensome impediment to the Company's continued R&D program and product marketing. More importantly, a required reallocation of the Company's balance sheet would create a precedential imbalance where similarly situated companies are treated differently under the 1940 Act.<sup>28</sup> Namely, the Commission did not require those companies to significantly change their balance sheets based on a technical application of the Asset Test. Rather, the Commission's orders recognize the substantive function of those companies' operations rather than the form their balance sheets took. Like those other orders reveal, an order granted to the Company would recognize that Exact Sciences is primarily engaged in an operating business, not

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<sup>28</sup> See, supra, notes 25-27.

an investment management business recognizing value from investing, reinvesting, owning, holding, and trading in securities.

V. RELIEF REQUESTED

For the above reasons, Exact Sciences respectfully requests an order of the Commission, pursuant to Section 3(b)(2) of the 1940 Act, declaring that it is primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities. Exact Sciences acknowledges that any order of the Commission issued on this Application will not apply retroactively.

VI. CONDITIONS

Exact Sciences agrees that any order granting the requested relief will be subject to the following conditions:

1. Exact Sciences will continue to allocate and use its accumulated cash and investment securities for bona fide business purposes; and
2. Exact Sciences will refrain from investing or trading in securities for short-term speculative purposes.

VII. PROCEDURAL MATTERS

A. Communications

Pursuant to Rule 0-2(f) under the 1940 Act, Exact Sciences states that its address is 441 Charmany Drive, Madison, Wisconsin 53719. Exact Sciences further states that all communications or questions should be directed to Jeffrey T. Elliott, Chief Financial Officer, Exact Sciences Corporation, 441 Charmany Drive, Madison, Wisconsin 53719, with a copy of written communications to each of (a) D. Scott Coward, Senior Vice President, General Counsel and Corporate Secretary, Exact Sciences Corporation, 441 Charmany Drive, Madison, Wisconsin 53719, and (b) C. Dirk Peterson, Esq., K&L Gates LLP, 1601 K Street NW, Washington, D.C. 20006.

B. Authorization

Pursuant to Rule 0-2(c)(1) under the 1940 Act, Exact Sciences hereby states that the officer signing this Application on its behalf is fully authorized to do so, that under the provisions of its Certificate of Incorporation, responsibility for the management of its affairs and business is vested in its Board of Directors, that by resolution (a copy of which is attached as Exhibit B), the Board of Directors has authorized any officer to prepare or cause to be prepared and to execute and file with the Commission the Application and any amendments thereto, and that Exact Sciences has complied with all requirements for the execution and filing of this Application in its name and on its behalf.

C. Proposed Notice

The proposed notice of the proceeding initiated by the filing of this Application required by Rule 0-2(g) under the 1940 Act is attached as Exhibit C hereto.

D. Verification

The verification required by Rule 0-2(d) under the 1940 Act is attached as Exhibit D hereto.

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Exact Sciences requests that the Commission issue an order without a hearing pursuant to Rule 0-5 under the 1940 Act.

January 30, 2018 Respectfully submitted,

EXACT SCIENCES CORPORATION

By: /s/ D. Scott Coward  
Name: D. Scott Coward  
Title: Senior Vice President,  
General Counsel, and Secretary



EXHIBIT LIST

Exhibit A. Quarterly Report on Form 10-Q for the nine-month period ended September 30, 2017

Exhibit B. Secretary's Certificate and Resolutions of the Board of Directors of Exact Sciences Corporation

Exhibit C. Proposed Form of Notice

Exhibit D. Verification

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EXHIBIT A

FORM 10-Q

A-1

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

FORM 10-Q

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

For the quarterly period ended September 30, 2017

OR

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

Commission File Number: 001-35092

EXACT SCIENCES CORPORATION  
(Exact name of registrant as specified in its charter)

DELAWARE	02-0478229
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

441 Charmany Drive, Madison WI	53719
(Address of principal executive offices)	(Zip Code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Emerging growth company

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

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

As of October 27, 2017, the registrant had 119,730,401 shares of common stock outstanding.

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EXACT SCIENCES CORPORATION

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## Part I — Financial Information

## EXACT SCIENCES CORPORATION

## Condensed Consolidated Balance Sheets

(Amounts in thousands, except share data - unaudited)

	September 30, 2017	December 31, 2016
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 50,837	\$ 48,921
Marketable securities	411,684	262,179
Accounts receivable, net	24,553	8,526
Inventory, net	18,064	6,833
Prepaid expenses and other current assets	8,551	7,114
Total current assets	513,689	333,573
Property and Equipment, at cost:		
Computer equipment and computer software	27,374	20,767
Laboratory equipment	20,352	14,749
Leasehold improvements	14,200	13,549
Assets under construction	20,868	6,711
Buildings	4,792	4,792
Furniture and fixtures	3,156	2,515
	90,742	63,083
Less—Accumulated depreciation	(35,036)	(24,941)
Net property and equipment	55,706	38,142
Other long-term assets, net	17,784	5,325
Total assets	\$ 587,179	\$ 377,040
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 8,774	\$ 710
Accrued liabilities	38,390	28,106
Debt, current portion	180	174
Other short-term liabilities	2,345	1,702
Total current liabilities	49,689	30,692
Long-term debt	4,511	4,633
Other long-term liabilities	5,611	5,734
Lease incentive obligation, less current portion	224	686
Total liabilities	60,035	41,745
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at September 30, 2017 and December 31, 2016	—	—
Common stock, \$0.01 par value Authorized—200,000,000 shares issued and outstanding—119,590,733 and 110,236,127 shares at September 30, 2017 and	1,196	1,102

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December 31, 2016

Additional paid-in capital	1,365,112	1,080,432
Accumulated other comprehensive loss	(314)	(418)
Accumulated deficit	(838,850)	(745,821)
Total stockholders' equity	527,144	335,295
Total liabilities and stockholders' equity	\$ 587,179	\$ 377,040

The accompanying notes are an integral part of these condensed consolidated financial statements.

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## EXACT SCIENCES CORPORATION

## Condensed Consolidated Statements of Operations

(Amounts in thousands, except per share data - unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Laboratory service revenue	\$72,574	\$28,115	\$178,583	\$64,135
Cost of sales	20,729	12,174	55,701	31,330
Gross margin	51,845	15,941	122,882	32,805
Operating expenses:				
Research and development	11,725	7,625	29,464	26,391
General and administrative	30,763	20,292	75,442	55,400
Sales and marketing	37,768	26,308	113,297	82,320
Total operating expenses	80,256	54,225	218,203	164,111
Loss from operations	(28,411)	(38,284)	(95,321)	(131,306)
Other income (expense)				
Investment income	1,334	535	2,612	1,426
Interest expense	(51)	(54)	(155)	(161)
Total other income	1,283	481	2,457	1,265
Net loss before tax	(27,128)	(37,803)	(92,864)	(130,041)
Income tax benefit	231	—	231	—
Net loss	\$(26,897)	\$(37,803)	\$(92,633)	\$(130,041)
Net loss per share—basic and diluted	\$(0.23)	\$(0.36)	\$(0.81)	\$(1.30)
Weighted average common shares outstanding—basic and diluted	119,215	104,807	114,246	100,006

The accompanying notes are an integral part of these condensed consolidated financial statements.



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EXACT SCIENCES CORPORATION  
 Condensed Consolidated Statements of Comprehensive Loss  
 (Amounts in thousands - unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Net loss	\$(26,897)	\$(37,803)	\$(92,633)	\$(130,041)
Other comprehensive loss, net of tax:				
Unrealized gain (loss) on available-for-sale investments	49	(145)	7	410
Foreign currency translation gain (loss)	16	(25)	97	(164)
Comprehensive loss	\$(26,832)	\$(37,973)	\$(92,529)	\$(129,795)

The accompanying notes are an integral part of these condensed consolidated financial statements.

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## EXACT SCIENCES CORPORATION

## Condensed Consolidated Statements of Cash Flows

(Amounts in thousands, except share data - unaudited)

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$(92,633)	\$(130,041)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of fixed assets	10,507	8,237
Loss on disposal of property and equipment	301	101
Deferred tax benefit	(231)	—
Stock-based compensation	23,002	16,773
Amortization of other liabilities	(1,199)	(713)
Amortization of deferred financing costs	40	40
Amortization of premium on short-term investments	56	412
Amortization of intangible assets	645	150
Changes in assets and liabilities, net of effects of acquisition:		
Accounts receivable, net	(15,663)	(2,930)
Inventory, net	(11,231)	(989)
Prepaid expenses and other current assets	(1,391)	1,702
Accounts payable	8,022	(973)
Accrued liabilities	9,306	5,453
Other short-term liabilities	(29)	—
Lease incentive obligation	(462)	(159)
Net cash used in operating activities	(70,960)	(102,937)
Cash flows from investing activities:		
Purchases of marketable securities	(345,039)	(151,456)
Maturities of marketable securities	195,485	142,813
Purchases of property and equipment	(24,442)	(12,166)
Business acquisition, net of cash acquired	(2,996)	—
Internally developed software	(25)	—
Purchased intangible assets	(8,442)	—
Net cash used in investing activities	(185,459)	(20,809)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	3,350	1,049
Proceeds from sale of common stock, net of issuance costs	253,389	144,247
Payments on mortgage payable	(130)	(124)
Proceeds in connection with the Company's employee stock purchase plan	1,629	1,048
Net cash provided by financing activities	258,238	146,220
Effects of exchange rate changes on cash and cash equivalents	97	(164)
Net increase in cash and cash equivalents	1,916	22,310
Cash and cash equivalents, beginning of period	48,921	41,135
Cash and cash equivalents, end of period	\$50,837	\$63,445

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Supplemental disclosure of non-cash investing and financing activities:

Property and equipment acquired but not paid	\$3,930	\$549
Unrealized gain on available-for-sale investments	\$ 7	\$410
Issuance of 158,717 and 341,507 shares of common stock to fund the Company's 401(k) matching contribution for 2016 and 2015, respectively	\$3,008	\$2,151
Interest paid	\$151	\$157

The accompanying notes are an integral part of these condensed consolidated financial statements.

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EXACT SCIENCES CORPORATION

Notes to Condensed Consolidated Financial Statements  
(Unaudited)

(1) ORGANIZATION AND BASIS OF PRESENTATION

Organization

Exact Sciences Corporation (“Exact” or the “Company”) was incorporated in February 1995. Exact is a molecular diagnostics company currently focused on the early detection and prevention of some of the deadliest forms of cancer. The Company has developed an accurate, non-invasive, patient-friendly screening test called Cologuard® for the early detection of colorectal cancer and pre-cancer, and is currently working on the development of tests for other types of cancer.

Basis of Presentation

The accompanying condensed consolidated financial statements, which include the accounts of Exact Sciences Corporation and those of its wholly owned subsidiaries, Exact Sciences Laboratories, LLC, Exact Sciences Finance Corporation, CG Growth, LLC, Sampleminded, Inc., Exact Sciences Europe LTD, Beijing Exact Sciences Medical Technology Company Limited, and variable interest entities are unaudited and have been prepared on a basis substantially consistent with the Company’s audited financial statements and notes as of and for the year ended December 31, 2016 included in the Company’s Annual Report on Form 10-K (the “2016 Form 10-K”). These condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) and follow the requirements of the Securities and Exchange Commission (“SEC”) for interim reporting. In the opinion of management, all adjustments (consisting only of adjustments of a normal and recurring nature) considered necessary for a fair presentation of the results of operations have been included. The results of the Company’s operations for any interim period are not necessarily indicative of the results of the Company’s operations for any other interim period or for a full fiscal year. The statements should be read in conjunction with the audited financial statements and related notes included in the 2016 Form 10-K. Management has evaluated subsequent events for disclosure or recognition in the accompanying financial statements up to the filing of this report.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company’s wholly owned subsidiaries, Exact Sciences Laboratories, LLC, Exact Sciences Finance Corporation, CG Growth, LLC, Sampleminded, LLC, Exact Sciences Europe LTD, Beijing Exact Sciences Medical Technology Company Limited, and variable interest entities. All significant intercompany transactions and balances have been eliminated in consolidation.

References to “Exact”, “we”, “us”, “our”, or the “Company” refer to Exact Sciences Corporation and its wholly owned subsidiaries.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### Cash and Cash Equivalents

The Company considers cash on hand, demand deposits in bank, money market funds, and all highly liquid investments with an original maturity of 90 days or less to be cash and cash equivalents.

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## Marketable Securities

Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates such designation as of each balance sheet date. Debt securities carried at amortized cost are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Marketable equity securities and debt securities not classified as held-to-maturity are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the straight-line method. Such amortization is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in investment income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

At September 30, 2017 and December 31, 2016, the Company's investments were comprised of fixed income investments, and all were deemed available-for-sale. The objectives of the Company's investment strategy are to provide liquidity and safety of principal while striving to achieve the highest rate of return consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. Investments in which the Company has the ability and intent, if necessary, to liquidate, in order to support its current operations (including those with a contractual term greater than one year from the date of purchase), are classified as current. All of the Company's investments are considered current. There were no realized losses for the nine months ended September 30, 2017 and 2016. Realized gains were \$17,000 and \$21,000 for the nine months ended September 30, 2017 and 2016, respectively.

We periodically review our investments in unrealized loss positions for other-than-temporary impairments. This evaluation includes, but is not limited to, significant quantitative and qualitative assessments and estimates regarding credit ratings, collateralized support, the length of time and significance of a security's loss position, our intent not to sell the security, and whether it is more likely than not that we will have to sell the security before recovery of its cost basis. For the nine months ended September 30, 2017, no investments were identified with other-than-temporary declines in value.

Available-for-sale securities at September 30, 2017 consisted of the following:

(In thousands)	September 30, 2017		Losses in Accumulated Other Comprehensive Income	Estimated Fair Value
	Amortized Cost	Gains in Accumulated Other Comprehensive Income		
Corporate bonds	\$213,058	\$ 27	\$ (80)	\$ 213,005
Asset backed securities	101,167	2	(56)	101,113
U.S. government agency securities	64,972	—	(103)	64,869
Commercial paper	20,894	2	(1)	20,895
Certificates of deposit	11,800	2	—	11,802
Total available-for-sale securities	\$411,891	\$ 33	\$ (240)	\$ 411,684





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Available-for-sale securities at December 31, 2016 consisted of the following:

(In thousands)	December 31, 2016		Losses in Accumulated Other Comprehensive Income	Estimated Fair Value
	Amortized Cost	Gains in Accumulated Other Comprehensive Income		
Corporate bonds	\$137,013	\$ 17	\$ (93)	\$ 136,937
Asset backed securities	55,667	3	(30)	55,640
U.S. government agency securities	49,591	3	(120)	49,474
Commercial paper	19,069	8	(1)	19,076
Certificates of deposit	1,053	—	(1)	1,052
Total available-for-sale securities	\$262,393	\$ 31	\$ (245)	\$ 262,179

## Changes in Accumulated Other Comprehensive Income (Loss)

The amounts recognized in accumulated other comprehensive income (loss) (“AOCI”) for the nine months ended September 30, 2017 were as follows:

(In thousands)	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Securities	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2016	\$ (204)	\$ (214)	\$ (418)
Other comprehensive loss before reclassifications	97	(3)	94
Amounts reclassified from accumulated other comprehensive loss	—	10	10
Net current period change in accumulated other comprehensive loss	97	7	104
Balance at September 30, 2017	\$ (107)	\$ (207)	\$ (314)

The amounts recognized in AOCI for the nine months ended September 30, 2016 were as follows:

(In thousands)	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Securities	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2015	\$ 11	\$ (444)	\$ (433)
Other comprehensive (loss) income before reclassifications	(164)	346	182
Amounts reclassified from accumulated other comprehensive loss	—	64	64
Net current period change in accumulated other comprehensive (loss) income	(164)	410	246
Balance at September 30, 2016	\$ (153)	\$ (34)	\$ (187)

Amounts reclassified from AOCI for the nine months ended September 30, 2017 and 2016 were as follows:

Details about AOCI Components (In thousands)	Affected Line Item in the Statement of Operations	Nine Months Ended September 30,	
		2017	2016
Change in value of available-for-sale investments			
Sales and maturities of available-for-sale investments	Investment income	\$ 10	\$ 64
Total reclassifications		\$ 10	\$ 64

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## Property and Equipment

Property and equipment are stated at cost and depreciated using the straight-line method over the assets' estimated useful lives. Maintenance and repairs are expensed when incurred; additions and improvements are capitalized. The estimated useful lives of fixed assets are as follows:

Asset Classification	Estimated Useful Life
Laboratory equipment	3 - 5 years
Computer equipment and computer software	3 years
Leasehold improvements	Lesser of the remaining lease term or useful life
Building Improvements	Lesser of the remaining building life or useful life
Furniture and fixtures	3 years
Buildings	30 years

At September 30, 2017, the Company had \$20.9 million of assets under construction which consisted of \$10.0 million related to machinery and equipment, \$8.0 million related to buildings and leasehold improvements, \$2.7 million related to computer equipment and computer software projects and \$0.2 million related to furniture and fixtures. Depreciation will begin on these assets once they are placed into service. The Company expects to incur an additional \$8.4 million to complete the machinery and equipment, \$11.9 million to complete the building and leasehold improvements, and minimal costs to complete the computer equipment and computer software projects and furniture and fixtures. These projects are expected to be completed in 2017 and 2018. There were no impairment losses for the periods ended September 30, 2017 and December 31, 2016.

## Software Capitalization Policy

Software development costs related to internal use software are incurred in three stages of development: the preliminary project stage, the application development stage, and the post-implementation stage. Costs incurred during the preliminary project and post-implementation stages are expensed as incurred. Costs incurred during the application development stage that meet the criteria for capitalization are capitalized and amortized, when the software is ready for its intended use, using the straight-line basis over the estimated useful life of the software.

## Patent Costs and Intangible Assets

Patent costs, which have historically consisted of related legal fees, are capitalized as incurred, only if the Company determines that there is some probable future economic benefit to be derived from the transaction. A capitalized patent is amortized over its estimated useful life, beginning when such patent is approved. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is either sold or deemed to be no longer of value to the Company. The Company determined that all patent costs incurred during the nine months ended September 30, 2017 should be expensed and not capitalized as the future economic benefit to be derived from the transactions cannot be determined.

Under a technology license and royalty agreement entered into with MDxHealth ("MDx"), dated July 26, 2010 (as subsequently amended, the "License Agreement"), the Company was required to pay MDx milestone-based royalties on sales of products or services covered by the licensed intellectual property. Once the achievement of a milestone occurred or was considered probable, an intangible asset and corresponding liability was reported in other long-term

assets and accrued liabilities, respectively. The intangible asset is being amortized over the estimated ten-year useful life of the licensed intellectual property through 2024, and such amortization is reported in cost of sales. The liability was relieved once the milestone was achieved and payment was made. Payment for all remaining milestones under the License Agreement was made as part of the Royalty Buy-Out agreement outlined below.

Effective April 25, 2017, the Company and MDx entered into a Royalty Buy-Out Agreement (“Royalty Buy-Out Agreement”), which terminated the License Agreement. Pursuant to the Royalty Buy-Out Agreement, the Company paid MDx a one-time fee of \$8.0 million in exchange for an assignment of certain patents covered by the License Agreement and the elimination of all ongoing royalties and other payments by the Company to MDx under the License

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Agreement. Also included in the Royalty Buy-Out Agreement is a mutual release of liabilities, which includes all amounts previously accrued under the License Agreement. Concurrently with entering into the Royalty Buy-Out Agreement, the Company entered into a Patent Purchase Agreement (“Patent Purchase Agreement”) with MDx under which it paid MDx an additional \$7.0 million in exchange for the assignment of certain other patent rights that were not covered by the License Agreement. The total \$15.0 million paid by the Company pursuant to the Royalty Buy-Out Agreement and Patent Purchase Agreement, net of liabilities relieved of \$6.6 million, was recorded as an intangible asset and is being amortized over the estimated ten-year useful life of the licensed intellectual property through 2024, and such amortization is reported in cost of sales. The \$6.6 million of liabilities relieved were related to historical milestones and accrued royalties under the License Agreement.

As of September 30, 2017, an intangible asset of \$9.4 million related to historical milestone payments made under the License Agreement and intangible assets acquired as part of the Royalty Buy-Out Agreement and Patent Purchase Agreement is reported in other long-term assets. As of December 31, 2016, an intangible asset of \$1.6 million and a liability of \$1.3 million related to historical milestone payments made under the License Agreement, were reported in other long-term assets and accrued liabilities, respectively. Amortization expense was \$0.3 million and \$0.1 million for the three months ended September 30, 2017 and September 30, 2016, respectively. Amortization expense was \$0.6 million and \$0.2 million for the nine months ended September 30, 2017 and September 30, 2016, respectively.

The estimated remaining useful life of the intangible asset is seven years. The table below represents future amortization expense as of September 30, 2017:

(In thousands)

2017	\$ 335
2018	1,338
2019	1,338
2020	1,338
2021	1,338
Thereafter	3,680
	\$9,367

The Company reviews long-lived assets and certain identifiable intangibles for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. There were no impairment losses for the periods ended September 30, 2017 and December 31, 2016.

#### Goodwill and Other Intangible Assets

##### Goodwill

As more fully described in Note 11, during the third quarter of 2017, the Company recognized goodwill of \$2.0 million from the acquisition of Sampleminded, Inc., which was completed during the period. The Company will evaluate goodwill impairment on an annual basis or more frequently should an event or change in circumstance occur that indicate the carrying amount is in excess of the fair value.

##### Other Intangible Assets

As a result of the Sampleminded acquisition, the Company recorded an intangible asset of \$1.0 million which was comprised of developed technology acquired of \$0.9 million, customer relationships of \$0.1 million, and non-compete agreements of \$32,000. The intangible assets acquired are being amortized over the remaining useful life which was determined to be eight years for developed technology acquired, thirteen years for customer relationships, and five years for non-compete agreements. As of September 30, 2017, the Company recorded \$20,000 in amortization expense.

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The table below represents estimated future amortization expense of these intangible assets as of September 30, 2017:

(In thousands)	
2017	\$ 30
2018	118
2019	118
2020	118
2021	118
Thereafter	449
	\$951

The Company reviews these identifiable intangibles for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets.

## Net Loss Per Share

Basic net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. Basic and diluted net loss per share are the same because all outstanding common stock equivalents have been excluded, as they are anti-dilutive due to the Company's losses.

The following potentially issuable common shares were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect due to net losses for each period:

(In thousands)	September 30,	
	2017	2016
Shares issuable upon exercise of stock options	4,042	5,080
Shares issuable upon the release of restricted stock awards	6,164	5,989
	10,206	11,069

## Revenue Recognition

**Laboratory Service Revenue.** The Company's laboratory service revenues are generated by performing screening services using our Cologuard test, and the service is completed upon delivery of a test result to an ordering physician. The Company recognizes revenue in accordance with the provisions of ASC 954-605, Health Care Entities - Revenue Recognition. The Company recognizes revenue on an accrual basis, net of contractual and other adjustments, when amounts that will ultimately be collected can be reasonably estimated. Contractual and other adjustments represent the difference between the list price (the billing rate) and the estimated aggregate reimbursement rate from payers and patients. Upon ultimate collection, the aggregate amount received from payers and patients where reimbursement was estimated is compared to previous collection estimates and, if necessary, the contractual allowance is adjusted.



The estimates of amounts that will ultimately be collected require significant judgment by management, and the Company's judgments will continue to evolve as it gains payment experience with payers and patients. Historically, in the absence of the ability to reasonably estimate the amount that will ultimately be collected for services, revenue was recognized upon cash receipt. Effective during the first quarter of 2017, the Company determined that it had the ability to reasonably estimate the amount that will ultimately be collected from all payers, including the impact of patient cost-share collections. Accordingly, the Company now recognizes revenue on an accrual basis for all billed claims.

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The components of laboratory service revenue, as recognized upon accrual or cash receipt, for the three and nine months ended September 30, 2017 and 2016 were as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue recognized on an accrual basis	\$72,574	\$24,510	\$174,074	\$57,592
Revenue recognized when cash is received	—	3,605	4,509	6,543
Total	\$72,574	\$28,115	\$178,583	\$64,135

## Inventory

Inventory is stated at the lower of cost or market value (net realizable value). The Company determines the cost of inventory using the first-in, first out method (“FIFO”). The Company estimates the recoverability of inventory by reference to internal estimates of future demands and product life cycles, including expiration. The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated net realizable value, and records a charge to cost of sales for such inventory, as appropriate. In addition, the Company's products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, the Company records a charge to cost of sales to write down such unmarketable inventory to its estimated net realizable value.

Direct and indirect manufacturing costs incurred during process validation and for other research and development activities, which are not permitted to be sold, have been expensed to research and development.

Inventory consists of the following:

(In thousands)	September 30, 2017	December 31, 2016
Raw materials	\$ 7,033	\$ 2,408
Semi-finished and finished goods	11,031	4,425
Total inventory	\$ 18,064	\$ 6,833

## Foreign Currency Translation

For the Company's international subsidiaries, the local currency is the functional currency. Assets and liabilities of these subsidiaries are translated into United States dollars at the period-end exchange rate or historical rates, as appropriate. Condensed consolidated statements of operations are translated at average exchange rates for the period. The cumulative translation adjustments resulting from changes in exchange rates are included in the condensed consolidated balance sheet as a component of accumulated other comprehensive loss in total Exact Sciences Corporation's stockholders' equity. Transaction gains and losses are included in the condensed consolidated statement of operations.

## Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation in the condensed consolidated financial statements and accompanying notes to the condensed consolidated financial statements.

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(3) MAYO LICENSE AGREEMENT

Overview

As more fully described in the 2016 Form 10-K, in June 2009 the Company entered into a patent license agreement with MAYO Foundation for Medical Education and Research (“MAYO”). The Company’s license agreement with MAYO was amended and restated in February 2015 and further amended in January 2016. Under the license agreement, MAYO granted the Company an exclusive, worldwide license to certain MAYO patents and patent applications, as well as a non-exclusive, worldwide license with regard to certain MAYO know-how. As expanded by the January 2016 amendment to the license agreement, the scope of the license includes any screening, surveillance or diagnostic tests or tools for use in connection with any type of cancers, pre-cancers, diseases or conditions.

Pursuant to the Company’s agreement with MAYO, the Company is required to pay MAYO a low-single-digit royalty on the Company’s net sales of products using the licensed MAYO intellectual property, with minimum annual royalty fees of \$25,000 each year through 2033, the year the last patent expires. The January 2016 amendment to the MAYO license agreement established various low-single-digit royalty rates on net sales of current and future products and clarified how net sales will be calculated. As part of the amendment, the royalty rate on the Company’s net sales of Cologuard increased and, if in the future, improvements are made to the Cologuard product, the royalty rate may further increase, but, pursuant to the terms of the January 2016 amendment, would remain a low-single-digit percentage of net sales.

In addition to royalties, the Company is required to pay MAYO cash of \$0.2 million, \$0.8 million and \$2.0 million upon each product using the licensed MAYO intellectual property reaching \$5.0 million, \$20.0 million and \$50.0 million in cumulative net sales, respectively.

As part of the February 2015 amendment and restatement of the license agreement, the Company agreed to pay MAYO an additional \$5.0 million, payable in five annual installments, through 2019. The Company paid MAYO the annual installment of \$1.0 million in the first quarter of each of 2015 and 2016. The Company paid MAYO the 2017 installment in December 2016. The Company records the \$1.0 million installments to prepaid expenses and other current assets and amortizes each installment over a twelve-month period commencing on February 1 of each year. For the three and nine months ended September 30, 2017 and 2016 the Company has recorded \$0.3 million and \$0.7 million in amortization of the installments, respectively.

In addition, the Company is paying MAYO for research and development efforts. As part of the Company’s research collaboration with MAYO, the Company incurred charges of \$1.1 million and \$3.2 million for the three and nine months ended September 30, 2017, respectively. The Company made payments of \$0.3 million and \$2.2 million for the three and nine months ended September 30, 2017, respectively. The Company recorded an estimated liability of \$1.9 million for research and development efforts as of September 30, 2017. The Company incurred charges of \$0.8 million and \$2.6 million for the three and nine months ended September 30, 2016, respectively. The Company made payments of \$1.0 million and \$3.3 million for the three and nine months ended September 30, 2016, respectively. The Company recorded an estimated liability of \$0.5 million for research and development efforts as of September 30, 2016.



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(4) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

The Company maintains the 2010 Omnibus Long-Term Incentive Plan (As Amended and Restated Effective July 27, 2017), the 2010 Employee Stock Purchase Plan, the 2015 Inducement Award Plan, the 2016 Inducement Award Plan and the 2000 Stock Option and Incentive Plan (collectively, the “Stock Plans”).

Stock-Based Compensation Expense

The Company records stock-based compensation expense in connection with the amortization of restricted stock and restricted stock unit awards, stock purchase rights granted under the Company’s employee stock purchase plan and stock options granted to employees, non-employee consultants and non-employee directors. The Company recorded \$10.8 million and \$23.0 million in stock-based compensation expense during the three and nine months ended September 30, 2017, respectively. The Company recorded \$6.2 million and \$16.8 million in stock-based compensation expense during the three and nine months ended September 30, 2016, respectively.

Determining Fair Value

Valuation and Recognition – The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. The fair value of each market measure-based award is estimated on the date of grant using a Monte Carlo simulation pricing model. The fair value of service-based awards for each restricted stock unit award is determined on the date of grant using the closing stock price on that day. The estimated fair value of these awards is recognized to expense using the straight-line method over the vesting period. For awards issued to non-employees, the measurement date is the date when the performance is complete or when the award vests, whichever is the earliest. Accordingly, non-employee awards are re-measured at each reporting period until the final measurement date. The fair value of the award is recognized as stock-based compensation expense over the requisite service period, generally the vesting period. The Black-Scholes and Monte Carlo pricing models utilize the following assumptions:

Expected Term – Expected life of an option award is the average length of time over which the Company expects employees will exercise their options, which is based on historical experience with similar grants. Expected life of a market measure-based award is based on the applicable performance period.

Expected Volatility - Expected volatility is based on the Company’s historical stock volatility data over the expected term of the awards.

Risk-Free Interest Rate - The Company bases the risk-free interest rate used in the Black-Scholes and Monte Carlo valuation models on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent expected term.

Forfeitures – Beginning in 2017, the Company adopted Accounting Standards Update (“ASU”) No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (“Update 2016-09”). With the adoption of Update 2016-09, forfeiture estimates are no longer required, and the effects of actual forfeitures are recorded at the time they occur. The impact on the condensed consolidated balance sheet was a cumulative-effect adjustment of \$0.4 million, increasing opening accumulated deficit and additional paid-in capital.



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The fair value of each option and market measure-based award is based on the assumptions in the following table:

	Three Months Ended		Nine Months Ended	
	September 30, 2017	2016	September 30, 2017	2016
<b>Option Plan Shares</b>				
Risk-free interest rates	2.06%	(1)	2.06% - 2.13%	1.48% - 1.69%
Expected term (in years)	6.56	(1)	6.56 - 6.59	6.25 - 6.74
Expected volatility	62.5%	(1)	62.5% - 62.9%	58.9% - 59.4%
Dividend yield	0%	(1)	0%	0%
Weighted average fair value per share of options granted during the period	\$ 27.03	(1)	\$ 25.18	\$ 3.17
<b>Market Measure-Based Shares</b>				
Risk-free interest rates	(2)	0.76%	(2)	0.76% - 0.91%
Expected term (in years)	(2)	2.43	(2)	2.43 - 2.84
Expected volatility	(2)	79.6%	(2)	68.3% - 79.6%
Dividend yield	(2)	0%	(2)	0%
Weighted average fair value per share of stock purchase rights granted during the period	(2)	\$ 13.42	(2)	\$ 3.77
<b>ESPP Shares</b>				
Risk-free interest rates	(3)	(3)	0.98% - 1.28%	0.41% - 0.8%
Expected term (in years)	(3)	(3)	0.5 - 2.0	0.5 - 2.0
Expected volatility	(3)	(3)	66.4% - 85.5%	70.1% - 92.7%
Dividend yield	(3)	(3)	0%	0%
Weighted average fair value per share of stock purchase rights granted during the period	(3)	(3)	\$ 13.05	\$ 3.08

(1) The Company did not grant options under its 2010 Stock Plan during the period indicated.

(2) The Company did not issue market measure-based shares during the respective period.

(3) The Company did not issue stock purchase rights under its 2010 Employee Stock Purchase Plan during the respective period.

#### Stock Option and Restricted Stock Activity

A summary of stock option activity under the Stock Plans during the nine months ended September 30, 2017 is as follows:



Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(1)
(Aggregate intrinsic value in thousands)				
Outstanding, January 1, 2017	3,505,481	\$ 7.00	5.5	
Granted	942,997	21.68		
Exercised	(382,967)	8.75		
Forfeited	(23,879)	14.19		
Outstanding, September 30, 2017	4,041,632	\$ 10.22	5.9	\$ 149,127
Exercisable, September 30, 2017	2,281,645	\$ 5.81	3.6	\$ 94,250

- The aggregate intrinsic value of options outstanding, exercisable and vested and expected to vest is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for options that had exercise prices that were lower than the \$47.12 market price of the Company's common
- (1)

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stock at September 30, 2017. The total intrinsic value of options exercised during the nine months ended September 30, 2017 and 2016 was \$11.2 million and \$5.6 million, respectively.

As of September 30, 2017, there was \$100.8 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all Stock Plans. Total unrecognized compensation cost will be adjusted for future forfeitures. The Company expects to recognize that cost over a weighted average period of 3.0 years.

A summary of restricted stock and restricted stock unit activity under the Stock Plans during the nine months ended September 30, 2017 is as follows:

	Restricted Shares	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2017	5,601,316	\$ 9.19
Granted	1,946,736	31.81
Released	(1,075,538)	14.14
Forfeited	(308,471)	18.60
Outstanding, September 30, 2017	6,164,043	\$ 15.16

**(5) FAIR VALUE MEASUREMENTS**

The Financial Accounting Standards Board has issued authoritative guidance which requires that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy. The fair value hierarchy establishes and prioritizes the inputs used to measure fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs. Observable inputs are inputs that reflect the assumptions that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

The three levels of the fair value hierarchy established are as follows:

Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2 Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3 Unobservable inputs that reflect the Company's assumptions about the assumptions that market participants would use in pricing the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available.

Fixed-income securities and mutual funds are valued using a third-party pricing agency. The valuation is based on observable inputs including pricing for similar assets and other observable market factors. There has been no material change from period to period. The estimated fair value of the Company's long-term debt based on a market approach was approximately \$4.5 million and \$4.6 million as of September 30, 2017 and December 31, 2016, respectively, and represent Level 2 measurements. When determining the estimated fair value of the Company's long-term debt, the Company used market-based risk measurements, such as credit risk.

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The following table presents the Company's fair value measurements as of September 30, 2017 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall.

(In thousands)	Fair Value at September 30, 2017	Fair Value Measurement at September 30, 2017 Using:		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents				
Cash and money market	\$ 30,837	\$30,837	\$ —	\$ —
U.S. government agency securities	20,000	—	20,000	—
Available-for-sale Marketable securities				
Corporate bonds	213,005	—	213,005	—
Asset backed securities	101,113	—	101,113	—
U.S. government agency securities	64,869	—	64,869	—
Commercial paper	20,895	—	20,895	—
Certificates of deposit	11,802	—	11,802	—
Total	\$ 462,521	\$30,837	\$ 431,684	\$ —

The following table presents the Company's fair value measurements as of December 31, 2016 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall.

(In thousands)	Fair Value at December 31, 2016	Fair Value Measurement at December 31, 2016 Using:		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents				
Cash and money market	\$ 48,921	\$48,921	\$ —	\$ —
Available-for-sale Marketable securities				
Corporate bonds	136,937	—	136,937	—
Asset backed securities	55,640	—	55,640	—
U.S. government agency securities	49,474	—	49,474	—
Commercial paper	19,076	—	19,076	—
Certificates of deposit	1,052	—	1,052	—
Total	\$ 311,100	\$48,921	\$ 262,179	\$ —

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The following table summarizes gross unrealized losses and fair values of our investments in an unrealized loss position as of September 30, 2017, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

(In thousands)	September 30, 2017		12 months or greater		Total Fair Value	Gross Unrealized Loss
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss		
Marketable securities						
Corporate bonds	\$131,782	\$(70)	\$14,717	\$(10)	\$146,499	\$(80)
Asset backed securities	93,585	(56)	—	—	93,585	(56)
Commercial paper	5,458	(1)	—	—	5,458	(1)
U.S. government agency securities	64,869	(103)	—	—	64,869	(103)
Total	\$295,694	\$(230)	\$14,717	\$(10)	\$310,411	\$(240)

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The following summarizes contractual underlying maturities of the Company's available-for-sale investments in debt securities at September 30, 2017:

(In thousands)	Due one year or less		Due after one year through four years	
	Cost	Fair Value	Cost	Fair Value
Marketable securities				
Corporate bonds	\$138,989	\$138,964	\$74,069	\$74,041
U.S. government agency securities	50,016	49,928	14,956	14,941
Commercial paper	20,894	20,895	—	—
Certificates of deposit	9,801	9,802	1,999	2,000
Asset backed securities	17,617	17,612	83,550	83,501
Total	\$237,317	\$237,201	\$174,574	\$174,483

**(6) NEW MARKET TAX CREDIT**

As more fully described in the 2016 Form 10-K, during the fourth quarter of 2014, the Company received approximately \$2.4 million in net proceeds from financing agreements related to working capital and capital improvements at one of its Madison, Wisconsin facilities. This financing arrangement was structured with an unrelated third party financial institution, an investment fund, and its majority owned community development entity in connection with the Company's participation in transactions qualified under the federal New Markets Tax Credit ("NMTC") program, pursuant to Section 45D of the Internal Revenue Code of 1986, as amended. The \$2.4 million was recorded in Other Long-Term Liabilities on the consolidated balance sheets. The benefit of this net \$2.4 million contribution will be recognized as a decrease in expenses, included in cost of sales, as the Company amortizes the contribution liability over the seven-year compliance period as it is being earned through the Company's on-going compliance with the conditions of the NMTC program. The Company has recorded \$0.1 million and \$0.3 million as a decrease of expenses for the three and nine months ended September 30, 2017, respectively. At September 30, 2017, the remaining balance of \$1.4 million is included in Other Long-Term Liabilities. The Company recorded \$0.1 million and \$0.3 million as a decrease of expenses for the three and nine months ended September 30, 2016, respectively. At September 30, 2016, the remaining balance of \$1.8 million was included in Other Long-Term Liabilities. The Company incurred approximately \$0.2 million of debt issuance costs related to the above transactions, which are recorded as a direct deduction from the liability. The debt issuance costs are being amortized over the life of the agreements.

**(7) LONG-TERM DEBT**

During June 2015, the Company entered into a \$5.1 million credit agreement with an unrelated third-party financial institution to finance the purchase of a facility located in Madison, Wisconsin. The credit agreement is collateralized by the acquired building.

Borrowings under the credit agreement bear interest at 4.15%. The Company made interest-only payments on the outstanding principal balance for the period between July 12, 2015 and September 12, 2015. Beginning on October 12, 2015 and continuing through May 12, 2019, the Company is required to make monthly principal and interest payments of \$31,000. The final principal and interest payment due on the maturity date of June 12, 2019 is \$4.4 million.

Additionally, the Company has recorded \$73,000 in mortgage issuance costs, which are recorded as a direct deduction from the mortgage liability. The issuance costs are being amortized through June 12, 2019. The Company has recorded \$4,000 and \$13,000 in amortization of mortgage issuance costs for each of the three and nine months ended September 30, 2017 and 2016.

(8) WISCONSIN ECONOMIC DEVELOPMENT TAX CREDITS

During the first quarter of 2015, the Company entered into an agreement with the Wisconsin Economic Development Corporation (“WEDC”) to earn \$9.0 million in refundable tax credits if the Company expends \$26.3 million in capital investments and establishes and maintains 758 full-time positions in the state of Wisconsin over a seven-year period. The tax credits earned are first applied against the tax liability otherwise due, and if there is no such liability present, the claim for tax credits will be reimbursed in cash to the Company. The maximum amount of the

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refundable tax credit to be earned for each year is fixed, and the Company earns the credits by meeting certain capital investment and job creation thresholds over the seven-year period. Should the Company earn and receive the job creation tax credits but not maintain those full-time positions through the end of the agreement, the Company may be required to pay those credits back to the WEDC.

The Company records the earned tax credits as job creation and capital investments occur. The amount of tax credits earned is recorded as a liability and amortized as a reduction of operating expenses over the expected period of benefit. The tax credits earned from capital investment are recognized as an offset to depreciation expense over the expected life of the acquired capital assets. The tax credits earned related to job creation are recognized as an offset to operational expenses over the life of the agreement, as the Company is required to maintain the minimum level of full-time positions through the seven-year period.

As of September 30, 2017, the Company has earned \$6.4 million of tax credits and has received payment of \$1.1 million from the WEDC. The unpaid portion is \$5.3 million, of which \$1.3 million is reported in prepaid expenses and other current assets and \$4.0 million is reported in other long-term assets, reflecting when collection of the refundable tax credits is expected to occur. As of September 30, 2017, the Company also has recorded a \$1.5 million liability in other short-term liabilities and a \$3.1 million liability in other long-term liabilities, reflecting when the expected benefit of the tax credit amortization will reduce future operating expenses.

During the three and nine months ended September 30, 2017, the Company amortized \$0.3 million and \$0.9 million, respectively, of the tax credits earned as a reduction of operating expenses. During the three and nine months ended September 30, 2016, the Company amortized \$0.2 million and \$0.5 million, respectively, of the tax credits earned as a reduction of operating expenses.

### (9) ISSUANCE OF EQUITY

On June 7, 2017, the Company completed an underwritten public offering of 7,000,000 shares of common stock at a price to the public of \$35.00 per share. On June 26, 2017, the underwriters partially exercised their over-allotment option in connection with the offering and purchased an additional 450,000 shares of common stock at a price to the public of \$35.00 per share. The Company received, in the aggregate, approximately \$253.4 million of net proceeds from the offering, after deducting \$7.3 million for the underwriting discount and commissions and other stock issuance costs paid by the Company.

### (10) RELATED PARTY TRANSACTION

In May 2017, the Company entered into a professional services agreement for recruiting and related services with a firm whose principal is a non-employee director. In accordance with the agreement, the Company is expected to make cash payments totaling up to an aggregate of \$0.4 million under the agreement during 2017 and 2018. The Company incurred charges of \$0.1 million and \$0.2 million for the three and nine months ended September 30, 2017. The Company made payments of \$0.1 million and \$0.2 million for the three and nine months ended September 30, 2017.

### (11) ACQUISITIONS

On August 1, 2017, the Company acquired all of the outstanding equity of Sampleminded, Inc. (“Sampleminded”), the primary operations of which were customized software development for laboratory information systems and clinical information systems, for cash consideration of \$3.2 million and 86,357 of the Company’s restricted stock units. Prior to the acquisition, Sampleminded provided certain consulting and software support services to the Company, and it licensed certain software to the Company. The restricted stock units were recorded by the Company as employee stock-based compensation because their vesting is contingent upon continued employment with the Company of



certain former stockholders of Sampleminded. The \$3.2 million of cash consideration was allocated to the estimated fair market value of the net assets acquired of \$0.2 million, including \$1.0 million in identifiable intangible assets (comprised of developed technology, customer relationships and non-compete agreements) and a residual amount of goodwill of \$2.0 million. The purposes of acquisition were to reduce costs by bringing certain technology and expertise in-house and to prepare for anticipated future growth.

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## (12) INCOME TAXES

During the three and nine months ended September 30, 2017, the Company recorded an income tax benefit of approximately \$0.2 million. After considering the Sampleminded acquisition completed on August 1, 2017 and the related deferred tax liability acquired as part of the acquisition, the projected post-combination results and all available evidence, the Company released \$0.2 million of valuation allowance that was previously provided against the Company's deferred tax assets. In accordance with ASC 805 740-30-3, the Company recorded this income tax benefit as a discrete item in the tax provision for the third quarter of 2017. The Company continues to maintain a full valuation allowance against its deferred tax assets based on management's determination that it is more likely than not that the benefit will not be realized.

## (13) RECENT ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board issued ASU No. 2014-9, Revenue from Contracts with Customers (Topic 606), (the "New Revenue Standard") requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. Additional disclosures will also be required to enable users to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The New Revenue Standard will replace most existing revenue recognition guidance in GAAP when it becomes effective and permits the use of either the retrospective or modified retrospective method upon adoption. Adoption of the New Revenue Standard is required by the first quarter of 2018, and the Company has not yet selected a transition method. The Company has completed its preliminary evaluation of the potential financial statement impact of the New Revenue Standard on prior and future reporting periods. The Company does not expect material changes to the timing of when the Company recognizes revenue or the method by which the Company measures its single revenue stream, lab service revenue. Further, regarding the contract acquisition cost component of the New Revenue Standard, the Company's analysis supports use of the practical expedient when recognizing expense related to incremental costs incurred to acquire a contract, as the recovery of such costs is completed in less than one year's time. Additionally, incremental costs to obtain contracts have been immaterial to date. Accordingly, the Company does not expect any material changes to the timing of when it recognizes expenses related to contract acquisition costs. The Company will continue its evaluation of the New Revenue Standard through the date of adoption.

In February 2016, the Financial Accounting Standards Board issued ASU No. 2016-02, Leases (Topic 842), ("Update 2016-02") which requires recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Early adoption is permitted. The Company is currently evaluating the effects that the adoption of Update 2016-02 will have on the Company's consolidated financial statements. The Company anticipates that the new guidance will impact the Company's consolidated financial statements as it has several leases.

In August 2016, the Financial Accounting Standards Board issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, ("Update 2016-15"). Current GAAP either is unclear or does not include specific guidance on the eight cash flow classification issues included in the amendments in Update 2016-15. The amendments are an improvement to GAAP because they provide guidance for each of the eight issues, thereby reducing the current and potential future diversity in practice. The amendments in Update 2016-15 are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company has evaluated Update 2016-15 and does not expect the adoption of this guidance to have a material impact on its statements of cash flows.

In October 2016, the Financial Accounting Standards Board issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory, (“Update 2016-16”). This amendment improves the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Update 2016-16 is effective for fiscal years and interim periods within those years beginning after December 15, 2017. Early adoption is permitted. The Company does not expect the adoption of Update 2016-16 to have a significant impact on its consolidated financial statements.

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In October 2016, the Financial Accounting Standards Board issued ASU No. 2016-17, Consolidation (Topic 810): Interests Held through Related Parties That Are Under Common Control, (“Update 2016-17”). The amendments in Update 2016-17 change how a reporting entity that is the single decision maker of a variable interest entity should treat indirect interests in the entity held through related parties that are under common control with the reporting entity when determining whether it is the primary beneficiary of that variable interest entity. The amendment is effective for fiscal years and interim periods within those years beginning after December 15, 2016. The Company adopted this guidance during the three months ended March 31, 2017. The impact of adoption did not have an impact on the Company’s consolidated financial statements.

In November 2016, the Financial Accounting Standards Board issued ASU No. 2016-18, Statement of Cash Flows; Restricted Cash, (“Update 2016-18”). Update 2016-18 provides guidance on the classification of restricted cash in the statement of cash flows. The amendments are effective for interim and annual periods beginning after December 15, 2017. Early adoption is permitted. The amendments in Update 2016-18 should be adopted on a retrospective basis. The Company does not expect the adoption of this amendment to have a material effect on its consolidated financial statements, as the Company does not have restricted cash.

In January 2017, the Financial Accounting Standards Board issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business, (“Update 2017-01”) in an effort to clarify the definition of a business, with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments in Update 2017-01 are effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years. Early adoption is allowed for interim or annual periods for which the financial statements have not been issued or made available for issuance. The Company does not expect the adoption of this amendment to have a material effect on its consolidated financial statements.

In January 2017, the Financial Accounting Standards Board issued ASU No. 2017-03, Accounting Changes and Error Corrections , (“Update 2017-03”) which states that an entity should evaluate ASUs that have been issued but not yet adopted to determine the effects of those ASUs on the entity’s financial statements when adopted. If the effect is unknown or cannot be reasonably estimated, then additional qualitative disclosures should be considered, including a description of the effect of the accounting policies that the entity expects to apply, if determined, and a comparison to the entity’s current accounting policies, a description of the status of the entity’s process to implement the new standard and the significant implementation matters yet to be addressed. Transition guidance in certain issued but not yet adopted ASUs was updated to reflect Update 2017-03. Other than enhancements to the qualitative disclosures regarding the future adoption of new ASUs, adoption of Update 2017-03 is not expected to have any impact on the Company’s consolidated financial statements.

In January 2017, the Financial Accounting Standards Board issued ASU No. 2017-04, Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment, (“Update 2017-04”). Update 2017-04 eliminates Step 2 of the goodwill impairment test. Instead, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. The update is effective for public business entities for the first interim and annual reporting periods beginning after January 1, 2020 with early adoption permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company has adopted this standard effective January 1, 2017, and will utilize this approach for any interim or annual goodwill impairment tests performed in 2017.

In May 2017, the Financial Accounting Standards Board issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting, (“Update 2017-09”). Update 2017-09 provides guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. The amendments in Update 2017-09 are effective for interim and annual periods beginning after December 15, 2017. Early adoption is permitted. The amendments in Update 2017-09 should be applied prospectively to an award modified on or after the adoption date. The Company is currently evaluating the impact of this amendment on the Company’s consolidated financial statements.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Discussion and Analysis of Financial Condition and Results of Operations of Exact Sciences Corporation (together with its subsidiaries, "Exact," "we," "us," "our" or the "Company") should be read in conjunction with the condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2016, which has been filed with the SEC (the "2016 Form 10-K").

Forward-Looking Statements

This Quarterly Report on Form 10-Q 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" or other comparable terms. All statements other than statements of historical facts included in this Quarterly Report on Form 10-Q 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 the 2016 Form 10-K and 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.

Overview

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.

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### 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-Cologuard Commercialization Strategy



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

#### Physicians and Patients

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.

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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.

## Payers

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”), we anticipate that, effective January 1, 2018, the CMS reimbursement rate for Cologuard will be calculated based on the volume-weighted median of private payer rates for Cologuard. The initial data collection period for that purpose was January 1, 2016 to June 30, 2016. In the preliminary 2018 Clinical Laboratory Fee Schedule, CMS proposed reimbursement for Cologuard at \$508.87. The finalized 2018 Clinical Laboratory Fee Schedule is expected to be released in November 2017, and it is possible that the final reimbursement for Cologuard could vary from that

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proposed in the preliminary 2018 Clinical Laboratory Fee Schedule. 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. We do not anticipate applying for Advanced Diagnostic Laboratory Test (“ADLT”) status for Cologuard, which if granted would result in the rate being reset every year.

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.

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### Our Clinical Lab Facility

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 two and a half million or more tests per year. We are also evaluating options for a second lab facility to increase our total capacity to more than four and a half million tests per year.

### Product Pipeline

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. We have successfully performed validation studies on tissue samples for seven major cancers, including lung cancer, 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.

### Acquisitions

On August 1, 2017, we acquired all of the outstanding equity of Sampleminded, Inc. (“Sampleminded”), the primary operations of which were customized software development for laboratory information systems and clinical information systems, for consideration consisting of \$3.2 million of cash and 86,357 of our restricted stock units. Prior to the acquisition, Sampleminded provided certain consulting and software support services to us, and it licensed certain software to us. We recorded the restricted stock units as employee stock-based compensation because their vesting is contingent upon continued employment with us of certain former stockholders of Sampleminded. The \$3.2 million in cash consideration was allocated to the estimated fair market value of the net assets acquired of \$0.2 million, including \$1.0 million in identifiable intangible assets (comprised of developed technology, customer relationships and non-compete agreements) and a residual amount of goodwill of \$2.0 million. The purposes of acquisition were to reduce costs by bringing certain technology and expertise in-house and to prepare for future growth.

### How We Recognize Revenue

For tests performed where we have an agreed-upon reimbursement rate or where we can estimate the amount that we will ultimately collect at the time delivery is complete, we recognize the related revenue on an accrual basis upon delivery of a test result to an ordering physician. Accrual rates are based on the established billing rates less contractual and other adjustments, which yields the amount that we expect to ultimately collect. We determine the amount we expect to ultimately collect on a per-payer or per-agreement basis. The expected amount is typically lower than, if applicable, the agreed-upon reimbursement amount due to several factors, such as the amount of any patient co-payments, the existence of secondary payers and claim denials. Upon ultimate collection, the aggregate amount received from payers and patients where reimbursement was estimated is compared to previous collection estimates and, if necessary, the contractual allowance is adjusted. Finally, should we recognize revenue from claims on an accrual basis and later

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determine the judgments underlying estimated collections change, our financial results could be negatively impacted in future quarters. Historically, a portion of our revenue was recognized upon cash receipt when we were unable to reasonably estimate the amount that would ultimately be collected from a payer. Effective during the first quarter of 2017, we determined that we had the ability to reasonably estimate the amount that will ultimately be collected from all payers, including the impact of patient cost-share collections. Accordingly, we now recognize revenue on an accrual basis for all billed claims.

Our average reimbursement per test, as further defined below, was approximately \$428 and \$393 through September 30, 2017 and 2016, respectively. This cumulative average Cologuard reimbursement rate will change over time due to a number of factors, such as medical coverage decisions by payers, changes in the payer mix, the effects of contracts signed with payers, changes in allowed amounts by payers, our ability to successfully win appeals for payment, settlements reached with payers regarding previously denied claims and our ability to collect cash payments from payers and individual patients. Historical average reimbursement is not necessarily indicative of future average reimbursement.

We calculate the average Cologuard reimbursement per test on a trailing twelve-month basis for all tests that are at least six months old, since it can take that long, or in some cases longer, to collect from some payers and patients. Thus, the average reimbursement per test at September 30, 2017 represents the total cash collected through September 30, 2017 for all tests performed from April 1, 2016 through March 31, 2017 divided by the number of tests performed during that period.

The components of our revenue, as recognized upon accrual or cash receipt, were as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
(In thousands)	2017	2016	2017	2016
Revenue recognized on an accrual basis	\$72,574	\$24,510	\$174,074	\$57,592
Revenue recognized when cash is received	—	3,605	4,509	6,543
Total	\$72,574	\$28,115	\$178,583	\$64,135

Of the revenue recognized in the nine months ended September 30, 2017, approximately \$4.3 million relates to the one-time impact of certain payers meeting the Company's revenue recognition criteria for accrual-basis revenue recognition beginning with the period ended March 31, 2017. Approximately \$1.0 million of this one-time impact relates to tests completed in the prior year and for which our accrual revenue recognition criteria were not met until 2017.

### 2017 Priorities

Our top priorities for 2017 are to (1) grow revenue for Cologuard, (2) improve the customer experience and continue to deliver world class service to patients and providers, and (3) expand our product portfolio by developing additional cancer diagnostic tests as further outlined in the product pipeline section above.

### Results of Operations

We have generated significant losses since inception and, as of September 30, 2017, we had an accumulated deficit of approximately \$838.9 million. We expect to continue to incur losses for the near future, and it is possible we may



never achieve profitability.

Laboratory service revenue. Our laboratory service revenue is generated by performing screening services using our Cologuard test. For the three months ended September 30, 2017 and 2016, we completed approximately 161,000 and 68,000 Cologuard tests, respectively, and generated laboratory service revenue of \$72.6 million and \$28.1 million, respectively. For the nine months ended September 30, 2017 and 2016, the Company completed approximately 395,000 and 162,000 Cologuard tests, respectively, and generated laboratory service revenue of \$178.6 million and \$64.1 million, respectively. The increase in revenue was primarily due to an increase in completed Cologuard tests and an increase in average revenue recognized per test during the current period.

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**Our Cost Structure.** Our selling, general and administrative expenses consist primarily of non-research personnel salaries, office expenses, professional fees, sales and marketing expenses incurred in support of our commercialization efforts and non-cash stock-based compensation.

Cost of sales includes costs related to inventory production and usage, shipment of test collection kits, royalties and the cost of laboratory services to process tests and provide results to physicians. We incur expense for tests in the period in which the activities occur, therefore, gross margin as a percentage of laboratory service revenue may vary due to costs being incurred in one period that relate to revenues recognized in a later period.

We expect that gross margin for our laboratory services will continue to fluctuate and be affected by Cologuard test volume, operating efficiencies, patient compliance rates, payer mix, the levels of reimbursement, and payment patterns of payers and patients.

**Cost of Sales.** Cost of sales increased to \$20.7 million for the three months ended September 30, 2017 compared to \$12.2 million for the three months ended September 30, 2016. Cost of sales increased to \$55.7 million for the nine months ended September 30, 2017 compared to \$31.3 million for the nine months ended September 30, 2016. The increase in cost of sales is primarily due to the increase in completed Cologuard tests. The Company completed approximately 161,000 and 68,000 Cologuard tests for the three months ended September 30, 2017 and 2016, respectively. The Company completed approximately 395,000 and 162,000 Cologuard tests for the nine months ended September 30, 2017 and 2016, respectively.

(In millions)	Three Months Ended		
	September 30,		
	2017	2016	Change
Production costs	\$ 15.0	\$ 8.3	\$ 6.7
Personnel expenses	3.0	1.7	1.3
Facility and support expenses	2.2	1.9	0.3
Stock-based compensation	0.5	0.3	0.2
Total cost of sales expenses	\$ 20.7	\$ 12.2	\$ 8.5

(In millions)	Nine Months Ended		
	September 30,		
	2017	2016	Change
Production costs	\$ 40.5	\$ 20.2	\$ 20.3
Personnel expenses	8.1	5.0	3.1
Facility and support expenses	5.7	5.3	0.4
Stock-based compensation	1.2	0.8	0.4
Other cost of sales	0.2	—	0.2
Total cost of sales expenses	\$ 55.7	\$ 31.3	\$ 24.4

**Research and development expenses .** Research and development expenses increased to \$11.7 million for the three months ended September 30, 2017 compared to \$7.6 million for the three months ended September 30, 2016.

Research and development expenses increased to \$29.5 million for the nine months ended September 30, 2017

compared to \$26.4 million for the nine months ended September 30, 2016. The increase in research and development expenses was primarily due to an increase in personnel costs due to an increased headcount and an increase in direct research and development expenses for our pipeline.

(In millions)	Three Months Ended		
	September 30,		
	2017	2016	Change
Direct research and development expenses	\$4.7	\$ 3.0	\$ 1.7
Personnel expenses	3.8	2.6	1.2
Stock-based compensation	2.1	1.0	1.1
Other research and development	0.6	0.5	0.1
Legal and professional fees	0.5	0.5	—
Total research and development expenses	\$11.7	\$ 7.6	\$ 4.1

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(In millions)	Nine Months Ended		
	September 30,		
	2017	2016	Change
Direct research and development expenses	\$11.8	\$10.8	\$ 1.0
Personnel expenses	10.1	8.8	1.3
Stock-based compensation	4.4	3.0	1.4
Other research and development	1.7	2.2	(0.5)
Legal and professional fees	1.5	1.6	(0.1)
Total research and development expenses	\$29.5	\$26.4	\$ 3.1

General and administrative expenses . General and administrative expenses increased to \$30.8 million for the three months ended September 30, 2017 compared to \$20.3 million for the three months ended September 30, 2016. General and administrative expenses increased to \$75.4 million for the nine months ended September 30, 2017 compared to \$55.4 million for the nine months ended September 30, 2016. The increase in general and administrative expenses was primarily a result of increased personnel costs, stock-based compensation and legal and professional fees to support the overall growth of the Company.

(In millions)	Three Months Ended		
	September 30,		
	2017	2016	Change
Personnel expenses	\$11.5	\$7.4	\$ 4.1
Stock-based compensation	6.4	3.9	2.5
Facility and support expenses	5.7	4.1	1.6
Professional and legal fees	5.3	3.4	1.9
Other general and administrative	1.9	1.5	0.4
Total general and administrative expenses	\$30.8	\$20.3	\$ 10.5

(In millions)	Nine Months Ended		
	September 30,		
	2017	2016	Change
Personnel expenses	\$28.3	\$21.4	\$ 6.9
Professional and legal fees	15.8	8.9	6.9
Facility and support expenses	13.4	11.7	1.7
Stock-based compensation	12.8	10.0	2.8
Other general and administrative	5.1	3.4	1.7
Total general and administrative expenses	\$75.4	\$55.4	\$ 20.0

Sales and marketing expenses. Sales and marketing expenses increased to \$37.8 million for the three months ended September 30, 2017 compared to \$26.3 million for the three months ended September 30, 2016. Sales and marketing expenses increased to \$113.3 million for the nine months ended September 30, 2017 compared to \$82.3 million for the nine months ended September 30, 2016. The increase in sales and marketing expenses was a result of hiring additional sales and marketing personnel and increasing our advertising and patient marketing efforts as part of the ongoing commercialization of our Cologuard test.

(In millions)	Three Months Ended		
	September 30,		
	2017	2016	Change
Personnel expenses	\$19.2	\$15.0	\$ 4.2
Direct marketing costs and professional fees	16.5	10.0	6.5
Stock-based compensation	1.8	1.0	0.8
Other sales and marketing	0.3	0.3	—
Total sales and marketing expenses	\$37.8	\$26.3	\$ 11.5

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(In millions)	Nine Months Ended		
	September 30,		
	2017	2016	Change
Direct marketing costs and professional fees	\$56.4	\$35.6	\$ 20.8
Personnel expenses	51.3	42.9	8.4
Stock-based compensation	4.6	3.0	1.6
Other sales and marketing	1.0	0.8	0.2
Total sales and marketing expenses	\$113.3	\$82.3	\$ 31.0

Investment income . Investment income increased to \$1.3 million for the three months ended September 30, 2017 compared to \$0.5 million for the three months ended September 30, 2016. Investment income increased to \$2.6 million for the nine months ended September 30, 2017 compared to \$1.4 million for the nine months ended September 30, 2016. The increase in investment income was due to an increase in the average cash and marketable securities balance and an increase in the average rate of return on investments for the three and nine months ended September 30, 2017 when compared to the same periods in 2016.

Interest income and expense. Net interest expense of \$51,000 was realized for the three months ended September 30, 2017 compared to net interest expense of \$54,000 for the three months ended September 30, 2016. Net interest expense of \$0.2 million was realized for each of the nine months ended September 30, 2017 and September 30, 2016. Interest expense is related to the mortgage on one of our facilities in Madison, WI which was entered into in June 2015.

#### Liquidity and Capital Resources

We have financed our operations since inception primarily through public offerings of our common stock and through revenue generated by the sale of Cologuard. As of September 30, 2017, we had approximately \$50.8 million in cash and cash equivalents and approximately \$411.7 million in marketable securities.

All of our investments in marketable securities consist of fixed income investments, and all are deemed available-for-sale. The objectives of this portfolio are to provide liquidity and safety of principal while striving to achieve the highest rate of return. Our investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

Net cash used in operating activities was \$71.0 million for the nine months ended September 30, 2017 as compared to \$102.9 million for the nine months ended September 30, 2016. The principal use of cash in operating activities for the nine months ended September 30, 2017 was to fund our net loss. Our net loss decreased from the nine months ended September 30, 2016 primarily due to increased sales of Cologuard.

Net cash used in investing activities was \$185.5 million for the nine months ended September 30, 2017 as compared to net cash used in investing activities of \$20.8 million for the nine months ended September 30, 2016. The increase in cash used in investing activities for the nine months ended September 30, 2017 compared to the same period in 2016 was primarily the result of the timing of purchases and maturities of marketable securities. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was \$35.9 million for the nine months ended September 30, 2017. Such purchases consisted of property and equipment of \$24.4 million, a business acquisition, net of cash acquired of \$3.0 million, and purchased intangible assets of \$8.4 million. For the

same period in 2016 there were purchases of property and equipment of \$12.2 million and no acquisitions or purchases of intangible assets. The intangible asset purchase during the nine months ended September 30, 2017 was the result of the royalty buy-out and patent purchase from MDx Health in April 2017. The property and equipment purchases during the nine months ended September 30, 2017 were primarily the result of increased laboratory equipment purchases, computer equipment and computer software purchases, and assets under construction in order to continue to scale-up our operations. The business acquisition during the nine months ended September 30, 2017 was the result of the acquisition of Sampleminded, Inc.

Net cash provided by financing activities was \$258.2 million for the nine months ended September 30, 2017, as compared to \$146.2 million for the nine months ended September 30, 2016. The increase in cash provided by financing activities for the nine months ended September 30, 2017 compared to the same period in 2016 was primarily the result of proceeds from our issuance of common stock in an underwritten public offering in June 2017.

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We expect that cash and cash equivalents and marketable securities on hand at September 30, 2017 will be sufficient to fund our current operations for at least the next twelve months, based on current operating plans. However, we may need to raise additional capital to fully fund our current strategic plan, which includes successfully commercializing Cologuard and developing a pipeline of future products. If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of such plan, our results of operations and financial condition would be materially adversely affected, and we may be required to delay the implementation of our plan and otherwise scale back our operations. Even if we successfully raise additional funds, we cannot assure that our business will ever generate sufficient cash flow from operations to become profitable.

### Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, tax positions and stock-based compensation. We base our estimates on historical experience and on various other factors that are believed to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 of our financial statements included in our 2016 Form 10-K, we believe that the following accounting policies and judgments are most critical to aid in fully understanding and evaluating our reported financial results.

### Revenue Recognition

Laboratory service revenue. Our laboratory service revenues are generated by performing screening services using our Cologuard test, and the service is completed upon delivery of a test result to an ordering physician. We recognize revenue in accordance with the provisions of ASC 954-605, Health Care Entities - Revenue Recognition. We recognize revenue on an accrual basis, net of contractual and other adjustments, when amounts that will ultimately be collected can be reasonably estimated. Contractual and other adjustments represent the difference between the list price (the billing rate) and the estimated aggregate reimbursement rate from payers and patients. Upon ultimate collection, the aggregate amount received from payers and patients where reimbursement was estimated is compared to previous collection estimates and, if necessary, the contractual allowance is adjusted.

The estimates of amounts that will ultimately be collected requires significant judgment by management, and our judgements will continue to evolve as we gain payment experience with payers and patients. Historically, in the absence of the ability to reasonably estimate the amount that will ultimately be collected for our services, revenue was recognized upon cash receipt. Effective during the first quarter of 2017, we determined that we had the ability to reasonably estimate the amount that will ultimately be collected from all payers, including the impact of patient cost-share collections. Accordingly, we now recognize revenue on an accrual basis for all billed claims.

Inventory. Inventory is stated at the lower of cost or market value (net realizable value). We determine the cost of inventory using the first-in, first out method ("FIFO"). We estimate the recoverability of inventory by reference to internal estimates of future demands and product life cycles, including expiration. We periodically analyze our



inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated net realizable value, and record a charge to cost of sales for such inventory as appropriate. In addition, our products are subject to strict quality control and monitoring which we perform throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, we record a charge to cost of sales to write down such unmarketable inventory to its estimated net realizable value.

Direct and indirect manufacturing costs incurred during process validation and for other research and development activities, which are not permitted to be sold, have been expensed to research and development.

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Stock-Based Compensation. In accordance with GAAP, all stock-based payments, including grants of employee stock options, restricted stock and restricted stock units, market measure-based awards and shares purchased under an employee stock purchase plan (“ESPP”) (if certain parameters are not met), are recognized in the financial statements based on their fair values. The grant date fair value of market measure-based share-based compensation plans are calculated using a Monte Carlo simulation pricing model. The following assumptions are used in determining fair value for stock options, restricted stock and ESPP shares:

Valuation and Recognition — The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. The fair value of each market measure-based award is estimated on the date of grant using a Monte Carlo simulation pricing model. The fair value of service-based awards for each restricted stock unit award is determined on the date of grant using the closing stock price on that day. The estimated fair value of these awards is recognized to expense using the straight-line method over the vesting period. For awards issued to non-employees, the measurement date is the date when the performance is complete or when the award vests, whichever is the earliest. Accordingly, non-employee awards are re-measured at each reporting period until the final measurement date. The fair value of the award is recognized as stock-based compensation expense over the requisite service period, generally the vesting period. The Black-Scholes and Monte Carlo pricing models utilize the following assumptions:

Expected Term - Expected term is based on our historical life data and is determined using the average of the vesting period and the contractual life of the stock options granted. Expected life of a market measure-based award is based on the applicable performance period.

Expected Volatility - Expected volatility is based on our historical stock volatility data over the expected term of the awards.

Risk-Free Interest Rate – We base the risk-free interest rate used in the Black-Scholes and Monte Carlo valuation models on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent expected term.

Forfeitures – Beginning in 2017, we adopted Accounting Standards Update (“ASU”) No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (“Update 2016-09”). With the adoption of Update 2016-09, forfeiture estimates are no longer required, and the effects of actual forfeitures are recorded at the time they occur. The impact on the condensed consolidated balance sheet was a cumulative-effect adjustment of \$0.4 million, increasing opening accumulated deficit and additional paid-in capital.

The fair value of each award is estimated on the date of grant based on the assumptions noted above and as further described in Note 4 to our condensed consolidated financial statements.



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### Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued ASU No. 2014-9, Revenue from Contracts with Customers (Topic 606), (the “New Revenue Standard”) requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. Additional disclosures will also be required to enable users to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The New Revenue Standard will replace most existing revenue recognition guidance in GAAP when it becomes effective and permits the use of either the retrospective or modified retrospective method upon adoption. Adoption of the New Revenue Standard is required by the first quarter of 2018, and we have not yet selected a transition method. We have completed our preliminary evaluation of the potential financial statement impact of the New Revenue Standard on prior and future reporting periods. We do not expect material changes to the timing of when we recognize revenue or the method by which we measure our single revenue stream, lab service revenue. Further, regarding the contract acquisition cost component of the New Revenue Standard, our preliminary analysis supports the use of the practical expedient when recognizing expense related to incremental costs incurred to acquire a contract, as the recovery of such costs is completed in less than one year’s time. Additionally, incremental costs to obtain contracts have been immaterial to date. Accordingly, we do not expect any material changes to the timing of when we recognize expenses related to contract acquisition costs. We will continue our evaluation of the New Revenue Standard through the date of adoption.

In February 2016, the Financial Accounting Standards Board issued ASU No. 2016-02, Leases (Topic 842), (“Update 2016-02”) which requires recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Early adoption is permitted. We are currently evaluating the effects that the adoption of Update 2016-02 will have on our consolidated financial statements. We anticipate that the new guidance will impact our consolidated financial statements, as we have several leases.

In August 2016, the Financial Accounting Standards Board issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, (“Update 2016-15”). Current GAAP either is unclear or does not include specific guidance on the eight cash flow classification issues included in the amendments in Update 2016-15. The amendments are an improvement to GAAP because they provide guidance for each of the eight issues, thereby reducing the current and potential future diversity in practice. The amendments in Update 2016-15 are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. We have evaluated Update 2016-15 and we do not expect the adoption of this guidance to have a material impact on our statements of cash flows.

In October 2016, the Financial Accounting Standards Board issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory, (“Update 2016-16”). This amendment improves the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Update 2016-16 is effective for fiscal years and interim periods within those years beginning after December 15, 2017. Early adoption is permitted. We do not anticipate that the adoption of Update 2016-16 will have a significant impact on our consolidated financial statements.

In October 2016, the Financial Accounting Standards Board issued ASU No. 2016-17, Consolidation (Topic 810): Interest Held through Related Parties That Are Under Common Control, (Update 2016-17”). The amendments in Update 2016-17 change how a reporting entity that is the single decision maker of a variable interest entity should treat indirect interests in the entity held through related parties that are under common control with the reporting entity

when determining whether it is the primary beneficiary of that variable interest entity. The amendment is effective for fiscal years and interim periods within those years beginning after December 15, 2016. The adoption of Update 2016-17 did not have an impact on our consolidated financial statements.

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In November 2016, the Financial Accounting Standards Board issued ASU No. 2016-18, Statement of Cash Flows: Restricted Cash, (“Update 2016-18”). Update 2016-18 provides guidance on the classification of restricted cash in the statement of cash flows. The amendments are effective for interim and annual periods beginning after December 15, 2017. Early adoption is permitted. The amendments in the Update 2016-18 should be adopted on a retrospective basis. We do not expect that adoption of this amendment to have a material effect on our consolidated financial statements, as we do not have restricted cash.

In January 2017, the Financial Accounting Standards Board issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business, (Update 2017-01) in an effort to clarify the definition of a business, with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments of Update 2017-01 are effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years. Early adoption is allowed for interim or annual periods for which the financial statements have not been issued or made available for issuance. We do not expect that adoption of this amendment to have a material effect on our consolidated financial statements.

In January 2017, the Financial Accounting Standards Board issued ASU No. 2017-03, Accounting Changes and Error Corrections , (“Update 2017-03”) which states that an entity should evaluate ASUs that have been issued but not yet adopted to determine the effects of those ASUs on the entity’s financial statements when adopted. If the effect is unknown or cannot be reasonably estimated, then additional qualitative disclosures should be considered, including a description of the effect of the accounting policies that the entity expects to apply, if determined, and a comparison to the entity’s current accounting policies, a description of the status of the entity’s process to implement the new standard and the significant implementation matters yet to be addressed. Transition guidance in certain issued but not yet adopted ASUs was updated to reflect Update 2017-03. Other than enhancements to the qualitative disclosures regarding the future adoption of new ASUs, adoption of Update 2017-03 is not expected to have any impact on our consolidated financial statements.

In January 2017, the Financial Accounting Standards Board issued ASU No. 2017-04, Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment, (“Update 2017-04”). Update 2017-04 eliminates Step 2 of the goodwill impairment test. Instead, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. The update is effective for public business entities for the first interim and annual reporting periods beginning after January 1, 2020 with early adoption permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We adopted this standard effective January 1, 2017, and will utilize this approach for any interim or annual goodwill impairment tests performed in 2017.

In May 2017, the Financial Accounting Standards Board issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting , (“Update 2017-09”). Update 2017-09 provides guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. The amendments in Update 2017-09 are effective for interim and annual periods beginning after December 15, 2017. Early adoption is permitted. The amendments in Update 2017-09 should be applied prospectively to an award modified on or after the adoption date. We are currently evaluating the impact of this amendment on our consolidated financial statements.

Off-Balance Sheet Arrangements

As of September 30, 2017, we had no off-balance sheet arrangements.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk is principally confined to our cash, cash equivalents and marketable securities. We invest our cash, cash equivalents and marketable securities in securities of the U.S. government and its agencies and in investment-grade, highly liquid investments consisting of commercial paper, bank certificates of deposit, asset backed securities and corporate bonds, which, as of September 30, 2017 were classified as available-for-sale. We place our cash equivalents and marketable securities with high-quality financial institutions, limit the amount of credit exposure to any one institution and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity.

Based on a hypothetical ten percent adverse movement in interest rates, the potential losses in future earnings, fair value of risk-sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the hypothetical analysis.

Item 4. Controls and Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based upon that evaluation, our principal executive officer and our principal financial officer concluded that, as of September 30, 2017, our disclosure controls and procedures were effective. Disclosure controls and procedures enable us to record, process, summarize and report information required to be included in our Exchange Act filings within the required time period. Our disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed by us in the periodic reports filed with the SEC is accumulated and communicated to our management, including our principal executive, financial and accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

During the fiscal quarter covered by this report, there have been no significant changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



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Part II - Other Information

Item 1. Legal Proceedings

We are not currently a party to any pending legal proceedings that we believe will have a material adverse effect on our business, financial condition or results of operations. We may, however, be subject to various claims and legal actions arising in the ordinary course of business from time to time .

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this report, the risks and uncertainties that we believe are most important for you to consider are discussed in Part I, “Item 1A. Risk Factors” on the 2016 Form 10-K. There have been no material changes to the risk factors described in the 2016 Form 10-K.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Resignation of Lionel Sterling as Director; Election of Eli Casdin as Director .

On October 26, 2017, Lionel Sterling submitted his resignation as a member of the Board of Directors of the Company for personal reasons. Mr. Sterling did not indicate that his resignation was a result of any disagreement with the Company on any matter relating to the Company’s operations, policies or practices.

On October 26, 2017, the Board elected Eli Casdin to serve as a Class II director until the 2020 Annual Meeting of Stockholders. Mr. Casdin will serve as a member of each of the Audit Committee and Compensation Committee of the Board of Directors.

Mr. Casdin, age 44, founded Casdin Capital, LLC, a life sciences and healthcare investment company, in 2011 and has served as Chief Investment Officer and Managing Partner since its founding. Prior to founding Casdin Capital, Mr. Casdin was Vice President at Alliance Bernstein from 2007 to 2011 where he researched investment implications of new technologies for the life sciences and healthcare sectors. Prior to that, Mr. Casdin served as a research analyst at Bear Stearns and Cooper Hill Partners, specializing in healthcare investments in life sciences tools, diagnostics and medical devices. Mr. Casdin earned a bachelor’s degree from Columbia University and an MBA from Columbia Business School.

Mr. Casdin will receive compensation for his service as a director in accordance with the Company's Non-Employee Director Compensation Policy (the "Director Compensation Policy"), which is filed as Exhibit 10.2 to this Quarterly Report on Form 10-Q and incorporated herein by reference. Pursuant to the Director Compensation Policy, in connection with his initial appointment to the Board of Directors, Mr. Casdin received a stock option award covering 10,100 shares of Company common stock.

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Third Amended and Restated By-laws

On October 26, 2017, the Board of Directors of the Company approved the Company's Third Amended and Restated By-laws (the "Third Amended and Restated By-laws"), effective as of October 31, 2017. The Third Amended and Restated By-laws amend and restate in their entirety the Company's bylaws to, among other things:

- amend Article 3 to remove the specific requirement that certain officers be elected at the meeting of the board of directors immediately following each annual meeting, as the Company's officers may be appointed by the Board at any time as it deems appropriate;
- clarify that the voting requirement for matters to be approved by the stockholders is a majority of the voting power of stockholders present or represented, in person or by proxy, and voting on a matter, unless a different standard is required or permitted by express provision of law, the Certificate of Incorporation, the by-laws, or the rules and regulations of any stock exchange applicable to the Company or pursuant to any regulation applicable to the Company or its securities; and
- clarify that shares of the Company's stock may be certificated or uncertificated, as provided under Delaware law, and to clarify the procedures for transfer of uncertificated shares and the issuance of uncertificated shares in replacement of lost, stolen or destroyed certificates.

The foregoing summary is subject to, and qualified in its entirety by, the full text of the Third Amended and Restated By-laws, a copy of which is filed as Exhibit 3.3 to this Quarterly Report on Form 10-Q and incorporated herein by reference.

Item 6. Exhibits

The exhibits required to be filed as a part of this report are listed in the Exhibit Index.

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EXHIBIT INDEX

Exhibit Number	Description
3.1	<u>Sixth Amended and Restated Certificate of Incorporation of the Registrant (previously filed as Exhibit 3.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-48812), filed on October 27, 2000, and incorporated herein by reference)</u>
3.2	First Amendment to Sixth Amended and Restated Certificate of Incorporation of the Registrant (previously filed as Appendix B to the Definitive Proxy Statement for the Company's 2014 Annual Meeting of Stockholders, filed on June 20, 2014, and incorporated herein by reference)
3.3+	Third Amended and Restated By-Laws of the Registrant, dated October 31, 2017
10.1+*	Exact Sciences Corporation 2010 Omnibus Long-Term Incentive Plan (As Amended and Restated Effective July 27, 2017)
10.2+*	Non-Employee Director Compensation Policy, dated January 31, 2017 and effective July 27, 2017
31.1+	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934
31.2+	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934
32.1+	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101+	Interactive Data Files

+ Filed herewith

\* Indicates a management contract or any compensatory plan, contract or arrangement.



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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 thereunto duly authorized.

EXACT SCIENCES CORPORATION

Date: October 30, 2017 By: /s/ Kevin T. Conroy  
Kevin T. Conroy  
President and Chief Executive Officer  
( Principal Executive Officer )

Date: October 30, 2017 By: /s/ Jeffrey T. Elliott  
Jeffrey T. Elliott  
Chief Financial Officer  
( Principal Financial and Accounting Officer )

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EXHIBIT B

SECRETARY'S CERTIFICATE

I, D. Scott Coward, do hereby certify that I am the Secretary and General Counsel of Exact Sciences Corporation, a Delaware corporation (the "Corporation"). I hereby certify that the following resolutions were adopted by the Directors of the Corporation on July 27, 2017, and that said resolutions are in full force and effect on the date hereof, and that I am fully authorized to so certify:

RESOLVED, the Corporation is primarily engaged in the business of developing and marketing cancer screening and diagnostic technologies, and is not in the business of investing, reinvesting, owning, holding or trading in securities FURTHER, RESOLVED, that the officers of the Corporation be, and they thereby are, authorized and directed in the name and on behalf of the Corporation, to take any and all action which they determine to be necessary, advisable or appropriate to clarify with the SEC that the Corporation is not an "investment company" and is not in the business of investing, reinvesting, owning, holding or trading in securities, which action may include, without limitation, (i) seeking interpretative, no-action or other relief from the staff of the SEC that would provide assurances that the Corporation could continue to rely on Rule 3a-8 under the 1940 Act based on current and projected research and development expenses and the Corporation's business (ii) seeking an order from the Securities and Exchange Commission granting the Corporation an exemption from certain registration requirements under the 1940 Act and (iii) modifying the Corporation's ownership of "investment securities" to be less than 40% of the Corporation's total assets on an unconsolidated basis;

FURTHER, RESOLVED, that the officers of the Corporation be, and each of them hereby is, authorized and empowered in the name and on behalf of the Corporation, to make all such arrangements, to take all such actions and to execute, deliver and file such agreements, certificates, instruments and other documents as they, or any of them, may deem necessary, appropriate or advisable in order to effectuate fully the purpose of each and all of the foregoing resolutions, with any such determination to be evidenced conclusively by the making of any such arrangement, the taking of any such action or such execution, delivery or filing: and

FURTHER, RESOLVED, that all acts and things done by any officer, director, employee or agent of the Corporation on or prior to the date hereof in connection with the transactions contemplated by the foregoing resolutions be, and the same hereby are, in all respects ratified, confirmed, approved and adopted as acts on and behalf of the Corporation.

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\* \* \*

IN WITNESS WHEREOF, the undersigned has executed this Secretary's Certificate solely on behalf of the Company and not as an individual as of the 30th day of January 2018.

By: /s/ D. Scott Coward

Name: D. Scott Coward

Title: Senior Vice President, General Counsel and  
Secretary

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EXHIBIT C

PROPOSED FORM OF NOTICE

Exact Sciences Corporation; Notice of Application

Agency: U.S. Securities and Exchange Commission (“Commission”).

Action: Notice of application under Section 3(b)(2) of the Investment Company Act of 1940 (the “1940 Act”).

Summary of Application: Exact Sciences Corporation (“Exact Sciences”) seeks an order under Section 3(b)(2) of the 1940 Act declaring it to be primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities. Exact Sciences, directly and through its wholly-owned subsidiaries, develops, tests, markets, and commercializes cancer and pre-cancer screening and diagnostic tests.

Filing Dates: The application was filed on [Date].

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission’s Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on [Date], and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer’s interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission’s Secretary.

Addresses: Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549-9303. Applicant, 441 Charmany Drive, Madison, Wisconsin 53719.

For Further Information Contact:

Supplementary Information: The following is a summary of the application. The complete application may be obtained for a fee at the Commission’s Public Reference Desk, 100 F Street, NE, Washington, DC 20549-0102 (tel. 202-551-5850).

Applicant’s Representations:

1. Exact Sciences, a Delaware corporation, is in the business of developing, testing, marketing, and commercializing cancer and pre-cancer screening and diagnostic tests. Exact Sciences states that it conducts a cancer screening and related business directly and through certain wholly-owned subsidiaries. Exact Sciences states it is not in the business of investing, reinvesting, owning, holding or trading in securities.

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2. Exact Sciences states that it requires substantial liquid capital to fund its operations, finance research and development, and market its cancer-screening tests in order to take them from a concept to a finished and marketable product. Exact Sciences is currently invested in corporate bonds, asset-backed securities, U.S. government agency securities, commercial paper, and certificates of deposit. Exact Sciences represents that it has adopted an Investment Policy that requires these investments to be rated investment grade and of a nature to ensure that its investments consist of short-term debt instruments along with cash items and government securities for purposes of preserving capital necessary to fund research and development and operations. Exact Sciences also represents that it does not engage in speculative short-term trading with its cash management investments.

3. Exact Sciences states that the industry sectors in which it operates are competitive and require large capital outlays to fund research and development and operations. Success in this competitive environment is dependent on a number of factors, including the success and efficiency of research and development programs, availability of intellectual property, and implementation of sales and marketing initiatives. Exact Sciences bears significant expenses in running a successful research and development program and implementing marketing and sales efforts of finished products. Its investments in capital preservation assets are intended, in substantial part, to fund these expenses.

Applicant's Legal Analysis:

1. Exact Sciences seeks an order under Section 3(b)(2) of the 1940 Act declaring that it is primarily engaged in a business other than that of investing, reinvesting, owning, holding, or trading in securities, and therefore not an "investment company," as defined in the 1940 Act.

2. An "investment company" is, in pertinent part, an issuer that: (A) is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting, or trading in securities; or (B) is engaged or proposes to engage in the business of investing, reinvesting, owning, holding, or trading in securities, and owns or proposes to acquire "investment securities" having a value in excess of 40 percent of the value of the issuer's total assets (exclusive of government securities and cash items) on an unconsolidated basis. "Investment securities" include all securities except government securities, securities issued by employees' securities companies, and securities issued by majority-owned subsidiaries of the owner which (a) are not investment companies, and (b) are not relying on the exclusions from the definition of investment company in Sections 3(c)(1) or 3(c)(7) of the 1940 Act. Although Exact Sciences holds itself out as an operating company, and not an investment company, approximately 65% of Exact Sciences' total assets (exclusive of government securities and cash items), on an unconsolidated basis, consisted of investment securities as of the most recent third-quarter end.

3. Rule 3a-8 under the 1940 Act provides an exclusion from the definition of investment company for research and development companies, like Exact Sciences, if, among other conditions, a company's research and development expenses are a substantial percentage of its total expenses for the most recent four fiscal quarters combined.

Historically, Exact Sciences

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has relied on this rule, and has recorded over the years substantial research and development expenses compared to its overall expenses. More recently, research and development expenses have fluctuated due to cycles in a product's life from (i) guiding a concept from development through clinical testing and/or government approval where research and development expenses are most high to (ii) the commercialization of a finished product where non-research and development expenses increase potentially causing a reduction in the ratio of research and development expenses to overall expenses. Because of the varying life cycles of a product, the extent to which research and development expenses may be deemed "substantial" compared to overall expenses can be uncertain, particularly in the absence of any regulatory "bright lines". As a result, reliance on Rule 3a-8 may be uncertain in some years. Exact Sciences believes its research and development expenses are substantial. That is, in absolute dollar terms, these expenses have increased or remained steady over the past few years, but as a comparison to overall expenses, the ratio of research and development expenses have declined, particularly as Exact Sciences has borne increased sales and marketing expenses to successfully promote a finished, governmentally approved product. Notably, the change in research and development expenses is not the result of a change in business strategy or of the business itself from an operating company to an investment company. Exact Sciences remains the same cancer screening and diagnostics company now as it was upon its founding more than 20 years ago.

4. Exact Sciences seeks the certainty of a Commission order pursuant to Section 3(b)(2) of the 1940 Act declaring that Exact Sciences is primarily engaged in a business or businesses other than that of investing, reinvesting, owning, holding, or trading in securities either directly, through majority-owned subsidiaries, or controlled companies conducting similar types of business.

6. In determining whether a company is primarily engaged in a non-investment company business under Section 3(b)(2), the Commission considers a five-factor test that looks at a company's: (a) historical development; (b) public representations of policy; (c) officers and directors and their activities; (d) present assets; and (e) sources of its present income.<sup>29</sup>

7. Based on this test, it is clear that Exact Sciences is an operating company and not an investment company. Exact Sciences has historically operated as a cancer screening and diagnostics company since its founding. It has never publicly held itself out to be an investment company. Rather, its public pronouncements are consistent with those of an operating company. The officers and directors of Exact Sciences bring together significant experience in business, medicine, biotechnology/life sciences, and government in the management of the company's operations. They do not engage in a business of portfolio investing and asset management. Although Exact Sciences holds investment securities, the types of investment securities are consistent with companies engaged in significant research and development, which companies are not treated as investment companies. Namely, these investments are capital preservation assets used for funding research and development and operations. The Commission itself has recognized that the asset test for research and development companies, given their nature and the life cycles of their business, is different than may be the case, for example, with manufacturing

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<sup>29</sup>In re Tonopah Mining Co., 26 S.E.C. 426 (1947).

companies. Lastly, approximately 99% of the income of Exact Sciences is attributable to sales and use of its governmentally approved cancer-screening product.

8. Exact Sciences thus asserts that it satisfies the standards for an order under Section 3(b)(2) of the 1940 Act.

Applicant's Conditions:

Applicant agrees that the order granting the requested relief will be subject to the following conditions:

1. Exact Sciences will continue to allocate and use its accumulated cash and investment securities for bona fide business purposes.
2. Exact Sciences will refrain from investing or trading in securities for short-term speculative purposes.

For the Commission, by the Division of Investment Management, under delegated authority.

Secretary

EXHIBIT D

VERIFICATION  
VERIFICATION

The undersigned states that he has duly executed the attached Application dated January 30, 2018 for and on behalf of Exact Sciences Corporation; that he is the Corporate Secretary and General Counsel of Exact Sciences Corporation; and that all action by the stockholder, directors, and other bodies necessary to authorize the undersigned to execute and file such instrument has been taken. The undersigned further states that he is familiar with such instrument, and the contents thereof, and that the facts therein set forth are true to the best of his knowledge, information and belief.

/s/ D. Scott Coward  
D. Scott Coward  
Secretary and General Counsel

State of Wisconsin                    )  
Dane County                            )  
Subscribed and sworn to before me, a Notary Public, this 30<sup>th</sup> day of JANUARY, 2018

/s/ June M. Fontana  
June M. Fontana  
Notary Public  
My commission expires: 12/1/2018

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