EXACT SCIENCES CORP
Form 10-K
March 17, 2008

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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, 2007

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.)
100 Campus Drive, Marlborough, Massachusetts	**01752**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (508) 683-1200

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 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. ý

Indicate by checkmark 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 $73,273,910 (based on the closing price of the Registrant's Common Stock on June 29, 2007 of $2.89 per share).

The number of shares outstanding of the Registrant's $.01 par value Common Stock as of March 13, 2008 was 27,146,241.

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, 2007. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

EXACT SCIENCES CORPORATION
ANNUAL REPORT ON FORM 10-K
YEAR ENDED DECEMBER 31, 2007

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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 Act of 1934, as amended, and are subject to the "safe harbor" created by those sections. These statements relate to, among other things, our expectations concerning our commercial strategy, regulatory compliance, our reimbursement efforts and their likely successes, the marketing, sales and reimbursement efforts of our collaborators and their likely future success, our research and development efforts and the effectiveness and market acceptance of our technologies. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. Some of the forward-looking statements can be identified by the use of forward-looking terms such as "believes," "expects," "may," "will," "should," "seek," "intends," "plans," "estimates," "anticipates," or other comparable terms. These forward-looking statements involve risk and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those set forth in "Item 1A. Risk Factors" and elsewhere in this Annual Report on Form 10-K. Except as may be required by law, we have no plans to update our forward-looking statements to reflect events or circumstances after the date of this report. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made.

Item 1. Business

Overview

EXACT Sciences Corporation is an applied genomics company that develops proprietary DNA-based technologies for use in the detection of cancer. We have selected colorectal cancer as the first application of our technologies. We have licensed certain of our technologies, on an exclusive basis through December 2010, to Laboratory Corporation of America® Holdings ("LabCorp®") in connection with a commercial testing service that is marketed in the United States under the name "PreGen-Plus ." PreGen-Plus, which is based on our Version 1 technology, is LabCorp's non-invasive stool-based DNA testing service for the detection of colorectal cancer in the average-risk population. Royalties from LabCorp's sales of PreGen-Plus, and other license fees from LabCorp, represent our primary source of revenue.

Colorectal cancer is the second leading cause of cancer death in the U.S. and the leading cause of cancer death among non-smokers. Patients who are diagnosed early in the progression of the disease, however, are more likely to have a complete recovery and to utilize lower levels of expensive medical resources. Accordingly, the American Cancer Society, or ACS, recommends that all persons age 50 and above undergo regular colorectal cancer screening. Of the more than 89 million people in the United States for whom colorectal cancer screening is recommended, it is estimated that less than one-half have ever been screened, and a significant portion of the balance have been inadequately screened. We believe that this large population of unscreened patients represents an opportunity to reduce the mortality 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, such 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 including 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, stool-based DNA screening technology has been 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 above. PreGen-Plus is therefore

now the first DNA-based, non-invasive colorectal cancer screening test to be included in the colorectal cancer screening guidelines of the ACS and MSTF-CRC in the United States for the average risk population.

PreGen-Plus is currently offered commercially by LabCorp, the second largest commercial laboratory in the United States with more than 35 primary laboratories and over 1,600 patient service centers. LabCorp is the exclusive licensee, in the United States and Canada, of certain of our technologies utilized in PreGen-Plus through December 2010, followed by a non-exclusive license for the life of the licensed patents. LabCorp currently does not offer PreGen-Plus in Canada. LabCorp performs the PreGen-Plus testing service in a single specialized centralized laboratory and, by the terms of the license, pays us a royalty based on its net revenues from sales of PreGen-Plus. Pursuant to the terms of our license agreement with LabCorp, LabCorp has paid us $30 million in upfront license fees and milestones. In addition, we may be eligible for up to an additional $42.5 million in milestones and performance incentives under the agreement, primarily based on the achievement of significant sales thresholds. Pursuant to our amended license agreement with LabCorp, we are permitted to license our technology to select third-party organizations and commercial service laboratories, subject to LabCorp's preferential pricing terms. LabCorp maintains sole responsibility, at its expense, for all commercial activities including marketing, sales, and reimbursement related to PreGen-Plus under the agreement. LabCorp may terminate the license agreement if, among other things, the failure to commercially launch our Version 2 technology is attributable to a failure on our part or Version 2 does not attain certain sensitivity and specificity thresholds in connection with technical validation.

In addition to our Version 1 technology underlying the PreGen-Plus testing service offered by LabCorp, we have also developed a Version 2 colorectal cancer screening technology that we believe has greater sensitivity and is more cost effective than Version 1. In a recent research study evaluating stool-based DNA in 82 patients with confirmed colorectal cancer and 363 colonoscopically normal individuals, our Version 2 stool-based DNA technology demonstrated sensitivity of 83 percent and specificity of 82 percent for the detection of colorectal cancer. LabCorp has the exclusive right through December 2010 to our Version 2 technology, subject to certain rights that we maintain to offer our technology commercially. As of the date of this Annual Report on Form 10-K, we are in discussions with LabCorp, the exclusive licensee to our Version 2 technology, regarding the potential future commercialization of Version 2.

Background

Colorectal cancer is the third most common malignant disease and the second most frequent cause of cancer-related death in the United States, with more than 148,000 new cases and more than 49,000 deaths anticipated in 2008. We believe that many colorectal cancer deaths occur because people are not screened for colorectal cancer at all, or they use ineffective screening methods that either fail to detect the cancer or detect it at a later stage, when the five-year survival rate falls below 50%. Moreover, the number of people who die annually from the disease has remained materially unchanged over the last 20 years, despite the availability of multiple colorectal cancer screening options, all of which we believe fail to effectively meet the collective needs of patients, doctors and payors.

As reported in the February 3, 2005 issue of the *New England Journal of Medicine*, the tumor-node-metastasis, or TNM, system of the American Joint Committee on Cancer is now the most commonly used system for staging colorectal cancer and serves as a benchmark for predicting the likelihood of five-year survival. This staging system is described in the table below.

TNM Staging System for Colorectal Cancer*

Stage	TNM Classification	Five-Year Survival %
I	T1-2, N0, M0	>90
IIA	T3, N0, M0	60-85
IIB	T4, N0, M0	
IIIA	T1-2, N1, M0	25-65
IIIB	T3-4, N1, M0	
IIIC	T (any), N2, M0	
IV	T (any), N (any), M1	5-7

Primary Tumor (T)
TX: Primary tumor cannot be assessed
Tis: Carcinoma in situ
T1: Tumor invades submucosa
T2: Tumor invades muscularis propria
T3: Tumor penetrates muscularis propria and invades subserosa
T4: Tumor directly invades other organs or structures or perforates visceral peritoneum

Nodal status (N)
NX: Regional lymph nodes cannot be assessed
N0: No metastases in regional lymph nodes
N1: Metastases in one to three regional lymph nodes
N2: Metastases in four or more regional lymph nodes

Distant Metastases (M)
MX: Presence or absence of distant metastases cannot be determined
M0: No distant metastases detected
M1: Distant metastases detected

*
Source: Greene FL, Balch CM, Fleming ID, et al., eds. AJCC cancer staging handbook, 6th ed. New York: Springer, 2002.

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 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.

Our Solution

We believe that stool-based DNA detection in the general population offers an opportunity to increase screening rates and decrease mortality from colorectal cancer. We believe that our proprietary methods and technologies have several advantages over other screening options that may ultimately lead to decreased mortality associated with colorectal cancer, including:

Performance. We have conducted several clinical studies supporting the performance of stool-based DNA detection for colorectal cancer, including a 5,500 patient multi-center study, the results of which were published in the December 23, 2004 issue of the *New England Journal of Medicine*. Based on this study data, our bead-based stool-based DNA detection technology demonstrated sensitivity four times greater than the leading FOBT, Hemoccult II®, currently the most common non-invasive screening method for colorectal cancer, and was more than four times as effective as Hemoccult II in this study in detecting cancer at its early stages, when survival rates approach 90%. The PreGen-Plus stool-based DNA testing service that was developed by LabCorp and that

LabCorp is commercially offering today incorporates technical improvements over the test that was used in the multi-center study, which we believe result in higher assay sensitivity than that seen in our multi-center study. In addition, our Version 2 stool-based DNA technology demonstrated sensitivity of 83 percent and specificity of 82 percent for the detection of colorectal cancer in a research study evaluating stool-based DNA in 82 patients with confirmed colorectal cancer and 363 colonoscopically normal individuals.

Simplicity and Convenience. 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. 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. Unlike current invasive screening and diagnostic methods, stool-based DNA screening for colorectal cancer requires no pre-examination bowel cleansing preparation, no invasive procedures or anesthesia, and a sample can be collected in the privacy of one's home. The sample is then shipped to LabCorp for testing, with the results then sent to a patient's physician.

Compliance. Despite having been available as a screening modality for several years, colonoscopy has not been widely embraced by patients. A post-market survey of patients whom have used PreGen-Plus indicated that more than half of the people surveyed who were screened with stool-based DNA technology had never been screened for colorectal cancer before. We believe that this indicates that stool-based DNA screening can lead to greater patient screening compliance.

Our stool-based DNA screening technology includes proprietary and patented technologies 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, stool-based DNA technology looks for specific mutations and other abnormalities in that DNA known to be associated with colorectal cancer. A "positive" result from stool-based DNA detection 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 such circumstances, the clinical protocol is for the patient to then obtain a colonoscopy for confirmation. Moreover, a "negative" result from stool-based DNA screening does not mean that a person is free of colorectal cancer. Stool-based DNA detection, like virtually all screening tests (including mammography, Prostate Specific Antigen, or PSA, and Papanicolaou smear, or Pap smear) also reports false negatives. See "Clinical Studies" below for specific information on stool-based DNA technology.

The Testing Process

Diagnostic tests typically require sample collection and preparation procedures as well as detection methods. The stool-based DNA testing process involves proprietary sample preparation, DNA isolation, and analytical techniques that apply genomics discoveries to the early detection of colorectal cancer.

Specimen Collection and Transportation. Certain of our patents relating to stool-based DNA screening for colorectal cancer are based on collecting a single whole stool sample in an easy, non-invasive manner. Utilizing a specially designed specimen container, samples can be collected in the privacy of an individual's home and then sent directly to the laboratory for processing using one of the many national couriers.

Representative Sampling. We have invented proprietary stool homogenization methods designed to ensure that the stool sample that is processed at the laboratory will contain uniformly distributed DNA throughout the portion of the sample being tested which, in turn, helps to ensure that the DNA in the stool sample is representative of the entire stool and colon.

DNA Extraction, Purification and Amplification. The isolation and amplification of human DNA found in stool is technically challenging because over 99% of DNA in stool is not human DNA, but is actually DNA from bacteria normally found in the colon. In addition, there are substances in stool that make the isolation and amplification of human DNA a difficult task. Proprietary technologies are used to promote the reproducible isolation and amplification of the human DNA found in stool.

Cancer Detection Methods. Many of the specialized methods for detecting and identifying genomic markers associated with colorectal cancer can be performed on existing instruments commonly available in clinical laboratories conducting molecular testing.

Commercial Focus

Our goal has been to become a market leader in the development and licensing of technologies for the early detection of colorectal cancer. To accomplish this goal, we have been pursuing a strategy with respect to our technologies that includes the following components:

Obtain regulatory clearance for stool-based DNA screening. In October 2007, we were notified in a warning letter from the U.S. Food and Drug Administration, or FDA, that PreGen-Plus is a Class III medical device that cannot be commercially distributed without an appropriate pre-market approval or clearance from the FDA. Accordingly, among our primary business objectives is to obtain FDA approval or clearance for our technologies and, as of the date of this Annual Report on Form 10-K, we have met with the FDA on two separate occasions to specifically address the matters raised in the warning letter. Based on these discussions, we are currently focusing our efforts on concluding our pre-IDE, or pre-Investigational Device Exemption, discussions with the FDA to determine the appropriate premarket submission requirement. We believe, based on our most recent discussion with the FDA in February 2008 and the proposed intended use of the test, that a *de novo* 510(k) application for our test incorporating Version 1 technology may likely be the filing route that is available to us in satisfying the FDA's requirements. As described in the section "Government Regulation" below, obtaining FDA clearance or approval could require additional lengthy clinical or other studies to validate our technologies, the costs of which are likely to be material. We may not have sufficient funds to complete any FDA clearance or approval process for our technologies or we may delay any such process to preserve funds. Moreover, we will require the support of third parties to assist us in the achievement of objectives relating to FDA clearance of our technologies, which may be costly. Additionally, as a result of the warning letter, LabCorp may decide to halt commercial sales of PreGen-Plus until it is cleared or approved by the FDA, which could materially harm our business and revenue prospects. Alternatively, LabCorp may decide to discontinue the use of PreGen-Plus, which was the basis for the FDA's warning letter, and instead seek to begin commercializing our Version 2 stool-based DNA screening technology for colorectal cancer. Such conversion could result in an interruption in service and a lengthy delay during which no version of the test utilizing our technologies remains on the market. Further, the FDA may not approve of certain sales, marketing or promotional initiatives of EXACT or LabCorp, which could negatively affect our ability to build awareness around stool-based DNA testing, regardless of which version of the test remains on the market.

Obtain formal acceptance of stool-based DNA screening for reimbursement by Medicare and other third-party payors. Between the commercial launch of PreGen-Plus in August 2003 and December 31, 2007, LabCorp has received over 14,300 patient samples for testing from across the country, billed insurers and received payment from numerous third-party payors, including more than 350 health plans. None of these third-party payors have yet issued formal policy approval for PreGen-Plus. Our reimbursement strategy consists primarily of leveraging LabCorp's ability to educate large managed care organizations and large self-insured employers about the clinical benefits and cost-effectiveness of using stool-based DNA screening for colorectal cancer. An important component of our reimbursement strategy is to obtain a National Coverage Determination, or NCD, from the Centers for Medicare and Medicaid Services, or CMS, for inclusion of our stool-based DNA screening technologies for colorectal cancer in the Medicare program. In December 2004, we submitted our application for a NCD on our Version 1

technology, which was accepted by CMS on August 1, 2007. Following acceptance of our application to CMS, we received the warning letter from the FDA in October 2007. Based, in part, on the FDA's determination as set forth in the warning letter that PreGen-Plus required premarket clearance or approval, CMS issued a proposed decision memorandum regarding our application on January 30, 2008, which proposed not to provide coverage for our Version 1 technology. The proposed decision memo indicated that CMS would reconsider our application for coverage following any such FDA clearance or approval of our stool-based DNA screening technology. Accordingly, we intend to submit our NCD application for reconsideration following any such FDA clearance or approval of our technology. While we believe that the publication of our multi-center study results in the *New England Journal of Medicine* in December 2004 and patient preference and compliance study results regarding stool-based DNA screening will aid in our long-term efforts to gain reimbursement for our technologies, we also believe that additional performance data and patient compliance and preference data may likely be required before we submit to CMS with our request for reconsideration of our NCD application.

Pursue commercial introduction of next-generation stool-based DNA screening technology. In a recent research study that we designed to test the efficacy of technological advances to enhance colorectal cancer detection in stool, our Version 2 technology demonstrated sensitivity of 83 percent and specificity of 82 percent for the detection of colorectal cancer. The Version 2 research study involved the blinded analysis of post-colonoscopy collected stool samples from individuals whose colonoscopy results were positive for colorectal cancer. Although the specificity result in the Version 2 study was lower than our previous studies, we believe that the significant improvement in sensitivity compared to studies of Version 1 of our technology, including the multi-center study, will provide the basis to pursue the future commercial introduction of Version 2. Pursuant to our license agreement with LabCorp, LabCorp has exclusive rights through December 2010 to our Version 2 technology, subject to certain rights that we maintain to offer our technology commercially as well. As of the date of this Annual Report on Form 10-K, we are in discussions with LabCorp regarding their potential future commercialization of Version 2. We currently intend to pursue FDA clearance or approval for our Version 2 technology, which may require additional lengthy studies, the costs of which are likely to be material.

Leverage LabCorp's large sales force. In August 2007, as part of an amendment to our license agreement with LabCorp, we eliminated our sales and marketing functions and transferred responsibility for all sales and marketing activities related to PreGen-Plus to LabCorp. LabCorp is the second largest commercial laboratory in the country and processes over 370,000 patient specimens daily through its system of more than 35 primary laboratories and over 1,600 patient service centers across the United States. LabCorp's large sales force of more than 1,100 people is devoted to selling a wide range of diagnostic tests to physicians across all specialties. We currently intend to leverage LabCorp's relationships and infrastructure to build market demand for PreGen-Plus and Version 2 of our stool-based DNA technology.

We believe that the success of each of the foregoing components of our commercial strategy are critical to any future broad acceptance of our technologies. The achievement of certain of these components will also, at least in part, be dependent upon the successful accomplishment of others. For instance, FDA approval or clearance will be one of the key prerequisites for any future CMS approval of our NCD application which we believe will, in turn, be necessary for any broad commercial acceptance of our technologies. Similarly, despite the inclusion of our technologies in the colorectal cancer screening guidelines of the ACS and MSTF-CRC, we do not expect that third-party payors will issue formal policy approval for PreGen-Plus or Version 2 prior to any FDA approval of our technologies, and, absent any such formal policy approval, it is unlikely that PreGen-Plus or Version 2 will be broadly used by a payor's members.

Clinical Studies

Stool-based DNA testing has been the subject of extensive research and clinical studies. In numerous studies to date, the performance of our stool-based DNA technology has been examined in thousands of tissue and stool samples. In addition to several smaller clinical studies designed to measure the sensitivity and specificity of stool-based DNA testing in detecting colorectal cancer, the performance of our bead-based Version 1 stool-based DNA testing technology was compared to the most widely-used FOBT in a large multi-center study that enrolled approximately 5,500 average-risk, asymptomatic patients from more than 80 sites across the United States. The study was designed to determine whether stool-based DNA testing was clinically superior to Hemoccult II, an FOBT that is currently the most widely used non-invasive colorectal cancer screening test. The primary endpoint of this study was achieved with statistical significance, with a p-value of less than 0.003. Results from the study, which were published in the *New England Journal of Medicine* in December 2004, indicated that our bead-based Version 1 technology was four times more sensitive than Hemoccult II in the study in detecting colorectal cancer (52% for Version 1 versus 13% for Hemoccult II), and more than four times more sensitive in detecting colorectal cancer in its earliest, most curable stages (57% for Version 1 versus 13% for Hemoccult II). There was no difference in specificity between the bead-based Version 1 and this FOBT, with both tests demonstrating a specificity of approximately 95%.

In addition, a recent study evaluating Version 2 of our stool-based DNA colorectal screening technology in 82 patients with colorectal cancer and 363 colonoscopically normal individuals demonstrated sensitivity of 83 percent and specificity of 82 percent for the detection of colorectal cancer. These study results were statistically consistent with the interim study results on Version 2 published in the January 2007 issue of the American Gastroenterological Association's journal, *Clinical Gastroenterology and Hepatology*, which included a subset of samples from 40 cancer patients and 122 normal individuals and demonstrated sensitivity of 88 percent and specificity of 82 percent. Although we are encouraged by the increase in sensitivity shown for Version 2 in this study when compared to previous published studies for stool-based DNA screening, the specificity results in the Version 2 study were closer to 80% whereas prior studies have Version 1 have generally shown specificity above 90%. This performance metric may not be deemed clinically or commercially acceptable. Moreover, the blinded study of Version 2 involved the analysis of 82 post-colonoscopy collected cancer samples from individuals whose colonoscopy results were positive for colorectal cancer. By contrast, our multi-center study in 2004 was comprised of 31 cancer samples prior to colonoscopy from an asymptomatic population.

Sensitivity and specificity results from our clinical studies that have been published are summarized in the table below. The results of these studies may not be directly comparable as these studies were conducted across a variety of patient populations and clinical settings and employed varying sample collection protocols. Moreover, the clinical studies disclosed below do not include any non-published

studies regarding stool-based DNA testing, the results of which may differ significantly from those set forth below.

Technology & Study Name	Year Completed/Published	Number of Cancer Samples Analyzed	Number of Genetic Markers	DNA Capture Technology	DNA Stabilization Buffer Used(1)	Sensitivity	Specificity(2)
Version 1 Studies							
Mayo Clinic I Pilot Study	1999/2000	22	17	Bead-based	No	91%	93%
University of Nebraska	2002/2004	16	22	Bead-based	No	69%	(2)
Kaiser Clinic	2002/2003	52	23	Bead-based	No	64%	98%
Boston	2002/2006	68	23	Bead-based	No	63%	(2)
Multi-Center Study	2003/2004	31	23	Bead-based	No	52%(3)	94%
Effipure Technology Validation	2004/2004	86	23	Effipure(4)	No	70%(5)	96%
Mount Sinai School of Medicine	2005/2007	40	23	Effipure(4)	Yes	73%	89%
Version 2 Study							
Mount Sinai School of Medicine	2005/2007	40	2	Effipure(4)	Yes	88%	82%

(1) DNA stabilization buffer is used to protect against DNA degradation during sample transport.

(2) Specificity can only be derived in studies that include a certain number of individuals without cancer. The studies in the table without a specificity figure did not contain the requisite number of disease-free individuals.

(3) Based on published studies, including the Mount Sinai School of Medicine studies, we believe that the sample collection protocols used in this study resulted in DNA degradation that, in turn, resulted in lower sensitivity of our technology than that demonstrated in our prior published studies.

(4) Effipure is a technological improvement that has been utilized in LabCorp's commercial testing service, PreGen-Plus, designed to increase human DNA yield

(5) In November of 2004, we published a study in the *Journal of Molecular Diagnostics* that showed a 5.4 fold increase in the amount of DNA that could be captured using the Effipure technology rather than the older, bead-based technology. The sensitivity result from this study is not a conclusion regarding the sensitivity of the commercial test on the market today.

In October 2001, Mayo Clinic initiated a study of the bead-based version of our technology that was intended to include approximately 4,000 patients at average risk for developing colorectal cancer. This three-year study was designed to compare the results of our original technology with those of Hemoccult II, a common first-line FOBT colorectal cancer screening option. The Mayo study was principally powered for the detection of "screen relevant neoplasia" (an end-point that includes high grade dysplasia, invasive cancer, and adenomas ≥1cm) rather than invasive cancers as a stand alone category. After this study commenced, Hemoccult Sensa®, another brand of FOBT, was added to the study. Subsequently, we and the Mayo Clinic sought to include the gel-based Effipure DNA isolation technology in the study to improve DNA yield, rather than relying solely on our original bead-based technology. In connection with this technology transition, Mayo Clinic reviewed preliminary data from the study which showed that, while our bead-based technology was nearly twice as sensitive as Hemoccult II and as sensitive as Hemoccult Sensa in detecting screen-relevant neoplasia, Hemoccult II and Hemoccult Sensa appeared to have outperformed, at a preliminary stage, our bead-based technology in the detection of cancer among the thirteen cancer samples collected in the study. As the study

proceeded beyond this preliminary stage, however, Mayo Clinic evaluated additional screen relevant neoplasia and has offered the following updated principal findings on the larger data set: (1) stool-based DNA technology detected three times more screen relevant neoplasia than Hemoccult

II and two times more screen relevant neoplasia than Hemoccult Sensa, but at a much lower specificity; and (2) the addition of a stabilization buffer to stool samples at the time of collection would most likely have improved lesion detection by long DNA and possibly other analytes as well. We believe that the sample collection protocols used for the vast majority of samples in this study, like the sample collection protocols as those used in our multi-center study, resulted in DNA degradation that, in turn, resulted in lower sensitivity of our technology. In addition, although our older technology detected a small but significant percentage of advanced adenomas, this older version of our technology was designed only to detect cancer, not adenomas, both of which are included in the definition of screen-relevant neoplasia. Our Version 2 technology includes the addition of DNA stabilization buffer to the stool at the time of collection.

Research and Development

At December 31, 2007, our research and development efforts are primarily focused on supporting regulatory submissions required by the FDA for clearance or approval of our technologies, and may be focused on supporting any commercial launch of Version 2 of our DNA screening technology. Addressing the FDA compliance matters relating to our technologies and the future commercialization of our Version 2 technology could require additional lengthy studies and, accordingly, the timing and costs of any FDA clearances and commercialization of our technologies is uncertain. Additionally, the costs of additional clinical or other studies that may be required in connection with FDA approval or clearance of our technology are likely to be material. Moreover, transferring Version 2 from the laboratory to the commercial setting will also require the negotiation and licensing of necessary third-party intellectual property, as well as the likelihood of additional technical and clinical validations of the technology to demonstrate, among other objectives, the reliability and reproducibility of our prior Version 2 study results. Our research and development expenses were $4.9 million, $6.7 million and $8.0 million for the years ended December 31, 2007, 2006 and 2005, respectively.

Sales and Marketing

In August 2007, in connection with an amendment to our license agreement with LabCorp, we eliminated our sales and marketing functions and currently employ no sales or marketing personnel. We are, therefore, materially dependent on LabCorp's sales efforts in building market demand for PreGen-Plus and Version 2 of our stool-based DNA technology. LabCorp's large sales force of more than 1,100 people calls on primary care physicians and promotes numerous products. Our efforts with respect to building awareness of stool-based DNA screening for colorectal cancer are focused on the following key constituents:

Thought Leaders. Gastroenterologists are highly vocal in advocating colorectal cancer screening, and perform the vast majority of the reference standard diagnostic procedure, colonoscopy. They are also key to establishing new tests as standards of care for inclusion in screening guidelines.

Third-Party Payors. Another important focus includes third party payors, including Medicare, major national and regional managed care organizations, technology assessment groups, insurance carriers and self-insured employer groups. The goals with these target groups are to educate these groups regarding the benefits of stool-based DNA testing in order to gain formal policy-level reimbursement for stool-based DNA testing.

Advocacy Development. We seek to work with influential advocacy groups to promote their awareness of stool-based DNA testing and its potential value in clinical practice toward the goal of reducing mortality from colorectal cancer. To the extent possible based on our existing resources, we intend to continue to build on growing public awareness of colorectal cancer through our activities with these advocacy groups.

The FDA may not approve of certain of our promotional initiatives with respect to our stool-based DNA technology, which could restrict or negatively impact our ability to build awareness around stool-based DNA testing.

Reimbursement

We are continuing to work to obtain national coverage and reimbursement approval for our stool-based DNA colorectal cancer screening technologies from Medicare and, primarily through our relationship with LabCorp, major national and regional managed care organizations and insurance carriers, and self-insured employer groups. We support LabCorp in these efforts, from time to time, as circumstances warrant. Our reimbursement strategy consists primarily of leveraging our relationship with LabCorp toward the education of large managed care organizations, large self-insured employers and large physician groups about the clinical benefits and cost-effectiveness of stool-based DNA screening. We seek to complement these efforts through targeted, focused initiatives that benefit from direct relationships maintained by one or more of our employees.

An important component of our reimbursement strategy is to obtain an NCD from CMS that includes stool-based DNA screening technologies for colorectal cancer in the Medicare program. In December 2004, we submitted our application for a NCD on our Version 1 technology, which was accepted by CMS on August 1, 2007. Our Version 1 technology patents are the basis for LabCorp's PreGen-Plus testing service. Following acceptance of our application to CMS, we received the warning letter from the FDA in October 2007. Based in part on the FDA's determination as set forth in the warning letter that PreGen-Plus required premarket clearance, CMS issued a proposed decision memorandum regarding our application on January 30, 2008, which proposed not to provide coverage for our Version 1 technology. The proposed decision memo indicated that CMS would reconsider our application for coverage following any such FDA clearance or approval of our DNA screening technology. There can be no assurance that any version of our technology will be cleared or approved by the FDA. Even if cleared or approved by the FDA, there can be no assurance that CMS will reach a positive coverage decision regarding our request for an NCD for any version of our technologies. Moreover, even if CMS issues a positive coverage decision for any version of our stool-based DNA screening technology, such coverage may not provide adequate levels of reimbursement. Accordingly, our future plans will likely include working to accumulate additional performance data, and patient compliance and preference data to submit to CMS with our request for reconsideration of our NCD application. We could incur significant time and costs to accumulate such additional data which still may not yield a positive coverage decision from CMS at acceptable reimbursement levels. Additionally, despite the fact that our technology is included in the colorectal cancer screening guidelines of the ACS and MSTF-CRC, the FDA warning letter may have a similar impact on private third party payors in that those payors may defer reimbursement policy decisions with respect to our technology until we obtain FDA clearance for our technologies, if ever. Finally, certain members of the MSTF-CRC may separately fail to support the position of the MSTF-CRC, which could have a detrimental effect on our commercial and reimbursement efforts.

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.

FDA Background

Laboratories that make and perform certain types of laboratory-developed tests, known in the industry as "homebrew" testing services, have generally not been required to submit premarket submissions to the FDA including performance data on the test for FDA review and approval or clearance. Instead the FDA has said it would exercise enforcement discretion, which allowed laboratories to develop their own clinical diagnostic test without obtaining FDA approval or clearance by following the regulations of the Clinical Laboratory Improvement Amendments of 1988, or CLIA.

We had believed, since LabCorp's commercial launch of PreGen-Plus in 2003, that PreGen-Plus met the requirements to qualify for regulation under CLIA as a homebrew test and that in-house testing utilizing certain of our technologies, and using any analyte specific reagent that we developed, did not require FDA approval or clearance.

Since the commercial launch of PreGen-Plus in August 2003, LabCorp has validated and offered the PreGen-Plus testing service as an in-house developed laboratory test, or homebrew. On January 13, 2006, the FDA sent correspondence to us and to LabCorp with respect to the PreGen-Plus testing service, as well as the Effipure component used in processing PreGen-Plus tests, which indicated that PreGen-Plus is subject to FDA regulation as a medical device. The FDA also indicated that the device cannot be commercially distributed without an appropriate pre-market determination from the FDA. Pursuant to our and LabCorp's subsequent discussions with the FDA to clarify the regulatory status of PreGen-Plus, we and LabCorp agreed, among other things, to revise promotional activities with respect to LabCorp's PreGen-Plus testing service. In addition, LabCorp offered to eliminate its use of Effipure in processing PreGen-Plus tests. Based on the actions outlined above, LabCorp has continued to market and process the PreGen-Plus test as a homebrew testing service. LabCorp's supply of Effipure includes components that have a finite useful life the duration of which, we believe, may be nearly exhausted. If LabCorp is unable to extend the useful life of these components, then LabCorp may be unable to continue to process PreGen-Plus tests in the near term. We further believe that certain finite resources required for the ongoing processing of the Version 1 test may also be nearly exhausted, which may result in an interruption in the PreGen-Plus testing service.

On October 11, 2007 the FDA sent the warning letter to us with respect to the PreGen-Plus testing service, indicating that PreGen-Plus is a Class III medical device and that it cannot be commercially distributed without an appropriate pre-market approval or clearance from the FDA. We are currently in communication with the FDA to specifically address the matters raised in the warning letter and to determine the appropriate premarket submission requirements and regulatory submission pathway in order to resolve the matters raised in the warning letter. As of the date of this Annual Report on Form 10-K, we have met with the FDA on two separate occasions to specifically address the matters raised in the warning letter. Based on these discussions, we are currently concluding our pre-IDE request discussions with the FDA and we believe, based on our most recent discussion with the FDA in February 2008, that the filing of a *de novo* 510(k) application with the FDA relating to Version 1 of our technology is the probable premarket submission pathway, which, if it results in clearance or approval, will, we believe, satisfy the FDA with respect to the matters raised in the warning letter.

EXACT's Interactions with the FDA

On November 2, 2007, in response to the FDA warning letter, we submitted to the FDA a pre-IDE request that described our intended premarket submission filing approach, including the reproducibility studies that we proposed to perform in connection therewith. The FDA responded by letter to our pre-IDE submission in December 2007, and, in an in-person meeting with the FDA in February 2008, we learned that the likely regulatory path forward with respect to our Version 1 technology would be a *de novo* 510(k) application, which would likely include a single-site reproducibility study, the details of which still need to be confirmed by the FDA. We do not have final confirmation or assurance from the FDA that the regulatory path forward will in fact be a *de novo* 510(k) or that a single site study along the dimensions we described to FDA will be acceptable. There also can be no assurance that the FDA will not instead require a PMA or regulatory filing approach that is different from the approach described here and certain other smaller technical studies.

The FDA has not yet indicated definitively whether the submission with respect to Version 1 of our technology would be a *de novo* 510(k). Moreover, the FDA may determine that a pre-market approval application, or PMA, is the appropriate path forward for us with respect to Version 1 of our stool-based DNA technology. The FDA may also determine that additional clinical studies, which could be costly and time-intensive, are required in connection with our submission, or that our proposal is

otherwise inadequate. Accordingly, the costs of any such studies could require that we seek additional capital in the near term, which could have an adverse and material impact on our financial position. There can be no assurance that the filing of a *de novo* 510(k) for our Version 1 technology will bring us into compliance with the matters raised by the FDA in the warning letter, or that the FDA will not issue a similar letter to LabCorp or otherwise require LabCorp to stop offering its PreGen-Plus testing service during the regulatory clearance process. The clearance or approval process for any version of our DNA-based technologies may require, among other things, successfully completing additional clinical and other studies, may require a PMA (rather than a 510(k) or *de novo* 510(k)) and may also necessitate our submitting PMAs with the FDA for multiple versions of our technology simultaneously or in sequence, all of which could take substantial time and resources including investment by us of substantial additional funds.

There can be no assurance that any version of our stool-based DNA technology will be cleared or approved by the FDA, that our proposed *de novo* 510(k) approach will satisfy the FDA's regulatory requirements for our Version 1 technology or any subsequent version of our technology, or that such FDA clearance or approval process can be completed without significant delays or material additional expense resulting from additional FDA required clinical or other studies. We may not have sufficient funds to complete any FDA regulatory clearance or approval process for our DNA-based technologies. In addition, we may delay any such process to preserve funds for on-going operations or otherwise. Moreover, we will require the support of third parties to assist us in the achievement of objectives relating to FDA clearance of our technologies, which may be costly. Ongoing compliance with FDA regulations will also increase the cost of conducting our business, subject us and LabCorp to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements.

Moreover, we cannot assure you that the commercial sales of PreGen-Plus will not be delayed, halted or prevented during the regulatory approval process, or that the FDA will not initiate enforcement action, which could involve criminal or civil penalties and cause material harm to our business. Additionally, LabCorp could decide to stop offering the current version of PreGen-Plus, could decide not to launch the Version 2 technology, or could decide to defer any potential future launch of the Version 2 technology until that version has been approved or cleared by the FDA, if ever, any of which would materially increase our costs, limit our revenue and cause material harm to our business and result in impairments of our fixed assets or capitalized patent portfolio ($0.4 million at December 31, 2007) or other personnel or facility related restructuring charges.

In addition, any stool-based DNA *in vitro* diagnostic test kit that we may develop in the future that would require FDA clearance or approval would be distinct from LabCorp's PreGen-Plus testing service, which remains on the market today as a homebrew testing service.

Other Regulations

We and our strategic partner, LabCorp, 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 LabCorp fails to meet any applicable requirements of CLIA or state law, it could further delay acceptance of our CMS application, prevent its approval entirely, and/or interrupt the commercial sale of PreGen-Plus and otherwise cause us to incur significant expense.

In addition, the specimen containers that are used in connection with the PreGen-Plus test may also be deemed to be medical devices regulated by the FDA. Once a physician orders a test, the patient will need to receive a specimen container to collect the patient's stool. Specimen transport and storage containers generally have been exempted by regulation from the FDA's premarket clearance or

approval requirement and much of the Quality System Regulation. We believe that the specimen container falls within an applicable exemption, but we cannot be sure that the FDA will not assert that the container is not exempt and seek to impose a premarket clearance or approval requirement on the container itself.

Intellectual Property

To protect our proprietary technologies, we rely on a combination of patent, trademark, and copyright protection, and other contractual restrictions to protect our proprietary technologies, as well as confidentiality agreements with employees, consultants, and third parties.

We have pursued a patent strategy designed to maximize our patent position with respect to third parties. Generally, we have filed patents and patent applications that cover the methods we have designed to detect colorectal cancer as well as other cancers. We have also filed patent applications covering the preparation of stool samples and the extraction of DNA from heterogeneous stool samples. As part of our strategy, we seek patent coverage in the United States and in foreign countries on aspects of our technologies that we believe will be significant to our market strategy or that we believe provide barriers to entry for our competition. We believe that the United States and western Europe represent the most realistic near term markets for stool-based DNA testing.

As of December 31, 2007, we had 37 patents issued and 22 pending patent applications in the United States and, in foreign jurisdictions, 76 patents issued and 39 pending patent applications. Our success depends to a significant degree upon our ability to protect our technologies through patent coverage.

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. We have filed terminal disclaimers in certain later-filed patents, which means that such later-filed patents will expire earlier than the twentieth anniversary of their respective priority filing dates.

We and a third-party institution have filed a joint patent application under the Patent Cooperation Treaty that will be co-owned by us and the third-party institution relating to the use of various DNA markers, including the DNA Integrity Assay, to detect non-colorectal cancers in stool, including, for example, cancers of the lung, pancreas, esophagus, stomach, small intestine, bile duct, naso-pharyngeal, liver and gall bladder. This patent application does not relate to the detection of colorectal cancer and national rights are being pursued in the United States, Japan, Europe and Canada.

We license on an exclusive basis, in the field of stool-based colorectal cancer screening, from Matrix Technologies Corporation, d/b/a Apogent Discoveries, certain patents owned by Apogent relating to its Acrydite technologies, which we have sublicensed to LabCorp. The rights provided under this license provide LabCorp with the ability to manufacture and use the Acrydite technology in the PreGen-Plus test. The Acrydite technology is useful in connection with the proprietary electrophoretic DNA gel capture technology used in the isolation of nucleic acids and the diagnosis of disease. We no longer manufacture, supervise the manufacture, or ship any components used in connection with the Acrydite or Effipure technologies.

We license on an exclusive basis from Johns Hopkins University, or JHU, certain patents owned by JHU that relate to digital amplification of DNA. We believe that this license may ultimately allow us and our partners to develop and commercialize novel detection technologies to further enhance the performance of stool-based DNA screening technologies. In exchange for the license, we have agreed to pay JHU certain royalties on revenues received by us relating to our or our sublicensees' sales of products and service.

We license on a non-exclusive basis from Beckman Coulter certain patents owned by Beckman Coulter that relate to its Single Based Extension, or SBE, technology. The license provides us and our sublicensee, LabCorp, with the ability to use SBE in the PreGen-Plus test.

In June 2007, we licensed, on a non-exclusive basis, rights to our DNA stabilization, isolation and extraction technology to OncoMethylome Sciences for commercializing stool-based colorectal cancer screening tests in Europe that utilize OncoMethylome's methylation detection technology (Methylation-Specific PCR, or MSP). In exchange, OncoMethylome has agreed to pay royalties to us based on sales. Separately, we entered into a supply agreement with OncoMethylome in which OncoMethylome will sell reagents to us for use in stool-based colorectal screening services that EXACT may provide in North America. The reagents will enable us to detect methylation at certain DNA markers using MSP technology. In addition, under the terms of this agreement, OncoMethylome also agreed to sell reagents to our commercial partners, subject to their negotiation with OncoMethylome of certain financial terms and other elements.

In June 2007, we licensed, on a non-exclusive basis, our proprietary DIA®, or long-DNA, technology and related know-how to NorDiag ASA for commercializing colorectal cancer screening tests in Europe, Japan and Australia. The collaboration and license also includes the right to develop an in vitro diagnostic test kit as well for these markets.

LabCorp also maintains additional third-party technology license and supply agreements that are necessary for their PreGen-Plus testing service. We and LabCorp will also need to secure additional third-party intellectual property prior to any commercial introduction of the Version 2 technology.

Competition

To our knowledge, none of the large genomics or diagnostics companies are developing tests to conduct stool-based DNA testing in the United States. We are aware of other companies that have offered or are offering stool-based colorectal cancer tests outside of the United States, and we believe that other companies may be working on similar tests in the United States that have not yet been announced. In addition, other companies may succeed in developing novel technologies or improving existing technologies and marketing products and services that are more effective or commercially attractive than ours. Some of these companies may be larger than we are and can commit significantly greater financial and other resources to all aspects of their business, including research and development, marketing, sales and distribution.

Currently, stool-based DNA detection faces competition from procedure-based detection technologies such as flexible sigmoidoscopy, colonoscopy and "virtual" colonoscopy, a radiological imaging approach which visualizes the inside of the bowel by use of spiral computerized axial tomography, known as a CT scan, as well as existing and possibly improved traditional screening tests such as immunochemical FOBT and improvements to colonoscopy. In addition, some competitors are developing serum-based tests, or screening tests based on the detection of proteins or nucleic acids produced by colon cancer in the blood. Screening tests based on a patient's blood sample may prove to be equally effective in detecting colorectal cancer as stool-based DNA screening. Further, even if blood-based detection is proven less effective at detecting colorectal cancer than DNA-based technologies from a stool sample, a blood test may ultimately prove to have broader market advantage over our DNA-based technologies based on ease of use and other advantages that physicians, patients, third party payors and others find attractive. We believe that several companies are currently developing blood-based technologies for the early detection of colorectal cancer. Separately, we believe that pharmaceutical and medical device marketing efforts directed at physicians represent competition for physician attention for the sales force selling our DNA-based technologies.

We believe the principal competitive factors in the cancer screening market include:

high sensitivity;

high specificity;

non-invasiveness;

ease of use;

acceptance by the medical community, especially primary care medical practitioners;

adequate reimbursement from Medicare and other third-party payors;

price;

cost-effectiveness; and

patent protection.

Employees

As of December 31, 2007, we had fourteen employees, two of whom have a Ph.D. and one of whom has an M.D. We currently have eight employees engaged in research and development and six employees in general and administration. 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 100 Campus Drive, Marlborough, Massachusetts 01752. Our telephone number is 508-683-1200. 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 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.

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.

Our independent auditors have expressed substantial doubt about our ability to continue as a going concern, and we may be unable to raise additional capital on acceptable terms in the future.

We have incurred substantial losses to date and we expect to incur substantial losses for the foreseeable future. As of December 31, 2007, we had an accumulated deficit of approximately $162.7 million. We have received a report from Ernst & Young LLP, our independent registered public accounting firm, regarding our consolidated financial statements for the fiscal year ended December 31, 2007, which included an explanatory paragraph stating that the financial statements were prepared assuming we will continue as a going concern. The report also stated that our recurring operating losses and need for additional financing have raised substantial doubt about our ability to continue as a going concern. We believe that our existing cash, cash equivalents and investment balances will be sufficient to meet our anticipated cash requirements through 2008, based on our current cost structure and current assumptions regarding the clinical and other studies and other requirements that we believe may be necessary to obtain U.S. Food and Drug Administration, or FDA, clearance of Version 1 of our DNA-based colorectal cancer screening technology. We have not yet reached final agreement with the FDA regarding any studies that would be necessary for the FDA clearance of Version 1 of our DNA-based technology, however, and the costs of any such studies could require us to obtain

additional funding before previously expected. Our future liquidity and capital requirements will depend upon numerous factors, including the following:

- the regulatory requirements for PreGen-Plus, or other stool-based DNA testing services utilizing our technologies, and the timing of any required regulatory approval process;
- acceptance, endorsement and formal policy approval of stool-based DNA screening for reimbursement by Medicare and other third-party payors;
- our ability to achieve milestones under our strategic agreement with Laboratory Corporation of America Holdings, or LabCorp;
- a determination that additional studies surrounding our technologies are needed;
- a sustained level of interest and commitment by LabCorp in the commercialization of our technologies;
- stool-based DNA screening becoming a standard of care among prescribing physicians;
- the scope of and progress made in our research and development activities; and
- the successful commercialization and sales growth of PreGen-Plus, or other stool-based DNA testing services utilizing our technologies.

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. Since we have no current sources of material ongoing revenue, we will have to raise additional monies during 2008 through the sale of debt or equity securities, strategic collaborations with third parties and other strategic opportunities, if any, to continue our business operations beyond the end of our 2008 fiscal year. We cannot assure you that any of these alternatives will be successful, or even available, or that our actual cash requirements will not be greater than anticipated. In addition, the going concern explanatory paragraph included in our auditor's report on our consolidated financial statements could inhibit our ability to enter into license agreements or other collaborations or our ability to raise additional financing. If we are unable to obtain the required funds to enable us to fund our operations through the completion of any financing or other strategic opportunities that may become available to us, we will be required to further reduce the scale of our operations and our business, our results of operation and financial condition would be materially adversely affected and we may be required to seek bankruptcy protection.

Additionally, even if we do raise sufficient capital and generate revenues to support our operating expenses beyond fiscal 2008, there can be no assurances that the revenue will be sufficient to enable us to develop our business to a level where it will generate profits and cash flows from operations. In addition, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly-issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies, or grant licenses on terms that are not favorable to us. If we obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our 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, 2007, we have accumulated a total deficit of approximately $162.7 million. We expect that our losses will continue for at least the next several years and, depending upon our strategic direction, we may need to invest significant additional funds toward other

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areas in the oncology testing business. The FDA approval path for our colorectal cancer screening technology is likely to involve significant time as well as research and development expenditures. Given our current levels of cash and revenues, and without raising additional capital, we will not be able to spend the amounts that we believe will likely be necessary to fund these investments and there can be no assurance that LabCorp will invest sufficient amounts in sales and marketing activities for PreGen-Plus or other future testing services based on our technologies. In addition, while we believe we are permitted, from a regulatory standpoint, to promote stool-based DNA testing services generically, our inability to market the brand "PreGen-Plus" under current FDA regulations may limit our return on amounts that we have invested or may invest in sales and marketing activities. If our revenue does not grow significantly, we will not be profitable. We cannot assure you that the revenue from the sale of any of our technologies will be sufficient to make us profitable.

Our future revenues will depend, in large part, upon whether PreGen-Plus or other testing services offered by LabCorp based on our technologies are broadly ordered by medical practitioners and requested by patients. We believe that our ability to successfully commercialize our technologies may be affected by the following:

- the regulatory requirements for PreGen-Plus or Version 2, and the timing of any required regulatory filing and approval process;
- our ability to continue to fund our operations;
- whether LabCorp continues to offer PreGen-Plus or Version 2 commercially;