

SECURITIES AND EXCHANGE COMMISSION

Investment Company Act Release No. 33228; File No. 812-14875

Exact Sciences Corporation

September 14, 2018

AGENCY: Securities and Exchange Commission (“Commission”).

ACTION: Notice.

Notice of application for an order under Section 3(b)(2) of the Investment Company Act of 1940 (“Act”).

Applicant: Exact Sciences Corporation

Summary of Application: Applicant seeks an order under Section 3(b)(2) of the Act declaring it to be primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities. Applicant is in the business of producing and developing screening and diagnostic tests for the early detection and prevention of certain cancers.

Filing Dates: The application was filed on January 30, 2018 and amended on June 1, 2018, July 6, 2018 and August 24, 2018.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission’s Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on October 10, 2018 and should be accompanied by proof of service on Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer’s interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission’s Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549-1090. Applicant, 441 Charmany Drive, Madison, Wisconsin 53719.

FOR FURTHER INFORMATION CONTACT: Rochelle Kauffman Plesset, Senior Counsel, at (202) 551-6840, or Nadya B. Roytblat, Assistant Chief Counsel, at (202) 551-6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551-8090.

Applicant's Representations:

1. Formed in 1995, Applicant is a Delaware corporation that is in the business of developing, clinical testing, marketing and commercializing cancer and pre-cancer screening and diagnostic tests. Applicant currently manufactures a non-invasive, patient-friendly screening test called Cologuard and provides it to patients on a prescription-only basis through its clinical laboratory. Applicant is also currently working on the development of additional tests for other types of cancers.

2. Applicant states that companies in the healthcare sector such as itself generally need significant liquid capital to finance their operations and meet high production, commercialization and regulatory costs. Such companies often spend a significant proportion of their revenues on research and development ("R&D") in order to bring a product to market and to bring products through the Food and Drug Administration's ("FDA") approval process.

3. Applicant states that it currently depends on raised capital to finance operations and continued growth but ultimately seeks to generate cash from its operations to support its business.

Applicant states that it has successfully raised capital to finance its operations and commercialization of Cologuard in large part through various public offerings of its debt and equity securities. Applicant seeks to preserve its capital and maintain liquidity, pending the use of such capital to support its business operations, by investing in short-term investment grade and liquid fixed income and money market instruments that earn competitive market returns and provide a low level of credit risk (“Capital Preservation Investments”). Applicant also, to a limited extent, makes strategic investments in companies that are complementary to its core business. Applicant’s board of directors oversees Applicant’s investment practices and defines the parameters for investment activities. Applicant does not invest in securities for short-term speculative purposes.

Applicant’s Legal Analysis:

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

2. Section 3(a)(1)(A) of the Act defines the term “investment company” to include an issuer that is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities. Section 3(a)(1)(C) of the Act further defines an investment company as an issuer that is engaged or proposes to engage in the business of investing, reinvesting, owning, holding or trading in securities, and owns or proposes to acquire investment securities having a value in excess of 40% of the value of the issuer’s total assets (exclusive of Government securities and cash items) on an unconsolidated basis. Section 3(a)(2) of the Act defines “investment securities” to include all securities except Government securities, securities issued by employees’ securities companies, and securities issued by

majority-owned subsidiaries of the owner which (a) are not investment companies and (b) are not relying on the exclusions from the definition of investment company in Section 3(c)(1) or Section 3(c)(7) of the Act. While Applicant states that it does not hold itself out as being engaged primarily in the business of investing, reinvesting or trading in securities, Applicant states that it consistently holds investment securities that exceed 40% of its total assets on an unconsolidated basis (exclusive of Government securities and cash items). Applicant states that it therefore falls within the definition of investment company under Section 3(a)(1)(C) of the Act.

3. Rule 3a-8 under the Act provides an exclusion from the definition of investment company if, among other factors, a company's R&D expenses are a substantial percentage of its total expenses for the last four fiscal quarters combined. While Applicant believes that it complies with the conditions of Rule 3a-8, Applicant is concerned that its R&D expenses, while substantial in absolute terms, may not be substantial as a ratio of overall expenses, particularly given the expense increase in connection with the commercialization of Cologuard. Applicant's R&D expenses as a ratio of total expenses have declined from a high of 74% of total expenses in 2012 to approximately 11% of total expenses for year-end 2017 and 12% as of March 31, 2018. Applicant explains that since the FDA's approval of Cologuard, Applicant has devoted more resources to sales and marketing. Although Applicant's R&D expenses have generally increased or remained steady overtime, its overall expenses have disproportionately increased, causing a decline in the ratio of R&D expenses to overall expenses. While Applicant expects to increase funding for R&D for other products, it also expects to increase funding with respect to the commercialization of Cologuard. Thus, Applicant does not expect its additional funding for R&D to cause a significant increase in the ratio of R&D funding to overall expenses.

4. Section 3(b)(2) of the Act provides that, notwithstanding Section 3(a)(1)(C) of the Act, the Commission may issue an order declaring an issuer to be primarily engaged in a business other than that of investing, reinvesting, owning, holding, or trading in securities directly, through majority-owned subsidiaries, or controlled companies conducting similar types of businesses. Applicant requests an order under Section 3(b)(2) of the Act declaring that it is primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities, and therefore is not an investment company as defined in the Act.

5. In determining whether an issuer is “primarily engaged” in a non-investment company business under Section 3(b)(2) of the Act, the Commission considers the following factors: (a) the company’s historical development, (b) its public representations of policy, (c) the activities of its officers and directors, (d) the nature of its present assets, and (e) the sources of its present income.<sup>1</sup>

6. Applicant submits that it satisfies the criteria for issuance of an order under Section 3(b)(2) of the Act because Applicant is primarily engaged in the business of developing, testing, marketing and commercializing cancer and pre-cancer diagnostic screening tests and not in the business of investing, reinvesting, owning, holding or trading in securities.

a. Historical Development. Applicant states that since its inception in 1995 it has operated in the healthcare sector to develop and commercialize cancer and pre-cancer screening and diagnostic tests. Applicant has focused its strategic opportunities in developing a screening test for colorectal cancer, culminating in the development of Cologuard, which received FDA approval in 2014. Since 2014, Applicant has been engaged in sales and marketing Cologuard and has begun research and development on testing related to other types of cancers. Applicant has

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<sup>1</sup> Tonopah Mining Company of Nevada, 26 SEC 426, 427 (1947).

nine wholly-owned subsidiaries, each of which is an operating company integrally related to Applicant's business. Applicant has never sold any of its subsidiaries since inception.

b. Public Representations of Policy. Applicant states it has never made any public representations that would indicate that it is in any business other than developing and commercializing cancer screening technologies. Applicant represents that it has never held and does not now hold itself out as an investment company within the meaning of the Act. Applicant states that all annual reports, web postings, press releases and written communications issued by Applicant have related to its business as a cancer screening and diagnostics company. Applicant further states that its public representations make clear that shareholders invest in the Applicant's securities with the expectation of realizing gains from Applicant's development and commercialization of cancer-screening and diagnostic technologies and not from returns on an investment portfolio. Applicant's only public representations regarding its investment securities are those required to be disclosed in public filings with the Commission.

c. Activities of Officers and Directors. Applicant represents that its board of directors and officers devote substantially all of their time managing Applicant's business as a cancer screening and diagnostics company. Applicant states that its management and corporate governance structure is comprised of professionals with expertise in technology, science, medicine, life science/biotechnology, and government. Applicant states that day-to-day management of the Capital Preservation Investments is handled by external asset managers consistent with investment guidelines adopted by the Applicant's board of directors on an annual basis. Applicant states that while the board of directors may review strategic investments in companies that are complementary to the Applicant's business, these reviews are made for long-

term business, not speculative investment strategies. None of the members of management or the board of directors, even when reviewing strategic investments, spends or proposes to spend more than 1% of his or her time on any securities investment activities on behalf of the Applicant. They, along with the Applicant's approximately 1,268 full-time employees, are dedicated to the production and commercialization of Cologuard and the development of new cancer screening and diagnostic products.

d. Nature of Assets. Applicant states that as of March 31, 2018, Applicant's investment securities constituted approximately 79% of its total assets (excluding Government securities and cash items) on an unconsolidated basis.<sup>2</sup> Furthermore, more than 99% of its investment securities consisted of Capital Preservation Investments. Applicant's remaining investment securities consist of a strategic investment in a company whose business is complementary to the Applicant's business. Applicant anticipates that its investment securities other than Capital Preservation Investments will not exceed 10% of its total unconsolidated assets (excluding Government securities and cash items) in the future. Applicant uses current assets, including its Capital Preservation Investments, to finance its continued R&D program and operations in connection with the commercialization of Cologuard.

e. Sources of Income and Revenue. Applicant represents that since its inception it has had net operating losses. It does, however, derive income from its investment securities.

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<sup>2</sup> Applicant states that none of its subsidiaries owns investment securities.

Applicant states that, particularly given its commercialization of Cologuard, a review of its current sources of revenues provides a more accurate picture of its operating company status. Applicant states that, for the year ended December 31, 2017, Applicant had approximately \$266 million of revenues attributable to Cologuard. For the three months ended March 31, 2018, Cologuard revenues were approximately \$90.3 million. In contrast, Applicant earned \$3.9 million in net investment income in 2017, and \$3.7 million for the three months ended March 31, 2018, all derived from Capital Preservation Investments.<sup>3</sup> Applicant states that if investment income were compared to its revenues from Cologuard, it would account for less than 2%. Applicant states it does not expect its net investment income to exceed 2% of its revenues over the long term.

7. Applicant asserts that its historical development, its public representations of policy, the activities of its officers and directors, the nature of its assets and its sources of income and revenue, as discussed in the application, demonstrate that it is engaged primarily in a business other than that of investing, reinvesting, owning, holding or trading securities. Applicant thus asserts that it satisfies the criteria for issuing an order under Section 3(b)(2) of the Act.

Applicant's Conditions:

Applicant agrees that any order granted pursuant to the application will be subject to the following conditions:

1. Applicant will continue to allocate and use its accumulated cash and investment securities for bona fide business purposes; and

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<sup>3</sup> Applicant states that it has not, and does not expect to, earn investment income from its strategic investment.



2. Applicant will refrain from investing or trading in securities for short-term speculative purposes.

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

Eduardo A. Aleman  
Assistant Secretary