

Roche Freedman Announces the Filing of a Class Action Against CorMedix, Inc., and Certain Officers – CRMD

NEW YORK, NY, UNITED STATES,
September 17, 2021 /

EINPresswire.com/ -- Roche Freedman LLP announces that a class action lawsuit has been filed against CorMedix, Inc. ("CorMedix" or the "Company") (NASDAQ: CRMD) and certain of its officers. The class action,



filed in the United States District Court for the District of New Jersey, and docketed under 21-cv-16855, is on behalf of an expanded class consisting of all persons and entities other than Defendants that purchased or otherwise acquired CorMedix securities between October 16, 2019 and May 13, 2021, both dates inclusive (the "Expanded Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

If you are a shareholder who purchased CorMedix securities during the Expanded Class Period, you have until September 20, 2021 to ask the Court to appoint you as Lead Plaintiff for the class. To discuss this action and/or obtain a copy of the Complaint, contact Ivy T. Ngo at ingo@rochefreedman.com or 646-392-8842. Those who inquire by e-mail are encouraged to include their mailing address, telephone number, and the number of shares purchased.

CorMedix is a biopharmaceutical company that focuses on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases in the U.S. and internationally. The Company is focused on developing its lead product candidate, DefenCath, a purported novel antibacterial and antifungal solution designed to prevent costly and dangerous catheter-related bloodstream infections ("CRBSIs"). DefenCath has been available in Europe and the Middle East under the brand name Neutrolin since 2013.

In the U.S., CorMedix completed Phase 3 of clinical development of DefenCath in July 2019 and finally appeared ready to submit a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for approval, including its manufacturing information, on October 16, 2019. That day, the first day of the Class Period, the Company announced that "[t]he FDA was

supportive of Neutrolin's proposed manufacturing program, including the active pharmaceutical ingredients (API), the container closure and testing, and indicated that it will conduct a thorough review of all of the CMC ["Chemistry, Manufacturing, and Control"] information as well as assess the commercial readiness of the various manufacturing facilities at the time of NDA filing" and that "[n]o further CMC meetings with FDA [we]re planned prior to NDA submission."

In February 2020, CorMedix began its rolling submission of its NDA for DefenCath as a catheter lock solution with an initial indication for use of preventing CRBSIs in patients with end-stage renal disease who are receiving hemodialysis via a central venous catheter. The NDA submission was completed in July 2020.

The complaint alleges that, throughout the Expanded Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (i) deficiencies existed with respect to DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath; (ii) in light of the foregoing deficiencies, the FDA was unlikely to approve the DefenCath NDA for CRBSIs in its present form; (iii) Defendants had downplayed the true scope of the deficiencies with DefenCath's manufacturing process and/or at the facility responsible for manufacturing DefenCath; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

On March 1, 2021, CorMedix issued a press release "announc[ing] that the [FDA] cannot approve the [NDA] for DefenCath . . . in its present form." CorMedix informed investors that the "FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility"; that the "FDA did not specify the issues and CorMedix intends to work with the manufacturing facility to develop a plan for resolution when FDA informs the facility of the specific concerns"; that, "[w]hen we are informed of the issues, we will schedule an investor conference call to provide an update on our expected timeline for resolution"; and that, "[a]dditionally, FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications."

On this news, CorMedix's stock price fell \$5.98 per share, or 39.87%, to close at \$9.02 per share on March 1, 2021.

Then, on April 14, 2021, Defendants announced that CorMedix would have to take additional steps to meet the FDA's requirements for DefenCath's manufacturing process, including "[a]ddressing FDA's concerns regarding the qualification of the filling operation [that] may necessitate adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath."

On this news, CorMedix's stock price fell \$1.44 per share, or 15.37%, to close at \$7.93 per share on April 14, 2021.

Finally, on May 13, 2021, CorMedix announced that “[b]ased on our analyses, we have concluded that additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA.” After an analyst pressed for clearer information on DefenCath’s manufacturing deficiencies on a conference call held that same day, Defendant Phoebe Mounts, CorMedix’s Executive Vice President and General Counsel, finally disclosed, inter alia, that “there are times when there may be unexpected results obtained”; that the FDA “expect[s] us to generate sufficient data to demonstrate that[the filling] process is a controlled process and is consistent with the agency’s requirements for good manufacturing practice”; that “sterility is a very important part of that process,” as well as “the accuracy in making sure the right volume of DEFENCATH is loaded into the vials”; that “we are talking about thousands of vials during the manufacturing run”; that Defendant must “generat[e] of a lot of data to make sure that . . . all the equipment has been qualified for the intended use and every step in the manufacturing process has been qualified”; that “th[e] process needs to be very robust, [and] needs to be reproducible”; and that “the burden is on the manufacturer to demonstrate that the facility can do that process reducibly and generate the required product for commercial distribution.”

On this news, CorMedix’s stock price fell \$1.51 per share, or 19.97%, to close at \$6.05 per share on May 14, 2021.

About Roche Freedman LLP

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