

CORGENIX MEDICAL CORP/CO
Form 8-K
June 04, 2007

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): **June 4, 2007**

Corgenix Medical Corporation

(Exact Name of registrant as specified in its charter)

Nevada

(State or other jurisdiction
of incorporation)

000-24541

(Commission File Number)

93-1223466

(I.R.S. Employer
Identification No.)

**11575 Main Street
Suite 400**

Broomfield, Colorado 80020

(Address, including zip code, of principal executive offices)

(303) 457-4345

(Registrant's telephone number including area code)

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:

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

On June 4, 2007, the Registrant issued a press release announcing that the Company has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its AspirinWorks Test Kit, the Company's newest diagnostic product.

More than one million Americans experience new or recurrent heart attacks each year. At risk individuals are eligible for aspirin therapy and should be tested for the presence or absence of the therapy's effect. The AspirinWorks® Test Kit is an enzyme-linked immunoassay (ELISA) to determine levels of 11-Dehydro Thromboxane B₂ (11dhTxB₂) in human urine, which aids in the qualitative detection of aspirin effect in apparently healthy individuals post ingestion.

The 510(k) clearance of AspirinWorks® is an enormous milestone for our Company and important to the health of millions in the U.S. in addition to the rest of the world, said Douglass Simpson, Corgenix President and Chief Executive Officer.

We have significant expectations for this product due to the strong interest it has already attracted from the investment and health care communities. We believe that this product, in the intermediate-to long term, has the potential to generate worldwide revenues equal to or in excess of all of our other products combined.

The AspirinWorks® diagnostic test kit targets a potential U.S. market of over 60 million individuals and a potential global market exceeding 200 million individuals.

Simpson said the new test kit, already CE marked and available in Europe, will be sold through Corgenix's U.S. sales force and distributed through its established network of laboratories.

Research has shown that up to 25 percent of individuals may be non-responsive to aspirin's benefits, and are more than three times more likely to die from heart disease, said Corgenix Clinical Affairs Director Gordon Ens. This test can tell us if the aspirin fails to elicit an effect, thereby allowing physicians to individualize their patient's therapy.

Unlike other platelet aggregation tests, which require freshly drawn blood that must be evaluated within at least 4 hours, the AspirinWorks® test requires a urine sample that can easily be obtained in any doctor's office. Ens believes that any doctor should be able to order the AspirinWorks® test now that FDA clearance has been received.

This can not come at a better time considering the recent American Heart Association guidelines that suggest that women should consider an aspirin regimen to reduce their potential risk of heart attack and stroke, stated Ens.

The AspirinWorks® product was developed in conjunction with strategic partners, Creative Clinical Concepts, a Denver-based biotechnology company, and Cayman Chemical Company, an Ann Arbor, Mich. manufacturer of biochemical research products.

Corgenix previously announced collaboration with McMaster University (McMaster), Hamilton, Ontario, for McMaster's proprietary technology for aspirin therapy testing. The McMaster technology includes one U.S. issued patent as well as several patents pending in the United States, Canada and Europe. In addition to licensing the McMaster technology, Corgenix also has one U.S. patent pending on the AspirinWorks® product.

Physicians and clinics interested in ordering the test can call 1-800-729-5661 x180, or e-mail techsupport@corgenix.com.

ITEM 9.01 Financial Statements and Exhibits

- a) Not applicable
- b) Not applicable
- c) Exhibits:

99.1 Press Release dated June 4, 2007 Corgenix Aspirin Works Test Kit Cleared by FDA

2

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.

CORGENIX MEDICAL CORPORATION

Date: June 4, 2007

By: /s/ Douglass T. Simpson
Douglass T. Simpson
President and Chief Executive Officer
