EXACT SCIENCES CORP
Form 10-K
March 12, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended: December 31, 2009

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

Commission file number 000-32179

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE	**02-0478229**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
441 Charmany Drive, Madison, WI	**53719**
(Address of principal executive offices)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, $.01 Par Value	**The NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ý

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ý

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period

that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer ý	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, as of the last business day of the Registrant's most recently completed second fiscal quarter was approximately $87,355,000 (based on the closing price of the Registrant's Common Stock on June 30, 2009 of $2.65 per share).

The number of shares outstanding of the Registrant's $.01 par value Common Stock as of March 11, 2010 was 35,832,021.

DOCUMENT INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days after the end of the fiscal year ended December 31, 2009. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

Table of Contents

EXACT SCIENCES CORPORATION
ANNUAL REPORT ON FORM 10-K
YEAR ENDED DECEMBER 31, 2009

TABLE OF CONTENTS

Table of Contents

PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange and Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "could," "seek," "intend," "plan," "estimate," "anticipate" or other comparable terms. Forward-looking statements in this Annual Report on Form 10-K may address the following subjects among others: statements regarding the sufficiency of our capital resources, expected operating losses, expected license fee revenues, expected research and development expenses, expected general and administrative expenses and our expectations concerning our business strategy. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, as a result of various factors including those risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of this report. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward -looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

Item 1. Business

Overview

Exact Sciences Corporation is a molecular diagnostics company focused on the early detection and prevention of colorectal cancer. We have exclusive intellectual property protecting our non-invasive, molecular screening technology for the detection of colorectal cancer.

Our primary goal is to become the market leader for a patient-friendly diagnostic screening product for the early detection of colorectal pre-cancer and cancer. Our strategic roadmap to achieve this goal includes the following key components:

develop and refine our non-invasive stool-based (sDNA) colorectal pre-cancer and cancer screening test;

advance our product through U.S. Food and Drug Administration, or FDA, clinical trials;

secure insurance coverage and reimbursement for our product; and

commercialize an FDA-cleared product that detects colorectal pre-cancer and cancer.

Our current focus is on the commercial development and seeking U.S. Food and Drug Administration (FDA) clearance and approval of our stool-based DNA (sDNA) colorectal cancer screening product. We believe obtaining FDA approval is critical to building broad demand and successful commercialization for our sDNA colorectal cancer screening technologies. As part of our product development efforts, we are exploring the marker combinations and platform requirements necessary for optimal performance of our technology based on market need. Objectives around performance, throughput and cost are among the elements that will need to be met in the design and development of a commercial product based on our technology.

Table of Contents

Colorectal cancer is the third leading cause of cancer death overall, the second leading cause of death from cancers that affect both men and women in the United States, and the leading cause of cancer death among non-smokers. Patients who are diagnosed early in the progression of the disease with pre-cancerous lesions or polyps, or early-stage cancer are more likely to have a complete recovery and to be treated less expensively. Accordingly, the American Cancer Society, or ACS, recommends that all people age 50 and older undergo regular colorectal cancer screening. Of the more than 89 million people in the United States for whom routine colorectal cancer screening is recommended, only 25 percent have been screened according to current guidelines. It is estimated that about one-half of those who should be, have never been screened at all. We believe that this large population of unscreened and inadequately screened patients represents an opportunity to reduce colorectal cancers deaths and the health care costs associated with colorectal cancer.

Professional colorectal cancer screening guidelines in the United States, including those of the ACS, the American College of Gastroenterology, and the American Gastroenterological Association, recommend regular screening by a variety of methods. Historically, these recommendations consisted of colonoscopy, flexible sigmoidoscopy and fecal occult blood testing, or FOBT, as well as combinations of some of these methods. On March 5, 2008, the ACS and the U.S. Multi-Society Task Force on Colorectal Cancer, or MSTF-CRC, a consortium of several organizations that includes representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and the American College of Physicians/Society of Internal Medicine, announced that non-invasive, sDNA screening technology is included in the updated national colorectal cancer screening guidelines as a screening option for the detection of colorectal cancer in average risk, asymptomatic individuals age 50 and older.

Our product includes DNA markers, which in published studies have been shown to be associated with colorectal cancer. These markers include the aberrant methylation of the Vimentin gene promoter region, which we refer to as Vimentin. We have exclusive rights to the Vimentin technology through our license agreement with Case Western Reserve University. Our test also will include a fecal immunochemical test, or FIT. This immunoassay will increase sensitivity without affecting specificity, improving the overall sensitivity of our test.

Background

It is widely accepted that colorectal cancer is among the most preventable, yet least prevented cancers. Colorectal cancer typically takes up to 15 years to progress from a pre-cancerous lesion to metastatic cancer and death. However, it is the second-leading cause of cancer death in the United States, killing almost 50,000 people each year.

Medical experts believe that many colorectal cancer deaths can be avoided. These deaths occur needlessly because people are not screened for colorectal cancer at all, or they are screened using ineffective methods, often outside the recommended screening interval. As a result, the cancer is either not detected at all or it is detected at a later stage, when the five-year survival rate falls below 50%. The number of people who die annually from the disease has remained materially unchanged during the last 20 years, despite the availability of multiple colorectal cancer screening options, all of which we believe fail to effectively meet the needs of patients, doctors and payors.

There is a significant unmet clinical need related to the diagnosis of colorectal cancer. Only 25 percent of those who should be screened for colorectal cancer are screened according to current guidelines. Half of those age 50 years and older have not been screened at all. Poor compliance has meant that nearly two-thirds of colon cancer diagnoses are made in the disease's late stages. The five-year survival rates for stages 3 and 4 are 54 percent and 8 percent, respectively.

Detection of pre-cancerous adenomas and colorectal cancer in its earliest stages increases the likelihood of survival and reduces the significant cost associated with treating late-stage colorectal

Table of Contents

cancer. Accordingly, the ACS recommends that the more than 89 million Americans age 50 and above undergo regular colorectal cancer screening with the methods endorsed by the ACS.

The competitive advantages of sDNA-based screening provide a massive market opportunity. Assuming a 30-percent test adoption rate and a three-year screening interval, the potential U.S. market for sDNA screening is $1.2 billion. The total available U.S. market is more than $5 billion which is approximately 89 million people to be screened every three years.

Our Solution

Our screening test includes proprietary and patented methods that isolate and analyze the trace amounts of human DNA that are shed into stool every day from the exfoliation of cells that line the colon. When colorectal cancer is present, a minute portion of the total isolated human DNA will often represent DNA shed from cancerous or pre-cancerous lesions. Once the human DNA in the sample is isolated, sDNA-based detection looks for specific mutations and other abnormalities in that DNA known to be associated with colorectal cancer. Our test will also detect blood in stool, utilizing a Fecal Immunochemical Test (FIT). A "positive" result from sDNA detection or a positive FIT result does not necessarily mean that a patient has colorectal cancer. A "positive" result means that one or more of the genetic markers that can be associated with colorectal cancer has been identified. Under these circumstances, the clinical protocol is for the patient to obtain a colonoscopy for confirmation.

We believe that sDNA-based screening in the general population offers an opportunity to increase screening rates, decrease deaths and lower health care costs from colorectal cancer. We believe that our proprietary methods and technologies have several advantages over other screening options that may lead to decreased mortality associated with colorectal cancer.

The benefits of sDNA-based screening are clear.

It detects both pre-cancers and cancers, and we are targeting sensitivities greater than 50 percent and 85 percent, respectively.

sDNA-based screening is non-invasive and requires no bowel preparation or dietary restriction like other methods.

The sample for sDNA-based screening can be collected easily at home and shipped to the laboratory, where the testing would be conducted.

sDNA-based screening also is affordable, particularly compared to colonoscopy.

Of those people for whom screening is recommended, many reject the option of colonoscopy which, while accurate as a means of detecting colorectal cancer, is invasive and requires a bowel preparation. In addition, many FOBT screening tests require unpleasant stool sampling and stool manipulation by the patient, and certain FOBT screening tests also require dietary modifications.

Reimbursement

We are continuing to work to obtain national coverage for sDNA colorectal cancer screening technologies from Medicare and positive coverage decisions from major national and regional managed care organizations and insurance carriers, and self-insured employer groups.

Twelve states and the District of Columbia have legislative mandates requiring that available colorectal cancer screening options offered by certain categories of insurers in these states must include all tests identified in the current ACS screening guidelines, which include sDNA screening. These states include Alaska, Georgia, Illinois, Indiana, Kentucky, Maine, Maryland, Missouri, Nevada, New Jersey, North Carolina, and Rhode Island. Additionally, in the second half of 2008, CIGNA, one of the nation's largest insurers, included sDNA screening among its nationwide covered benefits. While we

Table of Contents

view inclusion of sDNA screening for colorectal cancer in the state mandates and the positive coverage decision by CIGNA as important first steps in securing wide-spread coverage for stool-based DNA screening for colorectal cancer from private insurance carriers, we believe that obtaining a positive national coverage decision from the Center for Medicare and Medicaid (CMS) for our sDNA screening product will be a necessary element in achieving any material commercial success.

Competition

There are a number of established primary screening methods that are recommended for colorectal cancer. All of the colorectal cancer detection methods in use today are constrained by some combination of poor sensitivity, poor compliance and cost. Colonoscopy remains the most widely used and is considered the 'gold standard' method that is most widely practiced as a primary colorectal cancer screen. However, colonoscopy is uncomfortable and expensive and suffers from a high rate of non-compliance. Following colonoscopy, the next most widely used method of colorectal cancer screening is FOBT or a newer version of FOBT called Fecal Immunochemical Testing (FIT). Fecal blood testing suffers from poor sensitivity, including 50 percent detection rates for cancer and 12 percent detection rates for pre-cancers. Recently, CT colonography (also called virtual colonoscopy) has emerged as an option. CT colonography requires a bowel preparation (as does colonoscopy) and consists of a radiological examination of the colon. CT colonography was recently rejected for reimbursement by the Centers for Medicare and Medicaid (CMS). Another potential alternative method is blood-based DNA testing. The principle disadvantage of blood DNA testing is poor sensitivity for cancer and an inability to detect pre-cancerous lesions. Data from a clinical trial of one blood-based DNA test was released in early 2010. It demonstrated only 50 percent sensitivity across all stages of cancer.

We are aware of three companies, Epigenomics, OncoMethylome Sciences and Gene News, developing screening tests for the detection of colorectal cancer. Additionally, Quest Diagnostics and Abbott Diagnostics have sublicensed technology from Epigenomics and are offering versions of the Epigenomics test to customers as lab developed tests (LDT) and as CE marked kits, respectively. Epigenomics is headquartered in Berlin, Germany and has a U.S. location in Seattle, Washington. OncoMethylome Sciences has several offices located in Belgium and U.S. offices in North Carolina. Gene News is located in Ontario, Canada.

Research and Development

Our current focus is on the commercial development and seeking U.S. Food and Drug Administration (FDA) clearance and approval of our sDNA colorectal cancer screening product. Accordingly, research and development costs account for a substantial portion of our operating expenses. Our research and development expenses were $4.2 million, $2.0 million and $4.9 million for the years ended December 31, 2009, 2008 and 2007, respectively.

Government Regulation

Certain of our activities are subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug, and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing and export of certain technologies. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions and criminal prosecution.

Table of Contents

U.S. Food and Drug Administration

The Food, Drug and Cosmetic Act requires that medical devices introduced to the U.S. market, unless otherwise exempted, be subject to either a premarket notification clearance, known as a 510(k), or a premarket approval, known as a PMA. Our current focus is on the commercial development and seeking FDA clearance and approval of our sDNA colorectal cancer screening product. The 510(k) process means that the FDA will not require a PMA, a generally but not necessarily more time-consuming and costlier process than the 510(k) process, because the FDA finds that either (a) our product is substantially similar to a legally marketed product (a "predicate device") or (b) in the absence of a predicate device that the FDA concludes that our product may use a process known as a de novo classification, which is reserved for low-risk products; however, the 510(k) process still involves substantial costs and time and may have to be repeated for any number of reasons, including but not limited to, the FDA's discretion or if the product is modified during the process. The PMA process, which is necessary when a device cannot be cleared through the 510(k) process, involves providing extensive data to the FDA to allow the FDA to find that the device is safe and effective for its intended use, which may also include providing additional data and updates to the FDA, the convening of expert panels, inspection of manufacturing facilities, and new or supplemented PMAs if the product is modified during the process. Even if granted, a 510(k) or PMA approval may place substantial restrictions on how our device is marketed or sold, and the FDA will continue to place considerable restrictions on our products, including but not limited to registering manufacturing facilities, listing the products with the FDA, complying with labeling, and meeting reporting requirements. We believe that the studies required in connection with any approval or clearance of our technology, regardless of whether the regulatory pathway is the 510(k) process or a PMA, will be material in cost and time-intensive. There can be no assurance that FDA will ultimately approve any 510(k) request or approve any PMA submitted by us in a timely manner or at all.

Other Regulations

We are also subject to U.S. and state laws and regulations regarding the operation of clinical laboratories. Federal CLIA requirements and laws of certain other states impose certification requirements for clinical laboratories, and establish standards for quality assurance and quality control, among other things. Clinical laboratories are subject to inspection by regulators, and to sanctions for failing to comply with applicable requirements. Sanctions available under CLIA include prohibiting a laboratory from running tests, requiring a laboratory to implement a corrective plan, and imposing civil monetary penalties. If we fail to meet any applicable requirements of CLIA or state law, it could adversely affect any future CMS consideration of any of our technologies, prevent its approval entirely, and/or interrupt the commercial sale of any products and otherwise cause us to incur significant expense.

In addition, the specimen transport and storage containers that are used in connection with certain of our products are deemed to be Class I medical devices regulated by the FDA. Once a physician orders a test, the patient will need to receive a specimen container to collect and transport the patient's stool sample. Under 21 CFR Sec. 864.3250, specimen transport and storage containers generally have been exempt from the FDA's premarket notification requirement and much of the Quality System Regulation. However, there can be no assurance that the FDA will consider our products' collection containers to be exempt from the premarket notification requirement or the majority of the Quality System Regulation requirements. Moreover, we believe that if the collection kit becomes part of a cleared or approved device, the FDA will seek to include the container in the premarket clearance or approval requirement as part of the sDNA test system.

Table of Contents

Intellectual Property

Our intellectual property portfolio positions us as the leading player in the sDNA market. Our patent estate broadly protects our position in the market, including the platform technology, methods and biomarkers. In 2009, we expanded our intellectual property estate through our collaboration with the Mayo Clinic as well as by licensing Invader detection chemistry from Hologic, which we plan to incorporate into our test. Previously we licensed Case Western's important Vimentin DNA methylation marker, as well as on an exclusive basis, Johns Hopkins' digital PCR technologies for colon cancer detection.

Our success depends to a significant degree upon our ability to protect our technologies through patent coverage. As of December 31, 2009, we owned 14 issued patents and 9 pending applications in the United States, and 51 issued patents and 11 pending patent applications in foreign jurisdictions. In addition, as part of the Genzyme transaction, we received an exclusive license back from Genzyme Corporation in the fields of colorectal cancer screening and stool-based detection of any disease or condition to the 25 patents issued and 9 pending patent applications in the U.S., and 33 patents issued and 15 pending patent applications in foreign jurisdictions sold to Genzyme.

Each of our patents generally has a term of 20 years from its respective priority filing date. Consequently, our first patents are set to expire in 2016.

Genzyme Transaction

On January 27, 2009, we entered into a strategic transaction with Genzyme Corporation. As a result of the Genzyme transaction, we assigned certain aspects of our intellectual property applicable to the fields of prenatal and reproductive health to Genzyme. We also granted Genzyme a license to use and sublicense some of our remaining intellectual property in fields other than colorectal cancer detection and stool-based disease detection. With respect to the assigned intellectual property, Genzyme granted us a license to use and sublicense such intellectual property in the fields of colorectal cancer detection and stool-based detection of any disease or condition. Accordingly, we retained our rights in both the assigned and licensed intellectual property in the fields of colorectal cancer detection and stool-based disease detection. In addition, we and Genzyme each granted to the other a license to use and sublicense any improvements we or Genzyme make to the intellectual property. Genzyme agreed to pay a double-digit royalty to us on income received by Genzyme as a result of any licenses or sublicenses to third parties of the assigned or licensed intellectual property.

Employees

As of December 31, 2009, we had nineteen full-time employees. None of our employees are represented by a labor union. We consider our relationship with our employees to be good.

Available Information

We were incorporated in the State of Delaware on February 10, 1995. Our executive offices are located at 441 Charmany Drive, Madison, Wisconsin 53719. Our telephone number is 608-284-5700. Our Internet website address is *http://www.exactsciences.com*. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. Our Internet website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

Table of Contents

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. This discussion highlights some of the risks which may affect future operating results. These are the risks and uncertainties we believe are most important for you to consider. We cannot be certain that we will successfully address these risks. If we are unable to address these risks, our business may not grow, our stock price may suffer and/or we may be unable to stay in business. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations.

We may never successfully commercialize any of our technologies or become profitable.

We have incurred losses since we were formed and have had only modest product and royalty fee revenues since the commercial launch of PreGen-Plus in August 2003. From our date of inception on February 10, 1995 through December 31, 2009, we have accumulated a total deficit of approximately $181.6 million. We expect that our losses will continue for at least the next several years and we will be required to invest significant additional funds toward development of our colorectal cancer screening technology. If our revenue does not grow significantly, we will not be profitable. We cannot be certain that the revenue from the sale of any of our technologies will be sufficient to make us profitable.

Our future revenues will depend on our ability to successfully commercialize an FDA-approved product for stool-based DNA colorectal cancer screening. Our ability to successfully commercialize our technologies may be affected by the following factors:

- the scope of and progress made in our research and development activities;
- our ability to successfully execute on a clinical trial;
- threats posed by competing technologies;
- acceptance, endorsement and formal policy approval of stool-based DNA screening reimbursement by Medicare and other third-party payors;
- our ability to commercialize our test through primary care physician awareness and consumer education and outreach.

Many of these factors are outside our control and, accordingly, we cannot assure you that one or more of the foregoing will occur in the near term, or at all. Failure to achieve one or more of the foregoing events could negatively impact the successful commercialization of stool-based DNA testing services or products utilizing our intellectual property and impair our ability to generate revenues and achieve profitability.

We will need additional capital to execute our business plan, and we may be unable to raise additional capital on acceptable terms.

Following the closing of our strategic transaction with Genzyme in January 2009, we have resumed our efforts to develop an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening. The FDA approval path for our colorectal cancer screening technology is likely to take significant time and require significant research, development and clinical study expenditures.

Although we believe we have sufficient capital to fund our operations for at least the next twelve months, we do not have sufficient capital to fully fund the commercial development of our stool-based DNA technology and related FDA submission and commercialization efforts. We do not expect that product royalty payments or milestone payments from LabCorp will materially supplement our liquidity position in the next twelve months, if at all. If we are unable to obtain needed financing on acceptable

Table of Contents

terms, we may not be able to implement our business plan which could have a material adverse effect on our business, financial condition and results of operations. If we raise additional funds through the sale of equity, convertible debt or other equity-linked securities, our shareholders' percentage ownership in us will be reduced. In addition, these transactions may dilute the value of our outstanding stock. We may issue securities that have rights, preferences and privileges senior to our common stock. If we raise additional funds through collaborations or licensing arrangements, we may relinquish rights to certain of our technologies or products, or grant licenses to third parties on terms that are unfavorable to us. Even if we successfully raise sufficient funds to continue our operations to fund the development, FDA submission, and commercialization of our technology, including an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening, we cannot assure you that our business will ever generate sufficient cash flow from operations to become profitable.

If Medicare and other third-party payors, including managed care organizations, do not issue positive policy decisions approving reimbursement for our stool-based DNA colorectal cancer screening technology, the commercial success of products utilizing our technologies would be compromised.

Successful commercialization of a stool-based DNA screening product will depend, in large part, on the availability of adequate reimbursement from government insurance plans, managed care organizations and private insurance plans. There is significant uncertainty concerning third-party reimbursement for the use of tests incorporating new technology. Reimbursement of stool-based DNA colorectal cancer screening by a third-party payor may depend on a number of factors, including a payor's determination that tests using our technologies are: sensitive for colorectal cancer; not experimental or investigational; approved by the major guidelines organizations; reliable, safe and effective; medically necessary; appropriate for the specific patient and cost-effective.

If we are unable to obtain positive policy decisions from third-party payors, including managed care organizations, approving reimbursement for stool-based DNA testing services or products at adequate levels, the commercial success of stool-based DNA screening for colorectal cancer would be compromised and our revenues would be significantly limited.

Other companies may develop and market novel or improved methods for detecting colorectal cancer, which may make our technologies less competitive, or even obsolete.

The market for colorectal cancer screening is large, approximating 89 million Americans age 50 and above, of which we believe approximately one-half fail to strictly follow the ACS's screening guidelines for colorectal cancer. As a result, the colorectal cancer screening market has attracted competitors, some of which have significantly greater resources than we have. Currently, we face competition from procedure-based detection technologies such as flexible sigmoidoscopy, colonoscopy and virtual colonoscopy, a procedure in which a radiologist views the inside of the colon through a scanner, as well as from existing guaic-based FOBT, and improved screening tests such as immunochemical FOBT. In addition, some companies and institutions are developing serum-based tests, or screening tests based on the detection of proteins, nucleic acids or the presence of fragments of mutated genes in the blood that are produced by colon cancer. For example, it is our understanding that Epigenomics AG has completed a large multi-center study to demonstrate the performance of its blood-based screening test for colorectal cancer. Additionally, we understand OncoMethylome Sciences is in the process of enrolling patients for a large blood-based colorectal cancer screening trial. These and other companies may also be working on additional methods of detecting colon cancer that have not yet been announced. We may be unable to compete effectively against these competitors either because their test is superior or because they may have more expertise, experience, financial resources and stronger business relationships.

Table of Contents

Our business would suffer if we are unable to license certain technologies or obtain raw materials and components or if certain of our licenses were terminated.

Any future commercialization of our stool-based DNA screening technology may require that we license certain third-party intellectual property. There can be no assurance that we can obtain these licenses on acceptable terms, if at all. Furthermore, there can be no assurance that any current contractual arrangements between us and third parties or between our strategic partners and other third parties, will be continued, or not breached or terminated early, or that we will be able to enter into any future relationships necessary to the continued commercial sale of any stool-based DNA testing services or products utilizing our technologies, or necessary to our realization of material revenues. For example, we have an exclusive license from Case Western Reserve University, or Case Western, for the use of the Vimentin gene in the field of colorectal cancer testing, pursuant to which we are permitted to sublicense such rights to others. If Case Western were to terminate this agreement as a result of a breach by us or otherwise, we would lose our ability to offer any test or testing service based on the Vimentin gene, including the right to develop an FDA-approved colorectal cancer screening product using the Vimentin gene, which would materially harm our business. Any failure to obtain necessary technologies or raw materials could require any stool-based DNA testing services or products utilizing our technologies to be re-configured which could halt such service or product entirely, negatively impact its commercial sale and increase the associated costs, any one of which could materially harm our business and adversely affect our future revenues.

If our clinical studies do not prove the reliability, effectiveness and superiority of stool-based DNA testing, we may experience reluctance or refusal on the part of physicians to order, and third-party payors to pay for, tests based on our technologies.

If the results of our research and clinical studies and our sales and marketing activities relating to communication of these results, do not convince thought-leading gastroenterologists, guidelines organizations, primary care physicians, third-party payors and patients that tests using our technologies are reliable, effective and superior to existing screening methods, including Hemoccult II, Hemoccult Sensa and immunochemical FOBT, we may experience reluctance or refusal on the part of physicians to order, and third-party payors to pay for tests using our technologies, which could prevent us from successfully commercializing our technologies.

We expect to rely on third parties to conduct any future studies of our technologies that may be required by the FDA, and those third parties may not perform satisfactorily.

We do not have the ability to independently conduct clinical or other studies that may be required to obtain clearance for our DNA-based colorectal screening technology with the FDA. Accordingly, we expect to rely on third parties such as contract research organizations, medical institutions and clinical investigators to conduct any such studies. Our reliance on these third parties for clinical development activities will reduce our control over these activities. Accordingly, these third-party contractors may not complete activities on schedule, or may not conduct studies in accordance with regulatory requirements or our study design. Our reliance on third parties that we do not control does not relieve us of our requirement to prepare, and ensure our compliance with, various procedures required under good clinical practices, even though third-party contract research organizations have prepared and are complying with their own, comparable procedures. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our technologies.

Table of Contents

We may experience limits on our revenue if only a small number of people decide to be screened for colorectal cancer using our technologies.

Even if our technologies are superior to other colorectal cancer screening options, adequate third-party reimbursement is obtained and we convince medical practitioners to order tests using our technologies, only a small number of people may decide to be screened for colorectal cancer. Despite the availability of current colorectal cancer screening methods as well as the recommendations of the ACS that all Americans age 50 and above be screened for colorectal cancer, a majority of these individuals do not complete a colorectal cancer screening test. Use of a stool-based DNA colorectal cancer screening will require people to collect a stool sample, which some people may be reluctant to do. If only a small portion of the recommended population is regularly screened for colorectal cancer or decides to utilize colorectal cancer screening tests using our technologies, we will, despite our efforts, experience limits on our revenue and our business would be materially harmed.

We may be subject to substantial costs and liability or be prevented from licensing our technologies for cancer detection as a result of litigation or other proceedings relating to patent rights.

Third parties may assert infringement or other intellectual property claims against our licensors, our licensees, our suppliers, our strategic partners, or us. We pursue a patent strategy that we believe provides us with a competitive advantage in the non-invasive early detection of colorectal cancer and is designed to maximize our patent protection against third parties in the U.S. and, potentially, in certain foreign countries. We have filed patent applications that we believe cover methods we have designed to help detect colorectal cancer and other cancers. In order to protect or enforce our patent rights, we may have to initiate actions against third parties. Any actions regarding patents could be costly and time-consuming, and divert our management and key personnel from our business. Additionally, such actions could result in challenges to the validity or applicability of our patents. Because the U.S. Patent & Trademark Office maintains patent applications in secrecy until a patent application publishes or the patent is issued, others may have filed patent applications covering technology used by us or our partners. Additionally, there may be third-party patents, patent applications and other intellectual property relevant to our technologies that may block or compete with our technologies. Even if third-party claims are without merit, defending a lawsuit may result in substantial expense to us and may divert the attention of management and key personnel. In addition, we cannot provide assurance that we would prevail in any such suits or that the damages or other remedies, if any, awarded against us would not be substantial. Claims of intellectual property infringement may require that we, or our strategic partners, enter into royalty or license agreements with third parties that may not be available on acceptable terms, if at all. These claims may also result in injunctions against the further development and commercial sale of services or products containing our technologies, which would have a material adverse affect on our business, financial condition and results of operations.

Also, patents and applications owned by us may become the subject of interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial cost to us, as well as a possible adverse decision as to the priority of invention of the patent or patent application involved. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application subject to such a proceeding.

If we are unable to protect our intellectual property effectively, we may be unable to prevent third parties from using our intellectual property, which would impair our competitive advantage.

We rely on patent protection as well as a combination of trademark, copyright and trade secret protection, and other contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, we will be unable to prevent third parties from using our technologies and they will be able to compete more effectively against us.

Table of Contents

We cannot assure you that any of our currently pending or future patent applications will result in issued patents, and we cannot predict how long it will take for such patents to be issued. Further, we cannot assure you that other parties will not challenge any patents issued to us, or that courts or regulatory agencies will hold our patents to be valid or enforceable. We have in the past been the subject of opposition proceedings relating to our patents. We cannot guarantee you that we will be successful in defending challenges made in connection with our patents and patent applications. Any successful third-party challenge to our patents could result in co-ownership of such patents with a third party or the unenforceability or invalidity of such patents.

In addition to our patents, we rely on contractual restrictions to protect our proprietary technology. We require our employees and third parties to sign confidentiality agreements and employees to sign agreements assigning to us all intellectual property arising from their work for us. Nevertheless, we cannot guarantee that these measures will be effective in protecting our intellectual property rights.

We cannot guarantee that the patents issued to us will be broad enough to provide any meaningful protection nor can we assure you that one of our competitors may not develop more effective technologies, designs or methods to test for colorectal cancer or any other common cancer without infringing our intellectual property rights or that one of our competitors might not design around our proprietary technologies.

If we or our partners fail to comply with regulatory requirements, we may be subject to stringent penalties and our business may be materially adversely affected.

The marketing and sale of stool-based DNA colorectal cancer screening services or products containing our technologies are subject to various state, federal and foreign regulations. We cannot assure you that we or our strategic partners will be able to comply with applicable regulations and regulatory guidelines. If we or our partners fail to comply with any such applicable regulations and guidelines, we could incur significant liability and/or our partners could be forced to cease offering such services or products in certain jurisdictions.

Moreover, healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments. Development of the existing commercialization strategy for stool-based DNA colorectal cancer screening has been based on existing healthcare policies. We cannot predict what additional changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations.

The success of our business and business strategy will be substantially dependent upon the efforts of our senior management team.

Our success will depend largely on the skills, experience and performance of key members of our senior management team. Effective April 2, 2009, Kevin T. Conroy was appointed as our new President and Chief Executive Officer. Similarly, Effective April 2, 2009, Maneesh Arora was appointed as our new Chief Financial Officer. On August 1, 2009, Dr. Graham Lidgard was hired as Chief Science Officer. Messrs. Conroy, Arora, and Dr. Lidgard are critical to directing and managing our growth and development in the future. Our success will be substantially dependent upon our senior management team's ability to gain proficiency in leading our company, implement or adapt our corporate strategies and initiatives, and develop key professional relationships, including relationships with our key collaborators and business partners. The efforts of each of these persons will be critical to us as we continue to develop our technologies and work towards the commercialization of an FDA-approved product. If we were to lose any of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

Table of Contents

If we lose the support of our key scientific collaborators, it may be difficult to establish tests using our technologies as a standard of care for colorectal cancer screening, which may limit our revenue growth and profitability.

We have established relationships with leading scientists at important research and academic institutions, such as Mayo Clinic, Case Western Reserve University, and The John Hopkins University, that we believe are key to establishing tests using our technologies as a standard of care for colorectal cancer screening. If our collaborators determine that colorectal cancer screening tests using our technologies are not appropriate options for colorectal cancer screening, or superior to available colorectal cancer screening tests, or that alternative technologies would be more effective in the early detection of colorectal cancer, we would encounter significant difficulty establishing tests using our technologies as a standard of care for colorectal cancer screening, which would limit our revenue growth and profitability.

Product liability suits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.

The sale and use of products or services based on our technologies, or activities related to our research and clinical studies, could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect which resulted in the failure to detect the disease for which it was designed. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our product liability insurance would protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

Certain provisions of our charter, by-laws and Delaware law may make it difficult for you to change our management and may also make a takeover difficult.

Our corporate documents and Delaware law contain provisions that limit the ability of stockholders to change our management and may also enable our management to resist a takeover. These provisions include a staggered board of directors, limitations on persons authorized to call a special meeting of stockholders and advance notice procedures required for stockholders to make nominations of candidates for election as directors or to bring matters before an annual meeting of stockholders. These provisions might discourage, delay or prevent a change of control in our management. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and cause us to take other corporate actions. In addition, the existence of these provisions, together with Delaware law, might hinder or delay an attempted takeover other than through negotiations with our board of directors.

Our stock price may be volatile.

The market price of our common stock has fluctuated widely. Consequently, the current market price of our common stock may not be indicative of future market prices and we may be unable to sustain or increase the value of an investment in our common stock.

Factors that may affect our stock price include the various risks identified in this "Item 1A. Risk Factors".

Because we are a company with no significant operating revenue, any one of these factors may be deemed material.

Table of Contents

Sharp drops in the market price of our common stock expose us to securities class-action litigation. Such litigation could result in substantial expenses and a diversion of management's attention and resources, which would seriously harm our business, financial condition, and results of operations.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2009, we occupied approximately 12,250 square feet of space in our headquarters located in Madison, Wisconsin under a lease which expires in October 2014. These facilities are adequate to meet our space requirements with respect to the development of an FDA-approved product for colorectal cancer screening.

Item 3. Legal Proceedings

From time to time we are a party to various legal proceedings arising in the ordinary course of our business. We are not currently a party to any pending litigation that we believe is likely to have a material adverse effect on our business operations or financial condition.

Item 4. Reserved

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is currently listed on the NASDAQ Capital Market under the symbol "EXAS." The following table provides, for the periods indicated, the high and low sales prices per share as reported on the NASDAQ Global Market, the market on which our common stock was previously listed until November 27, 2008, and on the NASDAQ Capital Market on and after November 28, 2008.

	High	Low
2009		
First quarter	$ 1.80	$ 0.53
Second quarter	2.98	0.96
Third quarter	3.15	1.95
Fourth quarter	3.40	2.32
2008		
First quarter	$ 4.25	$ 1.70
Second quarter	3.00	1.73
Third quarter	1.79	0.70
Fourth quarter	1.05	0.22

As of December 31, 2009, there were 35,523,140 shares of our common stock outstanding held by approximately 86 holders of record.

We have never paid any cash dividends on our capital stock and do not plan to pay any cash dividends in the foreseeable future.

On April 24, 2009, we issued 30,000 shares of our common stock to XMS Capital Partners, LLC ("XMS"), for partial consideration for services rendered to us under a financial advisor agreement with XMS. These shares were issued upon the exemption from the registration provisions of the Securities

Table of Contents

Act of 1933 provided for by Section 4(2) thereof for transactions not involving a public offering. Use of this exemption is based on the following facts:

Neither we nor any person acting on our behalf solicited any offer to buy or sell securities by any form of general solicitation or advertising.

At the time of the purchase, XMS was an accredited investor, as defined in Rule 501(a) of the Securities Act.

XMS has had access to information regarding us and is knowledgeable about us and our business affairs.

All shares issued to XMS were issued with a restrictive legend and may only be disposed of pursuant to an effective registration or exemption from registration in compliance with federal and state securities laws.

Item 6. Selected Financial Data

The selected historical financial data set forth below as of December 31, 2009 and for the year then ended are derived from our financial statements, which have been audited by Grant Thornton LLP, an independent registered public accounting firm and which are included elsewhere in this Form 10-K. The selected historical financial data set forth below as of December 31, 2008 and for the years ended December 31, 2008 and 2007 are derived from our financial statements, which have been audited by Ernst & Young LLP, an independent registered public accounting firm and which are included elsewhere in this Form 10-K. The selected historical balance sheet financial data as of December 31, 2007, 2006 and 2005 and statements of operations data for the years ended December 31, 2006 and 2005 are derived from our audited financial statements not included elsewhere in this Form 10-K.

The selected historical financial data should be read in conjunction with, and are qualified by reference to "Management's Discussion and Analysis of Financial Condition and Results of

Table of Contents

Operations", our financial statements and notes thereto and the report of independent registered public accountants included elsewhere in this Form 10-K.

	Year Ended December 31,				
	2009	2008	2007	2006	2005
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenue:					
Product royalty fees	$ 25	$ (2,234)	$ (1,137)	$ 179	$ 206
License fees	4,733	1,351	2,857	4,363	3,828
Product		16	78	208	216