CorMedix Inc.
Form 8-K
September 21, 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): September 15, 2011

CORMEDIX INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	001-34673	20-5894890
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

745 Rt. 202-206, Suite 303, Bridgewater, NJ	08807
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: (908) 517-9500

(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 (see General Instruction A.2. below):

¨ 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))

Item 8.01. Other Events.

On September 15, 2011, the U.S. Food and Drug Administration (the "FDA") advised CorMedix Inc., a Delaware corporation (the "Company"), that the Center for Drug Evaluation and Research had been assigned as the lead agency center for the pre-market review of Neutrolin®. As previously disclosed, the Company had filed a Request For Designation for Neutrolin® to be classified as a device drug combination and assigned to the Center For Devices and Radiological Health ("CDRH") as lead reviewer. The Company is considering all of its alternatives with respect to Neutrolin, including submitting an appeal to the FDA's decision regarding the assignment of the Center for Drug Evaluation and Research. The Company has approximately 15 days to submit its appeal to the FDA. Once received, the FDA will have approximately 15 days to review such appeal and respond to the Company with its final determination. In the event the Company decides not to submit an appeal, the Company may request a pre-Investigational New Drug ("pre-IND") meeting with the FDA in preparation of filing an IND. The FDA has 60 days to respond to the pre-IND meeting request. Once the Company submits an IND, the FDA has a statutory 30 days to review the IND submission. Once the FDA accepts the Company's IND, the Company can begin clinical studies.

SIGNATURE

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.

September 21, 2011 CORMEDIX INC.

By: /s/ Brian Lenz
Name: Brian Lenz
Title: Chief Financial Officer