EXACT SCIENCES CORP
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SEC File No. 812-14875

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

AMENDED AND RESTATED 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

IN THE MATTER OF
EXACT SCIENCES CORPORATION

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BEFORE THE
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I. SUMMARY OF RELIEF REQUESTED

This is an amended and restated application filed by Exact Sciences Corporation ("Exact Sciences" or the "Company") 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"). Exact Sciences hereby applies for an order of the Commission finding and 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 amended and restated 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 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").[1]

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.[2] As of its recently reported quarter end of March 31, 2018, the value of Exact Sciences' investment securities, as defined in Section 3(a)(2) of the 1940 Act, constituted approximately 79% of the value of the Company's total assets on an unconsolidated basis (exclusive of cash items and Government securities).[3] 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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1 15 U.S.C. §80a-3(a)(1).

2 15 U.S.C. §80a-3(a)(2).

3 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 1,268 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 303,000 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 April 25, 2018, Exact Sciences had market capitalization of approximately $5.5 billion and 121.9 million 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 Limited., 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:

- 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.
- CG Growth LLC has acquired and is developing real property for the expansion of the Company's business.
- Exact Sciences Finance Corporation facilitates Exact Sciences' intercompany financing.

- Exact Sciences Europe Ltd explores international business development and commercialization opportunities for the Company.
- Sampleminded, Inc., Data In Motion LLC, and Cimarron Medical Software, Inc. were acquired as part of a 2017 acquisition to augment and strengthen the Company's IT capabilities and hold certain contracts and intellectual property rights related to the Company's laboratory management software.

Beijing Exact Sciences Medical Technology Company Ltd. is non-operational and in the process of dissolution. No subsidiary has been sold since the Company's inception.

The Company's "investment securities" (which are listed as "marketable securities" on its balance sheet) are held directly by Exact Sciences. None of the subsidiaries owns "investment securities," and none engages in a business of investing, reinvesting, owning, holding, or trading in securities. A copy of the Company's most recent quarterly report on Form 10-Q, dated as of March 31, 2018, is attached hereto in Exhibit A.

1. Corporate Governance

The Company is managed by a nine-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 nine-member Board. Six Board members have extensive experience in the healthcare industry, all have extensive business and/or executive experience, and one has extensive experience in government.

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, President, 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 and Chairman, President and CEO of CereVasc, LLC, an early-stage medical device company. Mr. Levangie also served as President of Insulet Delivery Solutions from 2013-2017. 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 Cytyc Corporation, Cytyc Health Corporation, and Cytyc 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 Chair of Natural Products Group (the holding company of Arbonne, Natures Gate, and Levlad) since March 2010. 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 previously as 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.

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.

Mark Stenhouse joined Exact Sciences in April 2018 and serves as President, Cologuard. Prior to joining the Company, Mr. Stenhouse worked for over 25 years at Abbott Laboratories and AbbVie, Inc., including in a number of executive and managerial positions within its U.S. Immunology division. Most recently, from October 2016 until March 2018, Mr. Stenhouse served as Vice President, U.S. Immunology, where he developed AbbVie's U.S. expansion into the immunology marketplace. From April 2010 until September 2016, Mr. Stenhouse served as Vice President and Vice President/General Manager, U.S. Immunology—Gastroenterology Franchise, where he led a successful turnaround of the franchise, including approval of HUMIRA for treatment of Ulcerative Colitis. From September 2006 through March 2010, Mr. Stenhouse held various senior management, marketing and sales positions within Abbott Laboratories' U.S. Immunology division.

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,[4] 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

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[4] 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 based on genetic analysis and genetic engineering. The biotechnology industry's total market capitalization is approximately $1.03 trillion.

("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 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 (approximately $1.1 billion as of March 31, 2018) to finance its operations. The Company has experienced an accumulated deficit of approximately $900 million since its founding as it has worked to develop and commercialize its screening test. Although the commercial launch of Cologuard® has been highly successful,[5] 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 continue to commercialize Cologuard® and develop future products, the Company also makes investments in short-term investment grade and liquid fixed income and money market investments that earn competitive market returns and provide a low level of credit risk (collectively, "Capital Preservation Instruments").

These Capital Preservation Instruments have historically been government securities,[6] investment-grade corporate debt, investment-grade asset-backed securities, commercial paper,

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[5] The Company's revenues have grown rapidly from $39 million in 2015, to $99 million in 2016, to $266 million in 2017, and to $90 million through the first quarter of 2018.

[6] 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., Federal National Mortgage Association, SEC No-Action Letter (pub. avail. May 6, 1971) ("Fannie Mae"

certificates of deposits ("CDs"), and cash items. The Company's investment guidelines establish a maximum maturity for these Capital Preservation Instruments at 25 months and an investment strategy that emphasizes liquidity and preservation of capital to ensure that funds are available -- and available when needed -- to support the Company's business operations. The Board oversees Exact Sciences' investment practices and defines the parameters for investment activities, which is implemented by an external asset manager.

The Company also makes strategic investments in companies that are complementary to its core business. These investments are not considered Capital Preservation Instruments, but in any case are consistent with the "other investments" permitted by Rule 3a-8(a)(4)(i) and (ii) under the 1940 Act, as discussed in more detail herein.

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 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 364% for the fiscal year ended 2017 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, to $38.1 million for 2016 year-end, and to $58 million for 2017 year-end. For the first three months of 2018, ended March 31, 2018, sales and marketing of Cologuard® had already accounted for $53.4 million compared to $38.8 million for the three months ended March 31, 2017. The increase in sales and marketing expenses has been the result of hiring additional sales and marketing professionals and

increasing advertising and patient marketing efforts as part of the ongoing commercialization of the Cologuard® test. 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 from year-to-year. 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, highly 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. The Company estimates that by mid-2018 it expects to complete the expansion of this facility to increase the Company's lab processing capacity to more than 2.5 million Cologuard® tests. The lab is subject to production and quality standards and FDA periodic examinations to ensure satisfaction of quality-control standards. The Company also is constructing a new clinical lab facility, having closed in November 2017 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 liver and lung cancer. According to the American Cancer Society ("ACS"), approximately 42,000 Americans will be diagnosed with liver cancer and 234,000 Americans will be diagnosed with lung cancer in 2018. Of those, the ACS estimates that liver cancer will cause 30,000 deaths and lung cancer will cause 154,000 deaths in 2018. The Company believes it can successfully leverage its existing Cologuard® technology platform to develop additional cancer diagnostic tests, 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.[7] 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.

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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).

[7] 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 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 certain scientific professionals available for purposes of supporting R&D through 2020.

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.

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 screened for colorectal cancer, as well as the number of patients who use Cologuard® for screening 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® and the enforcement of those laws;
- The amount and nature of competition from other colorectal cancer or pre-cancer screening products and procedures;
- Maintaining FDA marketing approval of Cologuard®;
- The ease of use of 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 2017 and for the three months ended March 31, 2018:

	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%
2017	$333	43%	107%
Fiscal Quarter Ended 3/31/18	$(109.7)	(47)%***	(26)%

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 substantial investments in R&D and in its marketing efforts. Over the past six years, the Company devoted nearly $208 million to its R&D efforts, which on average for that same six-year period accounted for approximately 19.6% of the Company's overall expenses[8]. The table below depicts the R&D expenses[9] for fiscal years 2012 through 2017 and for the three months ended March 31, 2018, the Company's total expenses over the same period, and the change in R&D expenses from year to year.

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* "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 fiscal quarter ended March 31, 2017.

8 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.

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

Fiscal Year	R&D Expenses (in millions)	Change From Prior Year	R&D Expense as % of Total Expenses*	R&D Expense as % Beginning Cash and Short-Term Investments**
2012	$42.1	91%	74%	45%
2013	$27.7	(34)%	54%	26%
2014	$28.7	4%	28%	22%
2015	$33.9	18%	17%	12%
2016	$33.5	(1)%	12%	11%
2017	$42.1	26%	11%	14%
Fiscal Quarter Ended 3/31/18	$14.9	86%***	12%	4%

Exact Sciences' investments in R&D allowed it to 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 to continue funding R&D cyclically over the period required to take a product from a concept to commercialization. The Company 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 expenses by $41.1 million during 2017, while its R&D expenses increased by approximately $8.7 million

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* "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 fiscal quarter ended March 31, 2017.

for the same period. The Company expects to continue devoting significant expenditures to its Cologuard® sales and marketing.

3. Capital Expenditures

Exact Sciences has made substantial capital expenditures in connection with its operating business. The table outlines purchases of capital assets (net of retirements) used to support Exact Sciences' long-term growth during fiscal years 2012 through 2017 and the three months ended March 31, 2018:

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%
2017	$49	226%	16
Fiscal Quarter Ended 3/31/18	$15	467%	4%

Recent capital expenditures included the acquisition of a new R&D building for approximately $4.8 million in 2015, as well as the acquisition of property for redevelopment and construction of a second clinical lab and other operational facilities in 2017, which were necessary to keep pace with the demand for Cologuard® and the growth of the Company.

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 also may make other strategic investments that

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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 fiscal quarter ended March 31, 2017.

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 or strategically in related businesses. 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. The Company does not invest in securities for short-term speculative purposes.

When it makes securities investments in Capital Preservation Instruments, Exact Sciences invests in fixed-income securities that are rated investment grade.[10] 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. Interest and dividends on securities classified as available-for-sale are included in investment income.

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[10] 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).

As of March 31, 2018 and year-end at December 31, 2017, 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. In addition to investing in Capital Preservation Instruments, Exact Sciences makes investments in companies that are complementary to its business. In these cases, the Company follows the limitations on "other investments," prescribed by Rule 3a-8(a)(4)(i) or (ii).

The Company primarily recognizes revenues from performing screening services using the Cologuard® test. As of March 31, 2018, the Company's laboratory-service revenues were $90.3 million, which represents a substantial increase from the $48.4 million it recognized during the same three-month period in 2017. For the fiscal year ended December 31, 2017, the Company's laboratory-service revenues were approximately $266 million, which represents a substantial increase from the approximately $99.4 million it recognized during the fiscal year ended December 31, 2016.

For the fiscal year ended December 31, 2017, the Company recognized net investment income of approximately $3.9 million from its Capital Preservation Instruments, an approximately $1.9 million increase from the fiscal year ended December 31, 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 the net income attributed to Capital Preservation Instruments was less than 10% of the Company's expenses attributable to R&D![11] The Company expects investment income 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 directly 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

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[11] 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).

conditions for reliance. These conditions require that: (i) R&D expenses be "substantial"[12] in 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 especially during times when R&D expenses remain steady or do not increase proportionately with the Company's overall expenses.

For example, 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. R&D expenses, as a ratio of total expenses, has declined from a high of 74% of the Company's total expenses in 2012 to approximately 11% of total expenses for year-end 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 an absolute-dollar test or a specific "bright-line" to determine when the ratio of R&D expenses are "substantial" to overall expenses, it is difficult to conclude with absolute certainty when R&D is a substantial expense for the Company. The Commission staff, on the other hand, has explicitly agreed that a 20% ratio would be substantial for purposes of the rule,[13] thus potentially raising the implication that R&D expenses at a lower rate may not be substantial, and thus outside of the rule, notwithstanding the amount devoted to R&D in absolute dollars.

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 nine months to secondarily rely on Rule 3a-2

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12 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 Company Act Release 26077 (June 16, 2003) (adopting Rule 3a-8). A little more than fours 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).

13 See, supra, note 12.

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under the 1940 Act in an abundance of caution.[14] The Company acknowledges that its reliance 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

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

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 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"[15] and (i) it "is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting, or trading in securities,"[16] 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."[17]

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.[18] 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.[19] 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;"[20] 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.[21] Although Section 3(b)(2) prescribes an exemption only from the Asset Test, the operative

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15 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). Exact Sciences is an issuer because, as of October 27, 2017 it had 119,730,401 shares of common stock outstanding.

16 15 U.S.C. §80a-3(a)(1)(A).

17 15 U.S.C. §80a-3(a)(1)(C).

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

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

20 15 U.S.C. §80a-3(b)(1).

21 See Tonopah Mining, at 26 S.E.C. 426 (1947).

"primarily engaged" language of Section 3(b)(2) has been interpreted consistently with the similar language of the Business Test.[22] 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 June 2009, the Company entered into a license agreement with MAYO, pursuant to which MAYO granted the Company an exclusive, worldwide license within the field of stool or blood-based cancer diagnostics and screening with regard to certain MAYO patents and patent applications, as well as a non-exclusive, worldwide license with regard to certain MAYO know-how. The licensed patents covered advances in sample processing, analytical testing and data analysis associated with non-invasive, stool-based DNA screening for colorectal cancer. The license agreement was amended in May 2012 to expand the Company's license to include all gastrointestinal cancers and diseases and new cancer screening applications of stool- and blood-based testing.

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[22] 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 it exclusion to both Section 3(a)(1)(A) and Section 3(a)(1)(C). 17 C.F.R. §270.3a-8(a).

- 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 2010, the Company entered into a technology license agreement with MDx Health S.A ("MDx"), under which MDx granted the Company a royalty-bearing, exclusive, worldwide license to certain patents.
- 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.
- 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 February 2015, the Company amended and restated its 2009 license agreement with MAYO. The agreement was amended further in January 2016 and in October 2017. The 2015-2017 amendments expanded the scope of the license to cover most major cancers, secure additional support from certain of MAYO's scientific personnel and update milestone and other payments payable by the Company to MAYO. Through the collaboration with MAYO, the Company has identified proprietary biomarkers for several major cancers, including liver cancer and lung cancer.
- In January 2016, the Company began a national television advertising campaign for Cologuard®, with its efforts focused on cable television most commonly viewed by the target patient demographic. Since then, the Company has expanded its campaign and released new television spots highlighting the ease of use of 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.
- In April 2017, the Company acquired certain patents related to Cologuard® from MDx as part of a royalty buy-out agreement and patent purchase agreement.
- In December 2017, the Company acquired a portfolio of biomarkers, related technology and certain other assets underlying prostate cancer diagnostic tests developed by Armune BioScience, Inc. ("Armune"). The acquired assets are expected to complement the Company's product pipeline and the Company has begun incorporating the Armune biomarkers into the Company's research and development program.
- In 2018, the Company entered into several national partnerships designed to increase awareness of Cologuard®. Among these is The New 50, a public education campaign sponsored by the Company in partnership with leading colon cancer advocacy groups. The Company also sponsored the Cologuard Classic, a professional golf tournament on the PGA Tour Champions, and engaged a celebrity spokesperson.
- 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), 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. The Board annually adopts the Company's investment guidelines for external asset managers to follow. For extraordinary events, the Board may review credit risk on an episodic basis. Day-to-day investment decisions, however, are handled by external asset managers, not members of the Board. Thus, none of the members of management or the Board spends or proposes to devote more than 1% of his or her time, if even that, to any securities investment activities on behalf of the Company. They, along with the approximately 1,268 full-time employees, are dedicated to the production and commercialization of Cologuard®, and the development of new cancer screening and diagnostic products.

As noted above, the Company outsources certain of its treasury functions related to managing investments, and has retained a national bank to manage its Capital Preservation Instruments. Therefore, the Company's officers, directors, or employees are not responsible for, or tasked with, managing portfolio assets. The cost of asset management and related services for 2016 and 2017 were $395,088 and $404,790, respectively, which accounts for less than 2% of all expenses for the Company for each year. 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 March 31, 2018, these assets include property and equipment (valued at cost), as follows: computer equipment and software of $32.7 million; laboratory

equipment of $26.2 million; leasehold improvements of $17.5 million; assets under construction of $50.9 million; buildings, including office and laboratory space of $7.9 million; furniture and fixtures, $4.6 million; and other long-term assets of $9.9 million. Certain current assets, valued as of March 31, 2018, include accounts receivable of $34.6 million in connection with the Company's commercialization of Cologuard®, inventory of $32.4 million also consistent with those efforts, and pre-paid expenses and other assets of $12.9 million. These operating assets (less depreciation of $42.2 million for property and equipment) totaled approximately $187.4 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.[23] 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.[24]

The asset mix of Exact Sciences is no different than a typical R&D company. The Company maintains robust cash management assets, including investments in Capital Preservation Instruments, in order to fund its R&D and operations. These assets, as of March 31, 2018, include cash and cash equivalents of $148.7 million and Capital Preservation Instruments of $893.5 million. The Company's investment guidelines for capital preservation require these 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 three months ended March 31, 2018, of the $893.5 million of Capital Preservation Instruments, approximately $194 million are invested in government securities. Government securities, along with the Company's holdings of cash and cash items, would be excluded from the Asset Test, thus giving the Company investment securities accounting for approximately 79% 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 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 commercializing Cologuard®, Exact Sciences will continue to devote resources to R&D creating R&D expenses that, although expected to increase in absolute dollars in the future, are not expected to increase significantly as a ratio of overall

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

[24] 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.

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, $33.5 million in 2016, and $42.1 million in 2017. The costs of commercializing Cologuard®, however, have risen sharply over the same period, $38.9 million in 2014, $82.1 million in 2015, $112.8 million in 2016, and $153.9 million in 2017. For the three months ended March 31, 2018, the Company has already incurred sales and marketing expenditures of $53.4 million, which accounts for approximately half of the Company's overall expenses for that period. R&D expenses have not proportionately increased to keep pace with the steep costs of commercializing Cologuard®. 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 2% of the Company's total revenues. 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.[25] 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 primarily invested solely in Capital Preservation Instruments, although it has made, and may in the future make, strategic investments in "other investments" consistent with Rule 3a-8(a)(4)(i) or (a)(4)(ii).

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.[26] 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 and increased expenses necessary to commercialize a product. Like those predecessors, those

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[25] RealNetworks, Inc., Investment Company Act Release No. 27888 (July 24, 2007) (Order); and Investment Company Act Release No. 27877 (June 28, 2007) (Notice).

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

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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.[27]

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

Since its inception, Exact Sciences has carried net operating losses. This would not be unusual for an R&D company that experiences heavy losses as it develops and brings a product through FDA clinical trials to approval to commercialization. Inasmuch as Exact Sciences has entered the commercialization stage for Cologuard®, although still operating at a net loss, income may not be the single-most revealing aspect of its operating company status. Rather, a review of the Company's current source of revenues provides a more accurate reveal of its operating company status.

Since 2015, Exact Sciences' sole source of revenue has been the performance of Cologuard® testing at its clinical laboratory. For the year ended December 31, 2017, the Company earned approximately $266 million of revenues attributable to Cologuard® compared to 2016 when the Company generated $99.4 million of revenue. For the three months ended March 31, 2018 and 2017, Cologuard® revenues were approximately $90.3 million and $48.4 million, respectively, 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 $3.9 million in net investment income in 2017, and has earned $3.7 million for the three months ended March 31, 2018 compared to $0.6 million for the three months ended March 31, 2017. 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 months ended March 31, 2018 when compared to the same periods in 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

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[27] 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., 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).

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that it has completed the primary R&D process and entered the commercialization stage for Cologuard®. As previously noted, the Company expects to continue its R&D into screening tests for other forms of cancer.

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 Company experienced a decline in R&D expenses. This decline was not due to a change in its core business, but rather as a result of increased expenses associated with commercializing a successful product that emerged from its R&D program.

Because the Company relies on its holdings of Capital Preservation Instruments, 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.[28] Namely, the Commission did not require those companies to significantly

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[28] See, supra, notes 25-27.

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 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: C. Dirk Peterson, Esq., K&L Gates LLP, 1601 K Street NW, Washington, D.C. 20006, with a copy to D. Scott Coward, Senior Vice President, General Counsel and Corporate Secretary, Exact Sciences Corporation, 441 Charmany Drive, Madison, Wisconsin 53719.

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.

* * *

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

June 1, 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 three-month period ended March 31, 2018
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

EXHIBIT A
FORM 10-Q

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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 March 31, 2018

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 (State or other jurisdiction of incorporation or organization)	02-0478229 (I.R.S. Employer Identification Number)
441 Charmany Drive, Madison WI (Address of principal executive offices)	53719 (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

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 (Do not check if a smaller reporting company)	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 April 25, 2018, the registrant had 121,898,280 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)

	March 31, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$148,695	$ 77,491
Marketable securities	893,474	347,224
Accounts receivable, net	34,575	26,419
Inventory, net	32,380	26,027
Prepaid expenses and other current assets	12,867	10,055
Total current assets	1,121,991	487,216
Long-term Assets:		
Property, plant and equipment, net	103,448	79,986
Intangibles, net	21,558	22,160
Other long-term assets, net	9,919	9,198
Total assets	$1,256,916	$ 598,560
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$12,274	$ 16,135
Accrued liabilities	56,716	49,126
Accrued interest	1,407	—
Debt, current portion	183	182
Other short-term liabilities	2,750	2,681
Total current liabilities	73,330	68,124
Convertible notes, net	486,688	—
Long-term debt	4,237	4,269
Other long-term liabilities	5,643	5,749
Total liabilities	569,898	78,142
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at March 31, 2018 and December 31, 2017	—	—
Common stock, $0.01 par value Authorized—200,000,000 shares issued and outstanding—121,866,759 and 120,497,426 shares at March 31, 2018 and December 31, 2017	1,219	1,205
Additional paid-in capital	1,588,173	1,380,577
Accumulated other comprehensive loss	(2,336)	(750)
Accumulated deficit	(900,038)	(860,614)
Total stockholders' equity	687,018	520,418
Total liabilities and stockholders' equity	$1,256,916	$ 598,560

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 March 31,	
	2018	2017
Laboratory service revenue	$90,296	$48,363
Cost of sales	22,914	16,981
Gross margin	67,382	31,382
Operating expenses:		
Research and development	14,935	8,002
General and administrative	35,567	20,070
Sales and marketing	53,408	38,801
Total operating expenses	103,910	66,873
Loss from operations	(36,528)	(35,491)
Other income (expense)		
Investment income	3,673	595
Interest expense	(6,510)	(50)
Total other income (expense)	(2,837)	545
Net loss before tax	(39,365)	(34,946)
Income tax expense	(59)	—
Net loss	$(39,424)	$(34,946)
Net loss per share—basic and diluted	$(0.33)	$(0.32)
Weighted average common shares outstanding—basic and diluted	121,016	110,582

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 March 31,	
	2018	2017
Net loss	$(39,424)	$(34,946)
Other comprehensive loss, net of tax:		
Unrealized loss on available-for-sale investments	(1,606)	(5)
Foreign currency translation gain (loss)	20	(8)
Comprehensive loss	$(41,010)	$(34,959)

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)

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(39,424)	$(34,946)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of fixed assets	4,281	3,247
Loss on disposal of property and equipment	98	20
Stock-based compensation	12,463	6,129
Amortization of debt discount	4,651	—
Amortization of debt issuance costs	402	—
Amortization of other liabilities	(533)	(377)
Amortization of deferred financing costs	23	14
Amortization of premium on short-term investments	(515)	37
Amortization of intangible assets	612	50
Changes in assets and liabilities, net of effects of acquisition:		
Accrued interest	1,407	—
Accounts receivable, net	(8,156)	(7,688)
Inventory, net	(6,353)	(1,026)
Prepaid expenses and other current assets	(2,812)	(329)
Accounts payable	(3,861)	181
Accrued liabilities	(623)	1,204
Other short-term liabilities	(29)	(154)
Lease incentive obligation	(153)	—
Net cash used in operating activities	(38,522)	(33,638)
Cash flows from investing activities:		
Purchases of marketable securities	(628,502)	(30,563)
Maturities of marketable securities	81,161	57,236
Purchases of property and equipment	(15,328)	(2,745)
Internally developed software	(62)	—
Net cash (used in) provided by investing activities	(562,731)	23,928
Cash flows from financing activities:		
Proceeds from issuance of convertible notes, net	671,091	—
Proceeds from exercise of common stock options	1,391	47
Payments on mortgage payable	(45)	(44)
Net cash provided by financing activities	672,437	3
Effects of exchange rate changes on cash and cash equivalents	20	(8)
Net increase (decrease) in cash and cash equivalents	71,204	(9,715)
Cash and cash equivalents, beginning of period	77,491	48,921
Cash and cash equivalents, end of period	$148,695	$39,206
Supplemental disclosure of non-cash investing and financing activities:		

Property and equipment acquired but not paid	$12,513	$775
Unrealized gain (loss) on available-for-sale investments	$(1,606)	$(5)
Issuance of 86,828 and 158,717 shares of common stock to fund the Company's 401(k) matching contribution for 2017 and 2016, respectively	$4,300	$3,008
Interest paid	$48	$50

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, with the goal of becoming a leader in cancer diagnostics.

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, Exact Sciences Development Company, 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, 2017 included in the Company's Annual Report on Form 10-K (the "2017 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 2017 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, Exact Sciences Development Company, 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