

EXACT SCIENCES CORP
Form 8-K
November 16, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 16, 2011**

EXACT SCIENCES CORPORATION

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-32179
(Commission
File Number)

02-0478229
(I.R.S. 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**

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Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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8.01. Other Events.

On November 16, 2011, Exact Sciences Corporation (We, us, our or the Company) presented further validation data for its colorectal cancer screening product at the Company's corporate workshop at the 2011 Association for Molecular Pathology Annual Meeting in Grapevine, Texas. The purpose of the study was to assess the performance of Cologuard on stools from normal, cancer, or pre-cancer subjects using the first development lots of reagents. The study demonstrated 98% sensitivity for cancer and 59% sensitivity for advanced adenomas ≥ 1 cm, at a specificity cut-off of 91%. The study included a total of 355 samples comprised of 277 normal samples, 46 cancer samples and 32 advanced adenoma samples. We would like to emphasize that this is a small sample size and the cancer and pre-cancer samples were collected primarily from referred subjects. Post-colonoscopy sample collections were used for most of the affected subjects which could elevate observed sensitivities. This study was not representative of a screening population.

In October of 2010, we presented validation data using a prototype assay tested on 1,178 samples. In the 2010 study, the combined training and test set results demonstrated an 85% sensitivity for cancer at an observed specificity of 88%, and demonstrated strong pre-cancer detection rates. The 2010 validation data has been through a data peer review process and has been accepted for publication. In the data peer-review process, and in discussions with key opinion leaders, we have determined that it is appropriate to clarify the classification and inclusion criteria for pre-cancers. In 2010, we classified pre-cancer as advanced adenomas >1 cm and reported a sensitivity of 64% for the samples tested. In the peer review process, we were asked to also include all advanced adenomas ~ 1 cm into the calculation of pre-cancer and to classify pre-cancer as advanced adenomas ≥ 1 cm. The reported sensitivity of the 2010 pre-cancer data for all samples ≥ 1 cm is 54%. The classification of pre-cancer as advanced adenomas ≥ 1 cm is the classification being used for our pivotal clinical trial and the way we will be categorizing pre-cancer in the future.

In the 2011 study, the assay demonstrated a 100% sensitivity for Stage I and Stage II cancers and a 91% sensitivity for Stage III cancers. The test also demonstrated a 96% sensitivity for Stages I, II and III combined. In addition the assay also showed 100% sensitivity for Stage IV cancers. All were at a specificity cut off of 91%.

The study also demonstrated a 94% sensitivity for right-sided cancer and 100% for left-sided cancer.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EXACT SCIENCES CORPORATION

Date: November 16, 2011

By: */s/ Maneesh Arora*
Maneesh Arora
Senior Vice President and
Chief Financial Officer