

Investor Presentation

February 2018



### Safe Harbor Statement

The information in this investor presentation may include 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.

### **Investment Highlights**

- The addiction treatment market represents a multi-billion dollar industry which is undergoing a radical transformation to new treatment modalities involving medications.
- ✓ BioCorRx has a two business models for treating addiction aligned with this change:
  - Seeking FDA approval of new medications to treat alcohol and opioid use disorders
  - Revenue generating BioCorRx<sup>®</sup> Recovery Program combining medication and therapy
- ✓ Formulations of naltrexone, which have a proven clinical track record
  - Sustained-release naltrexone formulas address major issues with patient compliance
- Commercialization for naltrexone implant focused on more rapid and cost effective 505(b)(2) regulatory pathway
  - Anticipated approval of one or more formulations by early 2020
- Private/public partnerships for BioCorRx<sup>®</sup> Recovery Program underway with municipalities (e.g. Philadelphia and Anaheim)
- ✓ BioCorRx<sup>®</sup> Recovery Program used in lieu of conviction in Ohio
- ✓ New partnership with CereCare as authorized distributer of BioCorRx<sup>®</sup> Recovery Program
- ✓ New weight-loss pilot program launched in October 2017
- $\checkmark$  Solid balance sheet and clean capital structure

### **Company Overview**

Substance abuse and addiction treatment company offering a two-pronged approach to the treatment of substance abuse addiction



Holding Company



Commercialization of naltrexone implant: **BICX102**, focused on 505(b)(2) regulatory pathway. Product Pipeline also includes ongoing development of injectable naltrexone technology: **BICX101**, an extended release injectable formulation of naltrexone using exclusively licensed, patented and patent pending delivery technology.

### BioCorRx® Recovery Program

Alcoholism and opioid addiction treatment program that includes peer support and behavioral therapy modules coupled with a naltrexone implant; many patients have been treated with **BioCorRx® Recovery Program** since launch with unprecedented results.

# The Addiction Epidemic

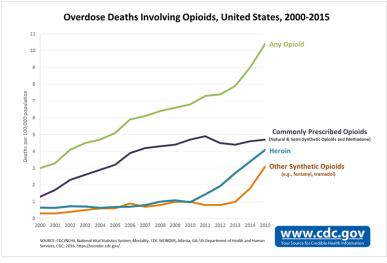
**Devastating Costs, Imperfect Solutions** 

### **The Addiction Epidemic**

" Medication-assisted treatment (MAT) – the use of medication combined with counseling and behavioral therapies is one of the major pillars of the federal response to the opioid epidemic in this country. This type of treatment is an important tool that has the potential to help millions of Americans with opioid use disorder regain control over their lives," said FDA Commissioner Scott Gottlieb, M.D.

	Estimated Annual Cost to Health Care System	Estimated Annual Overall Economic Cost
Alcohol	\$30 Billion	\$235 Billion
Illicit Drugs	\$11 Billion	\$193 Billion

- 23.5 million Americans are addicted to drugs and alcohol\*
- In 2015 15.1 million adults in the U.S. had alcohol use disorder
- About 6.7 percent of people with alcohol use disorder received treatment
- Alcohol is the nation's 4th leading preventable cause of death in U.S.
- Nearly **900,000** people dying from alcohol-related causes every year in U.S.
- Over **2 million** people in the U.S. abuse prescription pain relievers
- Heroin is most widely known illegal opiate; number of users estimated as high as 900,000
- According to the CDC, drug overdose was the leading cause of accidental death in 2015



\*According to the Substance Abuse and Mental Health Services Administration's (SAMHSA's) National Survey on Drug Use and Health.

#### The Opioid Epidemic in the U.S.

### In 2015...





People died from

overdosing on opioids"

2 million People had prescription opioid use disorder'

Deaths attributed to overdosing on commonly prescribed opioids<sup>13</sup>

People used heroin

Deaths attributed to overdosing on synthetic opioids 1.5

People used heroin for the first time



78.5 billion \$ In economic costs (2013 data)6

Sources: 12015 National Survey on Drug Use and Health (SAMHSA), / MMWR, 2016; 65(50-51), 1445–1452 (CDC), / Precorption Overdose Data (CDC), "Heroin Overdose Data (CDC), <sup>1</sup> Synthetic Opioid Data (CDC), <sup>4</sup> The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States; 2013. Florence C5, Zhou C. Luo F. Xu L. Med Care. 2016 Oct.54(10) 901-6

### **Addiction Treatment Market\***

Addiction treatment spending has grown faster than the total GDP inflation rate, the medical care inflation rate, and population growth. From 2008- 2014, growth in addiction treatment spending also exceeded growth in total health spending.

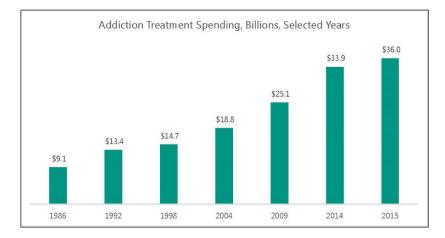
#### Spending

In 2015 addiction treatment spending was \$36 billion

- Largest payors were state and local funds 29% or almost \$10 billion
- Medicaid was second largest payor 21% (\$7.2 billion)
- Private Insurance 18% (\$6.1 billion)

#### **Care Setting**

- Outpatient care \$14.4 billion
- Residential care \$9.72 billion
- Inpatient care \$6.64 billion
- Prescription drugs \$1.8 billion in 2015



\* Substance Abuse and Mental Health Administration. (2016, August). Behavioral Health Spending & Use Accounts 1986 – 2014. Accessed online September 22, 2016 at https://www.openminds.com/market-intelligence/resources/behavioral-health-spending-use-accounts-1986-2014/

### **Medication Assisted Treatment**

#### Strong shift towards combining medication and counseling

"By its very definition, medication-assisted treatment has to include more than medication alone. It has to include counseling services and the other support services that are an important part of effective addiction treatment; that's an important point because many people do not recognize that aspect of MAT. It does not mean that you can take a pill for a couple of weeks and be cured of your substance use disorder. That's not actually how it works; in the same way that if you have diabetes, you don't take a pill for a couple of weeks and you're cured of your diabetes. It's a chronic illness that requires long-term management, and the same is true of addiction."

- Surgeon General Dr. Vivek Murthy



### The Big Three

#### The Most Common MAT Medications Include:

#### 1) Methadone:

- FDA approved
- Narcotic and addictive significant withdrawals when ceasing use
- Daily Dose
- Opioid Derived (full agonist)

#### 2) Suboxone/Buprenorphine

- FDA approved
- Narcotic and addictive significant withdrawals when ceasing use
- Daily Dose, monthly injectable, long term implant
- Opioid Derived (partial agonist)

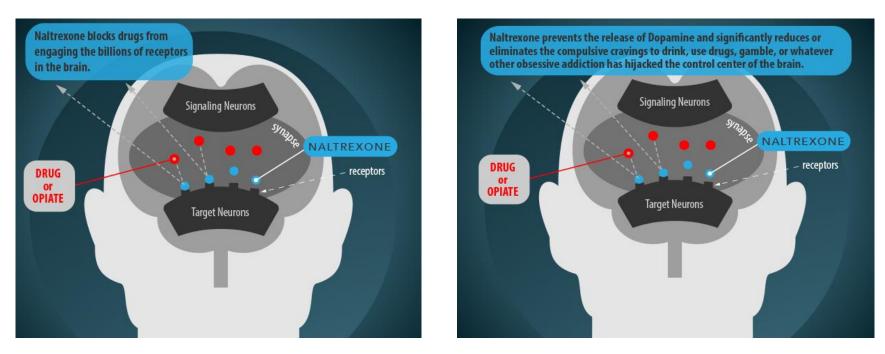
#### 3) Naltrexone

- FDA approved in 1984 long track record of safety
- Non-narcotic and non-addictive
- NOT opioid derived (antagonist)
- Significantly blocks cravings for drugs and alcohol
- No withdrawals when ceasing use



### Naltrexone Science

Naltrexone is a unique medication which binds with receptors and prevents the release of Dopamine – reducing cravings for alcohol and drugs



Naltrexone was approved by the FDA in 1984, in tablet form, for opioid addiction and approved subsequently in 1994 for alcohol use disorders (AUD).

## BioCorRx<sup>®</sup>: Product Pipeline

**Unlocking Value, Expanding Treatment Capacity** 

### BioCorRx<sup>®</sup> Pharmaceuticals

Naltrexone Implant BICX102 – for the treatment of opioid and alcohol use disorders Acquired North American rights to new implant formulations and Prodetoxone study data in 2016\*

- Extended release implant providing a therapeutic effect and maintain plasma levels approx. 90 days.
- 3 month formula has been used in Russia for several years with longer version just developed.
- Data acquired for Prodetoxone, which is one of only two known naltrexone implants approved by a regulatory body (Prodetoxone-Russia for 15+ years and another in Georgia)
- Prodetoxone been through multiple trials conducted at St. Petersburg Scientific-Research Center of Addictions and Psychopharmacology, Pavlov Medical University, in conjunction with the University of Pennsylvania, Department of Psychiatry, Philadelphia, USA
- Pre-IND meeting held with FDA January 24, 2018



\*Very similar formulas and protocols were purchased along with the North American rights to certain non-public Prodetoxone study data which is expected to assist in a more efficient FDA approval pathway.

### BioCorRx<sup>®</sup> Pharmaceuticals

### Naltrexone Injectable BICX101 – for the treatment of opioid and alcohol use disorders

- Partnered with TheraKine to complete development of a new injectable version of naltrexone using underlying patented and patent pending technology
  - Utilizing TheraKine's patented micro-delivery technology
  - Goal to be delivered subcutaneously (SQ) or intramuscularly (IM) in smaller muscle (deltoid)
- Anticipate cost efficient, outsourced manufacturing
- Ability to sub-license
- Product in formulation development phase



Not actual products. For illustration purposes only

### Competitive Landscape – Addiction Implants

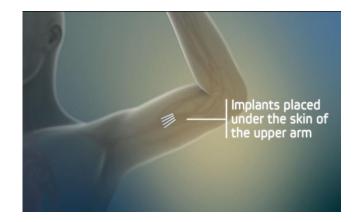
### **Titan Pharmaceuticals** (NASDAQ:TTNP) and **Braeburn Pharmaceuticals**

#### **Current buprenorphine implant product:**

- FDA approved buprenorphine implant in May 2016- sixmonth subdermal implant developed by Titan Pharmaceuticals
- Braeburn is developing a one week and one month injectable buprenorphine.

#### Implant has many drawbacks as reported by physicians:

- Needs to be surgically inserted and removed by trained medical professional
- (4) one-inch long rods placed inside upper arm
- Implant can be expelled or removed accidentally
- Possibility of exposure to large amount of medication (accidental or intentional) which could lead to misuse or abuse
- Variable blood levels
- Patient must be stable on low-to-moderate doses of buprenorphine to be eligible for implant
- Medication can be addictive





### Competitive Landscape – Naltrexone

#### **Vivitrol**<sup>®</sup> (Alkermes PLC, NASDAQ:ALKS)

#### Long lasting injectable naltrexone product:

- FDA approved sustained release naltrexone injection - lasts up to 30 days
- Strong demand over ~\$200 million in sales in 2016
- Parent Company Alkermes ~\$9 billion market cap, Vivitrol<sup>®</sup> product represents 25% of 2016 projected revenues



#### Vivitrol<sup>®</sup> injection has many drawbacks as reported by consumers and physicians:

- Can be painful
- Deep IM injection (gluteus)
- Large gauge needle
- Large volume injection (4ml), requires inefficient storage

...yet sales continue to skyrocket due to strong demand.



### Key Advantages of Naltrexone Implant BICX102

#### Advantages over buprenorphine implant:

- ✓ Addresses both alcoholism and opioid addiction
- ✓ Biodegrades eliminating the need to remove and replace
- ✓ Non-addictive active pharmaceutical ingredient
- ✓ Known to be effective against other obsessive compulsive disorders such as sex addiction, gambling, and food addiction

#### Advantages over naltrexone injectable currently on market:

- Approximately 3 months of release after one administration vs one month
- Removeable in the event narcotic pain relief is needed due to injury or elective surgery OTCQB:BICX



### R&D & FDA Objectives & Milestones

- Retained Dr. David Gastfriend previously served as VP of Scientific Communications for Alkermes; heavily involved with Vivitrol
- Retained Dr. Bal S. Brar as a lead drug development study design consultant – over 25 years of experience for drug and device development as well as worldwide regulatory submission of 50 INDs/510K's and 505(b)(2)'s; and approval of 8 NDA's
  - Experience includes working with major pharmaceutical companies Lederle/Wyeth, GlaxoSmithKline and Allergan
- Seeking FDA approval of naltrexone implant BICX102 and planned continued product development of BICX101 (injectable)
- Secured rights to patented micro-delivery technology for injectable BICX101
- Entered Non disclosure agreements with National Institute of Drug Abuse (NIDA) and National Institute on Alcohol Abuse & Alcoholism (NIAAA)



BioCorRx

### R&D & FDA Objectives & Milestones (cont.)

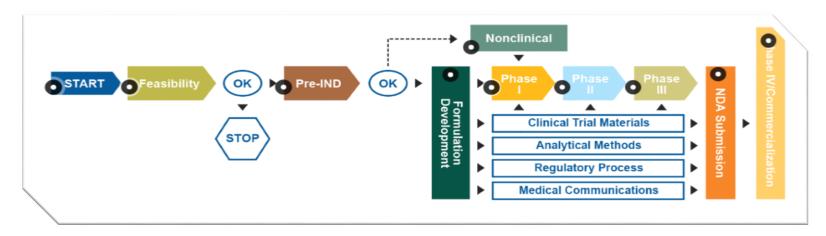
- Retained Innovative Science Solutions, LLC, a leading scientific consulting firm, to help guide the Company's regulatory strategy for FDA submission
- Held FDA Pre-IND meeting on January 24, 201
- 505(B)(2) pathway deemed acceptable by FDA
- As a result of meeting, seeking dual indication for both alcohol and opioid use disorders.
- Planning preclinical and clinical studies for safety, pharmacokinetics, and human factors (not planning to do efficacy studies per FDA meeting)
- Finalizing agreement with manufacturing partner
- Sources for naltrexone API secured with FDA compliant suppliers
- NIDA grant applications in process



BioCorRx



### 505(b)(2) Advantages / Cost /Pathway\*



- 505(b)(2) helps avoid unnecessary duplication of studies already performed on a previously approved ("reference" or "listed") drug
  - Gives the FDA express permission to rely on data not developed by the NDA applicant
- Less expensive and faster route to approval, compared with a traditional development path
  - Can take approximately 30 months to gain approval vs several years from traditional route
- In addition to any IP protection if any, 505(b)(2) pathway may be assigned 3, 5, or 7 years of exclusivity in certain situations\*

\*This is a general guide to 505(B)(2) and does not apply to all situations. Some or all may not apply to BICX102



### Revenue Forecast:

Implant/sustained release naltrexone (BICX102)

	Near-Term 2020/2021	Mid-Term 2022/2023	Long-Term 5+ Years
Market Penetration	1%	2%	3% +
Revenue	\$88-245M	\$386-540M	\$711M+

- Conservative assumptions based on current naltrexone reimbursement
  - Potential for higher reimbursement due to long lasting effects
  - Unmet treatment need for SUD; current medication-assisted therapies (MATs) are markedly underutilized

### The BioCorRx® Recovery Program Non-Addictive Medication-Assisted Treatment

### The BioCorRx<sup>®</sup> Recovery Program – Non-Addictive Medication-Assisted Treatment (MAT)

#### Proprietary Naltrexone Implant<sup>1</sup> - <u>cleared for use under state and federal compounding rules</u>

- Implant inserted in fatty tissue of abdomen
- Simple outpatient procedure by licensed medical professional
- Procedure only takes 20-30 minutes and begins to work within hours
- Substantially reduces cravings for drugs and alcohol for several months

#### Proprietary Cognitive Behavioral Therapy (CBT) Program/Peer Support/Tracking (virtual and inperson)

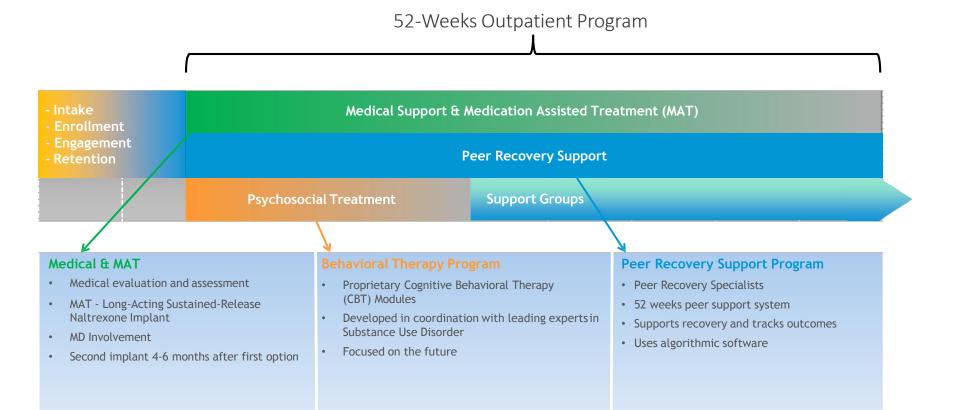
- Patients complete 35 treatment modules during 16 private sessions, typically in under 90 days
- Step-by-step approach for specific addiction and can include family and friend participation
- Therapists readily available
- 12 month peer recovery support in conjunction with, or after counseling
- Beta launch of mobile application completed on September 12, 2017 (includes 35 modules)

#### BioCorRx Recovery Program is distributed by partner clinics across the US

- Fees are paid to BioCorRx<sup>®</sup> per program sold by independent treatment providers
- Approximately 30+ partner clinics currently and growing
- Discussions being held to incorporate all or portions of the program into traditional residential treatment centers

<sup>1</sup>BioCorRx<sup>®</sup> purchased exclusive worldwide rights to an additional naltrexone implant (except for New Zealand/Australia) from Trinity in 2010. This implant is currently used in the program utilizing long standing compounding laws.

#### BioCorRx® Recovery Program: A Fully Integrated 52-week Program





### BioCorRx<sup>®</sup> Recovery Program vs Traditional Modalities

	BioCorRx <sup>®</sup> Recovery Program	Alcoholics Anonymous	In House Rehab
Significantly Blocks Cravings	Y	Ν	Y/N
<b>Outpatient &amp; Discrete</b>	Y	Y/N	Ν
Non-Narcotic, Non Addictive	Y	Y	Y/N
Return to Work Immediately	Y	Y	Ν
Combines Medication & Therapy	Y	Ν	Y/N
Cost	\$\$	\$	\$\$\$\$\$



### Target Business Model - MAT

	Near-Term 1-2 Years	Mid-Term *3-4 Years	Long-Term 5+ Years
Revenue	\$3-5M	\$7-10	\$12-18M
Gross Margin	50-75%	75-80%	80%+
EBITDA Margin	10-40%	40-50%	50-60%

- Specific fees charged by providers and collected by BioCorRx are confidential and vary based on region and other factors
- Can include higher upfront license fees with lower recurring per program sale fees, or higher recurring patient fees with lower upfront license fees
- BioCorRx targets a few thousand dollars per program sold; providers are highly incentivized by the ability to offer the program for, on average, 2-4 times the revenue paid to BioCorRx while still providing tremendous value to their patients at a cost that's usually half that of the average 30-day residential rehab stay



# Shareholder Value Focused

ISINES

BioCorRx

ISSUELT

### Management

#### Brady Granier, BSN: CEO/President, Director

- 4 years with BioCorRx Inc.; repositioned company as leader in the industry with the acquisition of TheraKine technology and R&D initiative, assembled a team of addiction experts worldwide, extensive experience with treatment of patients using naltrexone
- 12 years in media sales and business development for Clear Channel Media and Entertainment; former Healthcare Category Manager
- 9 years combined experience in the Healthcare and Behavioral Health Field

#### Lourdes Felix: CFO/COO, Director

- 4 years with BioCorRx Inc.; instrumental in completing multi-million dollar equity financing, extensive experience with clinic operations management, areas of expertise; SEC filings and reporting, treasury/banking, M&A, accounting & finance, business development, general management, financial and benchmark reporting, forecasts & budgets
- 8 years as former Controller for public accounting firm; responsible for operations and financial management
- 20 years experience in Finance and Operations Management in the private sector, public accounting and public company experience

#### Dr. David Gastfriend: Medical Consultant

- 9 years with Alkermes, Inc. as VP of Scientific Communication; worked on pivotal efficacy studies and research on effectiveness, health services, criminal justice systems and health economics.
- 5 years Massachusetts General Hospital as Director of Addiction Research Program
- 22 years Washington Circle Group non-profit as Vice President; national experts in substance abuse policy

#### Bal S. Brar, PhD: Lead Drug Development Study Design Consultant

- Over 25 years experience in drug and device development including worldwide regulatory submission of 50 INDs/510Ks and 505(b)(2)s, approval of 8 NDAs; prior work with Lederle /Wyeth, GlaxoSmithKline and Allergan; and over 55 scientific publications
- Participated in development efforts for Aristocort, Tazarotene, Botox, Alphagan, Lumigan, Restasis, Ofloxacin, Azelex, and Avage
- Ph.D. in Toxicology/Pathology from Rutgers University and D.V.M. from India with finance training from Harvard Business School



### Contact

#### Management

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### Appendix: Patent Portfolio

Applicant	Description	Application Date	Approval Date	U.S. Patent No./Patent Application No. <sup>1,2</sup>	Patent Expiration
TheraKine, Ltd.	Hydrophobic drug-delivery material, method for manufacturing thereof and methods for delivery of a drug- delivery composition	11/30/2011	6/14/2016	9,364,549	11/30/2031
TheraKine, Ltd.	Hydrophobic drug-delivery material, method for manufacturing thereof and methods for delivery of a drug- delivery composition	5/29/2014	pending	14/361,438	
TheraKine, Ltd.	Hydrophobic drug-delivery material, method for manufacturing thereof and methods for delivery of a drug- delivery composition	3/29/2016	pending	15/083,879	
TheraKine, Ltd.	MgStearate-Based Composite Nanoparticles, Methods of Preparation and Applications	10/10/2014	pending	62/062,212	
TheraKine, Ltd.	MgStearate-Based Composite Nanoparticles, Methods of Preparation and Applications	10/8/2015	pending	PCT/US15/54725	
TheraKine, Ltd.	Sustained Release Low Dose Formulations and Uses Thereof	9/8/2015	pending	62/215,248	
TheraKine, Ltd.	Sustained Release Low Dose Formulations and Uses Thereof	10/6/2015	pending	PCT/US15/00106	



### **Appendix: Patent Portfolio Continued**

Applicant	Description	Application Date	Approval Date	U.S. Patent No./Patent Application No. <sup>1,2</sup>	Patent Expiration
TheraKine, Ltd.	Conservation of Bioactivity by Hydrophobic Matrices	10/6/2015	pending	PCT/US15/54229	
TheraKine, Ltd.	Conservation of Bioactivity by Hydrophobic Matrices	10/7/2014	pending	62/060,654	
				Europe Patent Application No.	
Applicant	Description	Application Date	Approval Date	(1)(2)	Patent Expiration
TheraKine, Ltd.	Hydrophobic drug-delivery material, method for manufacturing thereof and methods for delivery of a drug- delivery composition	11/20/2011	pending	EP12794707.5	

<sup>1</sup>Includes further development of a specific formulation and drug patent

<sup>2</sup>Includes further relevant patents dependent upon these cited through continuation or division or expansion from PCT into National Phases