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

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

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

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

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

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

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

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 September 30, 2017, the value of Exact Sciences' investment securities constituted approximately 65% of the value of the Company's total assets on an unconsolidated basis (exclusive of cash items and Government securities).[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 1,235 full time employees and conducts business at leased and owned offices, laboratories, and other facilities in the Madison area (as well as a small office in Salt Lake City, Utah). These offices and labs give the Company approximately 407,000 square feet to devote to R&D, clinical testing and processing, product manufacturing, and general company operations.

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

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

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

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

1. Corporate Governance

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

a. Board Members

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

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

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

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

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

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

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

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

Daniel J. Levangie has served as a Director since July 2010. Mr. Levangie, an executive with operating experience in the field of medical devices and in vitro diagnostics, is co-founder and manager of ATON Partners, a private investment and management consulting firm. Mr. Levangie also served as President of Insulet Delivery Solutions. Prior to co-founding ATON Partners, Mr. Levangie was Chief Executive Officer of Dune Medical Devices, Inc. and co-founder and managing partner of Constitution Medical Investors, Inc., a Boston-based private investment and product development firm acquired by Roche Diagnostics Corporation in July 2013. Mr. Levangie has held a variety of executive management positions at 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 Chairman of Natural Products Group (the holding company of Arbonne, Natures Gate, and Levlad). From July 2002 to March 2006, Ms. Zanotti was a member of management of several well-known public companies, such as McDonald's Corporation and the Proctor & Gamble Company. Ms. Zanotti currently serves on the Board of Trustees of Xavier University and Director of the following companies: Hill-Rom Holdings, Inc., a worldwide manufacturer and provider of medical technologies and related services, Mentor Corporation, a medical device company, Alberto Culver Company, a personal care products company, and TWT.

b. Executive Management Team

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

Kevin T. Conroy - See above.

Maneesh K. Arora - See above.

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

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

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

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

2. State of the Market for Exact Sciences' Business

Exact Sciences operates in the healthcare sector, a market with a capitalization of approximately $4.8 trillion. This market is comprised of several industries (or subsectors), including, among others, the biotechnology and life-sciences industries,[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 ("FDA") and Medicare coverage in 2014. The Company is currently commercializing Cologuard®.

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

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

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[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.

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support its commercialization, and failure of a product to generate the necessary physician or patient demand or acceptance. Statistically, biotechnology companies can experience significant odds against successful launch and commercialization as they shepherd a product through all the required clinical trial stages before production and marketing may commence. Therefore, the Company's success in this market depends on a number of factors, including the success and efficiency of its R&D program, its ability to secure and maintain intellectual property, its operating capacity and efficiency, and its marketing efforts for a completed product, all of which require working capital and the astute management of its balance sheet through business cycles to meet operating and regulatory costs. To meet these challenges, Exact Sciences maintains substantial current assets ($513.7 million as of September 30, 2017) to finance its operations. The Company has experienced an accumulated deficit of more than $838 million since its founding as it has worked to develop and commercialize a non-invasive colorectal screening test. Although the commercial launch of Cologuard® has been highly successful,[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 commercialize Cologuard® and develop future products, the Company also makes targeted, conservative investments in, among other things, capital preserving financial instruments, such as government securities,[6] investment-grade corporate debt, investment-grade asset-backed securities, commercial paper, certificates of deposits ("CDs"), and various cash items (collectively, "Capital Preservation Assets"). The Company's strategy with regard to such investments emphasizes liquidity and preservation of capital to ensure that funds are available -- and available when needed -- to support its business operations.

3. Current and Future Product Lines

a. Cologuard®

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

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

[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).

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

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

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

b. Product Pipeline

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

expand diagnostic testing capabilities for several major cancers. The Company's continued collaboration with the MAYO Foundation for Medical Education and Research ("MAYO") also is a key component of this strategic business plan.[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.

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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 professionals available for purposes of supporting R&D through 2020.

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

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

B. Financing of Exact Sciences' Business

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

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

Acceptance of Cologuard® in the medical community;

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

Inclusion of Cologuard® in quality measures including the Healthcare Effectiveness Data and Information Set measures and CMS Star ratings;

Recommendations and studies regarding Cologuard® specifically or colorectal cancer screening generally that may be published by government agencies, professional organizations, academic or medical journals or other key opinion leaders;

Patient acceptance of and demand for the Cologuard® test and effectively keeping pace with product demand;

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

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

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

including federal or state laws that mandate coverage for colorectal cancer