

Edgar Filing: CorMedix Inc. - Form 8-K

- .. 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 March 5, 2013, TÜV-SÜD, the European notified body managing the CE Mark application for our product candidate CRMD003, or Neutrolin[®], informed us that the Medicinal Evaluation Board of the Netherlands, or MEB, gave us a positive response on the clinical aspect of our application. The MEB is responsible for authorizing and monitoring safe and effective medicinal products on the Dutch market and shares responsibility for authorizing medicinal products throughout the European Union.

We are now working on the final packaging for Neutrolin with internationally recognized consultants and a leading packaging systems company to meet TÜV-SÜD requirements. As a result, we anticipate final approval for the CE Mark certification for Neutrolin during the second quarter in 2013.

Additionally, to lead the commercialization of Neutrolin in the European Union, we have formed a European subsidiary, CorMedix Europe GmbH.

Item 5.02. Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers.

(e) On March 6, 2013, our Board of Directors approved an amendment to the vesting schedule of the options granted to our directors and executive officers on December 5, 2012. Such options are described further in our Current Report on Form 8-K filed with the SEC on December 7, 2012. Given the anticipated final approval for the CE Mark certification for Neutrolin during the first half of 2013, such options will now vest as follows: (a) fifty percent (50%) on the date of issuance of the CE Mark certification for Neutrolin in Europe, if the CE Mark approval is obtained on or before June 30, 2013 (as opposed to March 31, 2013 as previously provided by our Board), and (b) fifty percent (50%) on December 31, 2013.

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.

Date: March 6, 2013 CORMEDIX INC.

By: /s/ Randy Milby
Name: Randy Milby
Title: Chief Executive Officer