EXACT SCIENCES CORP
Form 40-APP/A
August 24, 2018

SEC File No. 812-14875

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

AMENDMENT NO. 3 TO, AND RESTATEMENT OF,
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

Please direct all communications concerning this application to:

C. Dirk Peterson, Esq.
K&L Gates LLP
1601 K Street, N.W.
Washington, D.C. 20006
(202) 778-9324

with copy to:

D. Scott Coward, Esq.

Exact Sciences Corporation
441 Charmany Drive
Madison, Wisconsin 53719

TABLE OF CONTENTS

UNITED STATES OF AMERICA
BEFORE THE
SECURITIES AND EXCHANGE COMMISSION

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

File No. 812-14875

I. SUMMARY OF RELIEF REQUESTED

Exact Sciences Corporation ("Exact Sciences" or the "Company") hereby applies for an order of the U.S. Securities and Exchange Commission (the "Commission," or the "SEC") pursuant to Section 3(b)(2) of the Investment Company Act of 1940 (15 U.S.C. §§80a-1 et seq.), as amended (the "1940 Act"). 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 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 Government securities and cash items).[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

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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.

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 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,

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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.

consisting of more than 85 million Americans age 50 and above. Given the potential for significant market demand, Exact Sciences pursued strategic opportunities to develop a screening test for colorectal cancer and pre-cancer. These efforts culminated in the development of Cologuard®, a patient-friendly, non-invasive stool-based DNA screening test for colorectal cancer and pre-cancer, which received approval by the U.S. Food and Drug Administration ("FDA") and Medicare coverage in 2014. The Company is currently commercializing Cologuard®.

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

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

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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.

These Capital Preservation Investments have historically been government securities,[6] investment-grade corporate debt, investment-grade asset-backed securities, commercial paper, certificates of deposits ("CDs"), and cash items. The Company's investment guidelines establish a maximum maturity for these Capital Preservation Investments 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.

In November 2017, the Company made a strategic $3 million investment in a privately held company, representing a 10% stake in the underling company. The Board reviewed and ultimately approved of the investment because the company, a supplier to Exact Sciences, fulfilled a long-term business strategy. The Board may from time to time consider, and review, other similar strategic investments, with a view to potentially acquiring all of a going concern to the extent that the business is complementary to Exact Sciences' mission and ownership supports the Company's overall business strategy. These kinds of investments, therefore, are not for speculative purposes or for purposes of earning high rates of return. Indeed, the Company has not recognized any returns or investment income from its strategic investment in the supplier. Rule 3a-8(a)(4)(i) and (ii) under the 1940 Act contemplates similar types of strategic business decisions, and the Company would expect to comply with the rule if it makes "other investments" that are not considered Capital Preservation Investments.

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.

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[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" 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).

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.

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

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[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.

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:

Fiscal Year	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-

* "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.

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.

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

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[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.

* "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.

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 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

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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.

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. The Board has approved of a $3 million strategic investment in a company whose business is complementary 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 predominantly to preserve capital necessary to fund R&D and operations or, on a more limited scale, strategically in companies the Board believes are complementary to the business of Exact Sciences. The Company believes it makes prudent capital-preservation investments for purposes of funding its operations, 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 Investments, 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

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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).

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.

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 Investments, the Board reviewed and approved of a $3 million strategic investment in a Company supplier. Although no similar investments are under current consideration, the Board may approve in the future similar strategic investments in companies that are complementary to the Company's business and that fulfill its business strategy. The Company expects that any future "other investments" would comply with 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 Investments, an approximately $1.9 million increase from the fiscal year ended December 31, 2016. It recognized no investment income from its investment in a Company supplier. 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 is limited and nevertheless continued to be less than 2% of revenues and the net investment income attributed to Capital Preservation Investments 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

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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).

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 (exclusive of Government securities and cash items), as prescribed by the Asset Test. Because of the nature of the Company's business and investments, it has historically relied on Rule 3a-8 under the 1940 Act in not registering with the Commission as an investment company. Rule 3a-8 prescribes an exclusion from the definition of "investment company" in recognition that R&D companies may not technically qualify as operating companies outside of the Asset Test because of their need to invest a significant portion of their capital in securities for purposes of financing their R&D and operational activities. Rule 3a-8 sets forth seven conditions for reliance. These conditions require that: (i) R&D expenses be "substantial"[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,

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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).

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 has relied on Rule 3a-2 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.

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[13] See, supra, note 12.

[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.

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

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

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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).

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 "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.

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[20] 15 U.S.C. §80a-3(b)(1).

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

[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 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.
- 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