CorMedix Inc.
Form 8-K
December 04, 2017

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 22, 2017

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

Delaware	001-34673	20-5894890
(State or Other Jurisdictionof Incorporation)	(CommissionFile Number)	(IRS EmployerIdentification No.)

400 Connell Drive, Suite 5000, Berkeley Heights, NJ	07922
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

On November 22, 2017, the Opposition Division at the European Patent Office (EPO) in Munich, Germany held an oral hearing to consider an opposition brought by TauroPharm GmbH against CorMedix's European Patent EP 1,814,562 B1, also known as the Prosl European Patent, alleging that it lacks novelty and inventive step. The Prosl European Patent covers the formulation of taurolidine and citrate with low dose heparin in a catheter lock solution for maintaining patency and preventing infection in hemodialysis catheters.

At the hearing, the panel held that the Prosl European Patent would be invalidated because it did not meet the requirements of novelty based on a technical aspect of the European intellectual property law. CorMedix disagrees with this decision and plans to appeal. Our appeal will be based, in part, on the written opinion to be issued by the Opposition Division, which is expected by the first quarter 2018. CorMedix continues to believe that the Prosl European Patent is indeed novel and that its validity should be maintained. In addition, the ongoing Unfair Competition litigation brought by CorMedix against TauroPharm is not affected and will continue.

Based on the advice of our U.S. patent counsel, we expect that, due to differences between the novelty requirements in intellectual property law in Europe and the U.S., the validity of our U.S. patent covering Neutrolin will be unaffected by a decision from the EPO. Importantly, the Company believes that the U.S. Food and Drug Administration's (FDA) designation of Neutrolin as a Qualified Infectious Disease Product (QIDP) provides the most significant protection for its intellectual property. Having this designation means that, upon FDA approval for the prevention of catheter-related blood stream infections in patients with end-stage renal disease receiving hemodialysis through a central venous catheter, Neutrolin would have five years of market exclusivity in the U.S. Beyond this, Neutrolin will have an additional five years of protection due to its status as a new chemical entity, and a further six months if granted pediatric exclusivity. Together, these designations are expected to serve as a significant barrier to entry in the U.S. marketplace for a period of ten and a half years following commercial launch and, in any case, would be effective after any potential patent protection expired.

Based on an extensive analysis of the global market potential for Neutrolin, we believe the U.S. represents a substantially more valuable commercial market for this product than the European market. Therefore, we have been focusing most of our resources on seeking regulatory approval of Neutrolin in the U.S. for multiple, high-value indications, beginning with the prevention of catheter-related blood stream infections in hemodialysis patients, which is currently in Phase 3 development.

Forward-Looking Statements

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks and uncertainties. All statements, other than statements of historical facts, regarding management's expectations, beliefs, goals, plans or CorMedix's prospects should be considered forward-looking. Readers are cautioned that actual results may differ materially from projections or estimates due to a variety of important factors, including; the risk of completing the development program for Neutrolin in the U.S., including FDA approval; the risk of challenges to our intellectual property; and the estimated markets for Neutrolin. These and other risks are described in greater detail in CorMedix's filings with the SEC, copies of which are available free of charge at the SEC's website at www.sec.gov or upon request from CorMedix. CorMedix may not actually achieve the goals or plans described in its forward-looking statements, and investors should not place undue reliance on these statements. CorMedix assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

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.

CORMEDIX INC.

Date: December 4, 2017 By: /s/ Robert W. Cook
Name: Robert W. Cook
Title: Chief Financial Officer