

September 8, 2021



Recro and BioCorRx Expand Development and Manufacturing Relationship to Support BICX104, an Implantable Naltrexone Pellet for the Treatment of Opioid Use Disorder

SAN DIEGO and ANAHEIM, Calif., Sept. 08, 2021 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. ("Recro"; NASD: [REPH](#)), a contract development and manufacturing organization (CDMO) dedicated to solving complex formulation and manufacturing challenges in small molecule therapeutic development, and BioCorRx, Inc. ("BioCorRx"; OTCQB: BICX), a developer and provider of advanced solutions in the treatment of substance use disorders, today announced the expansion of the companies' ongoing relationship with the signing of a new development and manufacturing agreement. Under terms of the new agreement, Recro will provide analytical validation services and cGMP manufacturing of registrational batches of BICX104 to support BioCorRx's potential filing of a New Drug Application (NDA) for BICX104 with the U.S. Food and Drug Administration (FDA).

This new agreement expands the previously signed Master Services Agreement (MSA) between BioCorRx and IriSys LLC ("IriSys"), the San Diego-based CDMO that was recently acquired by Recro. Under the initial MSA signed in 2019, IriSys provided development and manufacturing services in support of BICX102, the preclinical precursor to BICX104. Those efforts will now transition to support BICX104 as it advances toward first-in-human clinical trials. All activities covered under this new agreement will be conducted at Recro's San Diego facility.

BICX104 is a biodegradable, long-acting subcutaneous pellet of naltrexone for the treatment of opioid use disorder (OUD) being developed under BioCorRx Pharmaceuticals, Inc., BioCorRx's controlled R&D subsidiary. BioCorRx has received clearance from the FDA to proceed to human trials for BICX104 and expects to initiate the first-in-human clinical trial of the drug candidate as soon as scheduling permits. The project has been funded in large part by the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH), under award number UG3DA047925 and is a result of BioCorRx's application under RFA DA-19-002, Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose (UG3/UH3) (Clinical Trial Optional).

"The legacy IriSys team, now Recro, has had a valued and productive relationship with BioCorRx in support of the company's implantable naltrexone program since 2019 and we are pleased to expand the scope of the collaboration as BioCorRx prepares to initiate the first-in-human clinical trial of BICX104," said David Enloe, chief executive officer of Recro.

“This new agreement is a testament to the talented team of professionals that was built at IriSys and offers an immediate demonstration of the impact that our recent acquisition of IriSys will have on Recro’s ongoing growth strategy. We look forward to bringing the strength and experience of the entire Recro organization to the BioCorRx relationship. It is a privilege to continue to support the important work that BioCorRx is conducting in an effort to offer a key therapeutic option in the battle against opioid use disorder.”

“The exceptional service and support provided through our ongoing CDMO relationship have been critical to BioCorRx’s successful advancement of our implantable naltrexone program. Recro’s recent acquisition of IriSys further bolsters our confidence in our CDMO partnership as we move BICX104 into the clinical stage and a step closer to market for patients battling opioid use disorder, as well as alcohol use disorder (AUD),” said Brady Granier, president and director of BioCorRx, Inc., and chief executive officer of BioCorRx Pharmaceuticals, Inc.

About Recro

Recro (NASDAQ: [REPH](#)) is a bi-coastal contract development and manufacturing organization (CDMO) with capabilities spanning pre-Investigational New Drug (IND) development to commercial manufacturing and packaging for a wide range of small molecule therapeutic dosage forms. With an expertise in solving complex manufacturing problems, Recro is a leading CDMO providing small molecule therapeutic development, end-to-end regulatory support, clinical and commercial manufacturing, aseptic fill/finish, lyophilization, packaging and logistics services to the global pharmaceutical market.

In addition to our experience in handling DEA controlled substances and developing and manufacturing modified release dosage forms, Recro has the expertise to deliver on our clients’ pharmaceutical development and manufacturing projects, regardless of complexity level. We do all of this in our best-in-class facilities, which total 145,000 square feet, in Gainesville, Georgia and San Diego, California.

For more information about Recro’s CDMO solutions, visit recrocdmo.com.

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™. BioCorRx also conducts R&D under its controlled subsidiary, BioCorRx Pharmaceuticals. For more information on BICX and product pipeline, please visit www.BioCorRx.com.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements, among other things, Recro’s and BioCorRx’s expectations regarding their relationship, the new agreement with respect to BICX104 and the development of BICX104 and other statements. The words “anticipate”, “believe”, “could”, “estimate”, “upcoming”, “expect”, “intend”, “may”, “plan”, “predict”, “project”, “will” and similar terms and phrases may be used to identify forward-looking statements in this press release. Recro’s operations

involve risks and uncertainties, many of which are outside Recro's control, and any one of which, or a combination of which, could materially affect Recro's results of operations and whether the forward-looking statements ultimately prove to be correct. Factors that could cause Recro's actual outcomes to differ materially from those expressed in or underlying these forward-looking statements include risks and uncertainties associated with the ongoing economic and social consequences of the COVID-19 pandemic, including any adverse impact on the customer ordering patterns or inventory rebalancing or disruption in raw materials or supply chain; demand for services, which depends in part on customers' research and development and the clinical plans and market success of their products; customers' changing inventory requirements and manufacturing plans; customers and prospective customers decisions to move forward with the company's manufacturing services; the average profitability, or mix, of the products Recro manufactures; Recro's ability to enhance existing or introduce new services in a timely manner; fluctuations in the costs, availability, and suitability of the components of the products Recro manufactures, including active pharmaceutical ingredients, excipients, purchased components and raw materials, or Recro's customers facing increasing or new competition. These forward-looking statements should be considered together with the risks and uncertainties that may affect Recro's or BioCorRx's business and future results presented herein along with those risks and uncertainties discussed in Recro's or BioCorRx's filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to Recro's or BioCorRx's, and neither Recro nor BioCorRx assume any obligation to update any forward-looking statements except as required by applicable law.

The content presented in this release is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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Source: Recro Pharma, Inc.; BioCorRx, Inc.