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BioCorRx Inc. Announces Update on Commercialization Efforts for Naltrexone Implant

ANAHEIM, CA / ACCESSWIRE / September 28, 2017 /*BioCorRx Inc.* (OTCQB: BICX) ***(the "Company")***, a developer and provider of advanced solutions in the treatment of substance use disorders, today announced an update on commercialization efforts for the Company's naltrexone implant, BICX102. The Company has formally requested a pre-IND meeting for BICX102, while also working on the IND application. The pre-IND meeting date for BICX102 has been scheduled for January 24, 2018. Scheduling a pre-IND meeting does not preclude the Company from submitting the IND application beforehand.

As outlined in the Draft Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products, a response to the pre-IND meeting request is usually provided within 21 days, and the FDA aims to schedule the pre-IND meeting within 60 days of receipt of the request letter. However, with increasing workloads, many FDA divisions are increasingly unable to meet this goal, and the recently ended hiring freeze at the FDA has increased timelines.

"Last month, we reported that we had decided to seek FDA approval on our naltrexone implant product ahead of the injectable, BICX101. Innovative Science Solutions (ISS) has been communicating with the FDA on our behalf and they requested a pre-IND meeting while we finalize our documents. As previously stated, our desire is to submit an IND application using existing data. The application requires substantial preparation including the review of thousands of pages of research and data. After review of the information, ISS has presented us with a gap analysis of the remaining information that they feel will be needed to make a strong case to the FDA for expedited approval of BIXC102. We are currently working on the items identified in that analysis with ISS and Dr. Bal Brar, our VP of Drug Development."

According to Steven M. Weisman, Ph.D., Head of Clinical and Regulatory Support at ISS, "BioCorRx and ISS are working to finalize a comprehensive meeting package that includes a robust plan to demonstrate a scientific bridge. Given the national opioid epidemic, we believe we have developed a strong justification for why we believe the available data can and should be leveraged to expedite the IND review. We anticipate a productive conversation with the FDA."

Dr. Bal Brar, VP of Drug Development, stated, "We have the clinical and toxicology data that we feel will be sufficient for the application, and we are now completing the CMC information which involves agreements with drug suppliers and manufacturers. The implant must be made by a cGMP facility and we are negotiating with several FDA licensed contract manufacturers at this time. We are also close to finalizing commitments from manufacturers of the ingredients in the implant with drug suppliers that have open drug master files (DMF)

with the FDA. Once we have the CMC portion of the package in place, I feel we will be in a good position to file the IND."

Mr. Granier added, "While we would have hoped for an earlier meeting date with the FDA, we cannot control their timeline and it does not stop our progress as we still need the CMC portion of the package completed. That work is already in progress so that no time is wasted while we wait for the pre-IND meeting in the event we cannot submit the IND application prior to the meeting. Our desire remains to be able to go to human trials as quickly as possible by submitting the IND application. We do not want to rush things and submit something that's incomplete in the eyes of the FDA. It's also important to note that there is strong interest in this product from various government entities which has helped fuel our decision to get this product approved. We have been in discussions or meetings with ONDCP, NIDA, NIAAA, DoD, SAMHSA, some state DOCs, and others to explore opportunities for assistance in bringing this product to market. We believe that the medical community and government entities have a clear desire for an antagonist therapy that can last several months to fight this opioid epidemic. We feel that this product can save many lives once approved and, as a result, payers from different sources will emerge following approval."

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 an outpatient implant procedure performed by a licensed physician. The implant delivers the non-addictive medicine, naltrexone, an opioid antagonist that can significantly reduce physical cravings for alcohol and opioids. The second component of the program developed by BioCorRx Inc. is a one-on-one counseling program specifically tailored for the treatment of alcoholism and other substance abuse addictions for those receiving long-term naltrexone treatment. 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.

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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