

May 10, 2021



BioCorRx Receives FDA Clearance of Investigational New Drug (IND) Application for BICX104, its Implantable Naltrexone Pellet for the Treatment of Opioid Use Disorder

ANAHEIM, CA, May 10, 2021 (GLOBE NEWSWIRE) -- [via NewMediaWire](#) -- [BioCorRx Inc.](#) (OTCQB: BICX) ("BioCorRx" or the "Company"), a developer and provider of advanced solutions in the treatment of substance use disorders, announced today that the U.S. Food and Drug Administration (FDA) has given the Company clearance to proceed to human trials for BICX104, an implantable naltrexone pellet for the treatment of Opioid Use Disorder (OUD). The company submitted the IND to the FDA last month. The first-in-human clinical trial for BICX104 is expected to commence later this year.

BICX104 is a biodegradable, long-acting subcutaneous pellet of naltrexone being developed in collaboration with the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH), under RFA DA-19-002, "[Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose \(UG3/UH3\) \(Clinical Trial Optional\)](#)". The Company had a previous pre-IND meeting with the FDA, at which time the FDA deemed the potentially shortened 505(b)(2) pathway acceptable, as well the opportunity to seek eventual dual indication on the product for OUD and Alcohol Use Disorder (AUD).

According to [data provided](#) by the Centers for Disease Control and Prevention (CDC), over 81,000 drug overdose deaths occurred in the U.S. between June 2019 and May 2020. This data represents the most overdose deaths ever recorded in a 12-month period and experts attribute this increase, at least in part, to the COVID-19 pandemic.

Brady Granier, President, and Director of BioCorRx, Inc., and CEO of BioCorRx Pharmaceuticals, Inc., stated, "The FDA's communication that we are safe to proceed to our human study represents a major milestone for BICX104, a gradual release implantable pellet for opioid use disorder. We are looking forward to beginning the first-in human clinical trial of BICX104 which will assess longevity, safety and tolerability of BICX104. The COVID-19 pandemic has overshadowed the opioid epidemic, which unfortunately seems to have worsened over the last year. Our main goal is to bring this important medication to the masses, and we hope that BICX104 can one day soon be available to help those in need."

"We are very excited to move one step closer to bringing BICX104 to market in order to help people suffering from opioid use disorder. We would like to thank our partners and our shareholders for their support, and we are looking forward to launching the first-in-human clinical trial with BICX104 later this year," concluded CEO, CFO and Director Lourdes Felix of BioCorRx.

About BioCorRx Inc.

BioCorRx Inc. (OTCQB: BICX) is an addiction treatment solutions company offering a unique approach to the treatment of substance use and other related disorders. Beat Addiction Recovery is a substance use disorder recovery program that typically includes BioCorRx's proprietary Cognitive Behavioral Therapy (CBT) modules along with peer support via mobile app along with medication prescribed by an independent treating physician under their discretion. The UnCraveRx™ Weight Loss Program is also a medication assisted weight loss program; please visit www.uncraverx.com for more information on UnCraveRx™. The Company also conducts R&D under its controlled subsidiary, BioCorRx Pharmaceuticals. For more information on BICX and product pipeline, please visit www.BioCorRx.com.

Safe Harbor Statement

The information in this release includes forward-looking statements. These forward-looking statements generally are identified by the words "believe," "project," "estimate," "become," "plan," "will," and similar expressions. These forward-looking statements involve known and unknown risks as well as uncertainties. Although the Company believes that its expectations are based on reasonable assumptions, the actual results that the Company may achieve may differ materially from any forward-looking statements, which reflect the opinions of the management of the Company only as of the date hereof.

BioCorRx Inc.

investors@BioCorRx.com

714-462-4880

Investor Relations:

Crescendo Communications, LLC

(212) 671-1020 x304

bicx@crescendo-ir.com

Media Contact:

CMW Media

(858) 264-6600

biocorrx@cmwmedia.com



Source: BioCorRx Inc