

February 12, 2018



# BioCorRx Announces Results of Pre-IND meeting with FDA for Sustained Release Naltrexone Implant, BICX102

*505(b)(2) application plan acceptable per FDA*

*Application will seek dual indications for opioid and alcohol use disorders*

**ANAHEIM, CA, Feb. 12, 2018 (GLOBE NEWSWIRE) -- BioCorRx**

**Inc. (OTCQB: BICX) (the "Company")**, a developer and provider of advanced solutions in the treatment of alcohol and opioid addictions, today announced results of its pre-Investigational New Drug (pre-IND) meeting with the United States Food & Drug Administration (FDA). The FDA has deemed the 505(b)(2) pathway as an acceptable route for approval for BICX102, a sustained release naltrexone implant for the treatment of opioid and alcohol use disorders. The 505(b)(2) pathway is intended to provide an abbreviated route to approval with less study requirements than traditional applications. Based on the FDA's guidance, no additional efficacy studies are being considered. In addition, the Company announced that based on the FDA's responses, it plans to apply for dual indications, both opioid use disorder and alcohol use disorder, within the same application. A nonclinical safety study and a clinical pharmacokinetic (PK) study will be conducted as the Company expected and planned for prior to the pre-IND meeting. Clinical safety and human factor testing will also be performed as suggested by the FDA.

Brady Granier, President, CEO and Director, stated, "We are excited with the responses we have received on our development plan from the FDA. With the FDA agreeing that the 505(b)(2) pathway is acceptable for BICX102, this means that we should be able to help more people, sooner than traditional routes of approval. We expect to have relatively lower costs and a faster path to approval with this abbreviated route. Also, the ability to seek approval on two indications at the same time using the same studies would be an enormous time and cost savings to the Company. The opioid epidemic gets all the headlines for the right reasons, but alcohol use disorder is a continuous, massive problem that we have never neglected. We are particularly grateful for the support we have received from both the National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Preparation for certain National Institutes of Health (NIH) grant applications are underway now that we have enough information from the FDA to proceed. The submission period for these grants has just started. We also plan to file our IND application soon and hope to have updates available as things progress."

## **About BioCorRx**

BioCorRx Inc. (OTCQB: BICX) is an addiction treatment company offering a unique approach to the treatment of substance abuse addiction. The BioCorRx® Recovery

Program, a non-addictive, medication-assisted treatment (MAT) program, consists of two main components. The first component of the program consists of the use of sustained release naltrexone, usually in implantable form and under the direction and care of an independent licensed physician. Implant forms of naltrexone deliver the non-addictive medicine which is an opioid antagonist that can significantly reduce physical cravings for alcohol and opioids, as well as some of their effects. The second component of the program developed by BioCorRx Inc. is a proprietary cognitive behavioral therapy (CBT) program specifically tailored for the treatment of alcohol and opioid use disorders for those receiving sustain release naltrexone treatment. The behavioral portion of the program also includes overlapping peer recovery support and tracking. The Company also has an R&D subsidiary, BioCorRx Pharmaceuticals, which is currently developing injectable and implantable naltrexone products for potential future regulatory approval. For more information on BICX, visit [www.BioCorRx.com](http://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.*

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