

BioCorRx®, Inc. (OTCQB: BICX)

Key Statistics

52 Week Range	\$0.20 - \$1.45
Avg. Volume (3 months)	0.7K
Shares Outstanding	23.69M
Market Capitalization	\$10.42M
EV/Revenue	36.8x
Cash Balance*	\$287.69K
Analyst Coverage	1

*Cash balance as of September 2025

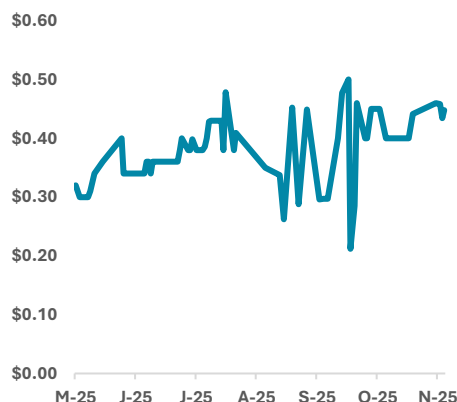
Revenue (in \$mm)

Dec – FY	2024A	2025E	2026E
Q1	0.04	0.13	0.71
Q2	0.04	0.18	0.73
Q3	0.00	0.64	0.75
Q4	0.00	0.70	0.78
FY	0.08	1.65	2.98

EPS (in \$)

Dec – FY	2024A	2025E	2026E
Q1	(0.14)	(0.06)	(0.09)
Q2	(0.13)	(0.07)	(0.05)
Q3	(0.14)	(0.11)	(0.05)
Q4	(0.08)	(0.06)	(0.06)
FY	(0.49)	(0.30)	(0.25)

Stock Price Chart (in \$)



Hunter Diamond, CFA

research@diamondequityresearch.com

BioCorRx® Inc. – LUCEMYRA®-Driven Revenue and Grant Support Shape Third-Quarter 2025 Financial Profile Amid Advancements in BICX104 Programs

Share Price

\$0.44

Valuation

\$0.80

Investment Highlights

Q3 2025 Financial Results Reflect Lucemyra®-Driven Revenue Ramp amid Increased Operating Costs:

For the three months ended September 30, 2025, BioCorRx® generated net revenues of \$0.64 million, compared with \$0 in the corresponding period of 2024. This increase primarily reflects the commencement of Lucemyra® distribution sales revenues, as well as an increase in the number of patients treated at licensed clinics. For the nine months, net revenue increased to \$0.95 million YoY from just \$7,665, underscoring the initial contribution from the USWM asset acquisition. Total operating expenses for the quarter increased to \$2.6 million from \$1.66 million, driven largely by higher research and development expenditure of \$1.0 million compared to \$0.46 million in Q3 2024. Selling, general, and administrative expenses totaled \$1.14 million for Q3 2025, compared to \$1.19 million for Q3 2024. Loss from operations widened to \$1.95 million compared with \$1.66 million a year earlier. This operating shortfall was partially offset by higher other income, including \$0.87 million of grant income and \$0.49 million of other miscellaneous income, resulting in a reduced net loss \$0.81 million compared to \$1.51 million in Q3 2024. Operating cash outflows totaled \$1.45 million for the nine months ended September 30, 2025, compared with \$0.85 million in the corresponding period of the previous year. The company concluded Q3 2025 with cash and cash equivalents of approximately \$288 thousand.

Valuation: A meaningful revenue contribution from Lucemyra®, coupled with substantial non-dilutive grant funding, is beginning to establish a more diversified funding base for BioCorRx®. This combination enhances the company's capacity to fund ongoing R&D, particularly the clinical development of BICX104, while partially offsetting operating cash burn and reducing its dependence on dilutive equity financing. We have revised our valuation model to incorporate Q3 financial results, updated share count, and reassessed the comparable company framework, yielding a valuation of \$0.80 per share, contingent on successful execution by the company. While BioCorRx®'s long-term outlook appears encouraging, investors should also consider the elevated risk associated with its OTC listing. These risks include limited trading liquidity, heightened price volatility, and greater regulatory uncertainty compared to exchange-listed peers.

Company Description

BioCorRx® Inc. is a biopharmaceutical company developing treatments for substance use disorders, led by its implantable naltrexone candidate BICX104 and the commercial drug LUCEMYRA®, along with BEAT Addiction Recovery Therapy and UnCraveRx® Weight Loss Program.

Demonstrates Steady Operational Momentum with LUCEMYRA® Integration, Advancements in BICX104 Programs, and Strengthened Commercial Positioning: During the quarter, BioCorRx® delivered meaningful operational progress across both commercial and development initiatives. The company continued integrating the recently acquired LUCEMYRA® franchise, enhancing distribution infrastructure and commercial readiness to support broader market availability. From a pipeline perspective, BioCorRx® advanced its sustained-release naltrexone platform, highlighted by the methamphetamine use disorder program supported by a \$11 million NIDA grant, an important external validation of BICX104's clinical and societal relevance. Preparations are underway to initiate grant-backed clinical studies, alongside continued progress in the Opioid Use Disorder (OUD) and Alcohol Use Disorder (AUD) indications, where prior evaluations have already generated supportive safety and Pharmacokinetic (PK) data*. Operationally, the company remains focused on strengthening revenue consistency, optimizing efficiencies, and exploring debt-restructuring opportunities, all while reinforcing the strategic rationale behind the LUCEMYRA® acquisition.

**Note: Research reported in this publication was supported by the National Institute on Drug Abuse of the National Institutes of Health under Award Number U01DA059994. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.*

Company Overview

BioCorRx® Inc. (OTCQB: BICX) is a commercial-stage biopharmaceutical company specializing in innovative solutions to treat substance use disorders (SUDs), including alcohol, opioid, and methamphetamine dependencies. Founded in 2008 and headquartered in Anaheim, California, the company has evolved from a treatment program provider to a vertically integrated organization combining pharmaceutical development with behavioral health services. The company operates through two main segments: commercial treatment programs and pharmaceutical development through its subsidiary BioCorRx® Pharmaceuticals Inc.

BioCorRx® is a commercial-stage biopharmaceutical company focused on treating substance use disorders through a combination of pharmaceutical products like BICX104 and LUCEMYRA® and behavioral health programs

The company's pharmaceutical operations are conducted through its subsidiary, BioCorRx® Pharmaceuticals Inc., which is actively advancing its lead product candidate, BICX104. BICX104 is a biodegradable, implantable naltrexone pellet designed to provide sustained-release treatment for opioid and alcohol use disorders (OUD/AUD). It is currently under clinical investigation in cooperation with the National Institute on Drug Abuse (NIDA), formerly supported by grants from the NIH HEAL Initiative. Specifically, BioCorRx® Pharmaceuticals secured a substantial grant from NIDA totaling approximately [\\$11 million](#) over three years to further develop BICX104 for methamphetamine use disorder (MUD), highlighting its growing recognition and support within the addiction treatment community. In Phase I clinical trials, BICX104 demonstrated strong safety and efficacy profiles, achieving therapeutic naltrexone plasma concentrations lasting up to 84 days, potentially significantly improving patient compliance compared to existing monthly treatments.

In a strategic expansion, BioCorRx® Pharmaceuticals recently acquired LUCEMYRA® (lofexidine), the only FDA-approved non-opioid medication for managing opioid withdrawal symptoms. This acquisition from specialty pharmaceutical firm USWM LLC marks BioCorRx®'s entry into commercialized pharmaceutical products, diversifying its portfolio and providing immediate revenue-generating opportunities. The integration of LUCEMYRA® positions BioCorRx® Pharmaceuticals to leverage its existing networks in addiction treatment centers, enhancing the drug's market presence and accessibility.

Beyond pharmaceuticals, BioCorRx® Inc. also offers comprehensive addiction recovery programs, notably the Beat Addiction Recovery Program, which includes proprietary Medication-Assisted Treatment (MAT), Cognitive Behavioral Therapy (CBT) modules, Opioid Treatment Programs (OTP), and peer support via a mobile application. Furthermore, the company's UnCraveRx® program supports weight loss management through medication-assisted strategies, supplemented by wellness specialists offering nutritional, fitness, and behavioral support. BioCorRx®'s business model further extends through licensing and distribution agreements with third-party entities operating addiction treatment facilities, ensuring broader access and implementation of its treatment methodologies.

The global addiction treatment market presents a substantial and growing opportunity, driven by the ongoing opioid crisis and increasing recognition of addiction as a treatable medical condition. Market research indicates the sector will experience robust growth, expanding from \$9.0 billion in 2023 to an estimated \$16.7

billion by 2033, representing a compound annual growth rate of approximately 7%.¹ Within this space, the opioid addiction segment is both the largest and the fastest-growing, with treatments targeting opioid use disorder expected to generate approximately \$8.24 billion in revenue by 2025.² Against this backdrop, BioCorRx®'s integrated approach, combining pharmaceutical development with behavioral health services, positions it to target a critical and underserved need within a high-growth market.

Corporate Structure

BioCorRx® Inc. is a Nevada-based holding company that operates through multiple subsidiaries, with a corporate structure that reflects its transformation from an early-stage alternative energy venture to a commercial-stage biopharmaceutical company focused on addiction treatment. The company was originally incorporated in 2008 as Cetrone Energy Company, with an initial focus on renewable fuel solutions. However, following the reverse acquisition of Fresh Start Private, Inc. (FSP) in 2011, the company exited the energy sector and reoriented itself around substance use disorder treatment. As a result of this transaction, BioCorRx® became the parent entity of FSP, which marked the beginning of its activities in behavioral health and addiction recovery services. The company subsequently changed its name to BioCorRx® Inc. in 2014, signaling its strategic realignment and brand consolidation around addiction recovery solutions. BioCorRx®'s current structure comprises two primary operational segments:

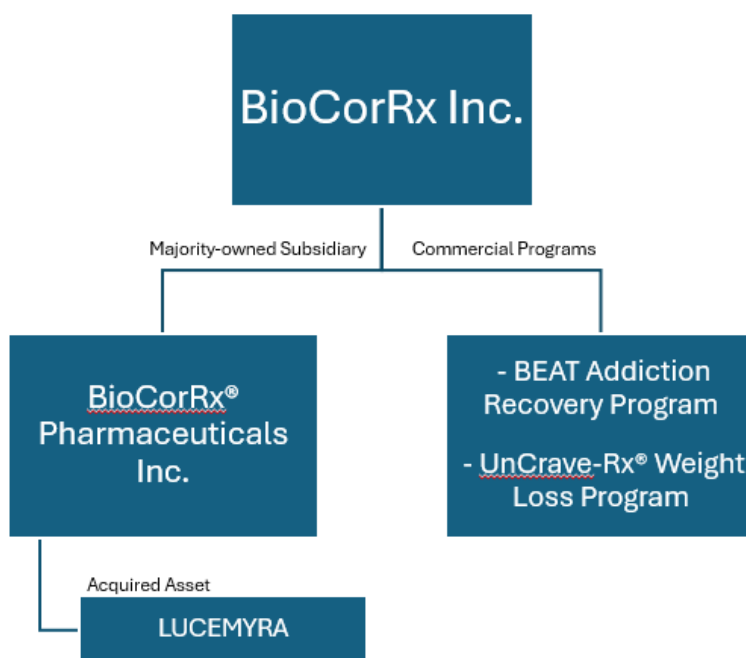


Exhibit 1: BioCorRx® Corporate Structure. Source: Company Filings, Diamond Equity Research

BioCorRx® Pharmaceuticals Inc. – Formed in 2016, this majority-owned subsidiary (BioCorRx® retains 75.8% ownership) is the company's clinical-stage pharmaceutical arm. It is responsible for developing long-acting, non-addictive treatments for opioid and alcohol use disorders. The subsidiary is currently advancing BICX104,

¹ [Allied Market Research](#)

² [Biospace.com](#)

an implantable naltrexone therapy for opioid and alcohol dependence, which is under cooperative development with the NIH and supported by multi-year federal grants. In March 2025, BioCorRx® Pharmaceuticals expanded its footprint in the addiction treatment landscape by acquiring LUCEMYRA®, a first and only FDA-approved, non-opioid therapy for opioid withdrawal, marking its first commercial-stage pharmaceutical product.

Behavioral Health and Digital Therapeutics Segment – This division includes the Beat Addiction Recovery Program, a non-addictive, medication-assisted treatment (MAT) model paired with proprietary cognitive behavioral therapy (CBT) and peer support. The company also operates the UnCraveRx® Weight Loss Program, a virtual, medication-assisted solution that integrates behavioral coaching with on-demand wellness services. These services are delivered through partnerships with healthcare providers, with the medical components independently prescribed by licensed practitioners.

Integrated Pipeline Strategy: Near-Term Commercialization with Long-Term Clinical Innovation Optionality

BioCorRx® has developed a diversified portfolio spanning FDA-approved commercial products, clinical-stage development candidates, and established treatment programs. The company's strategic approach combines immediate revenue generation through acquired assets with longer-term value creation through proprietary drug development, adding optionality for investors.

Product	Stage	Indication	Description	Status
LUCEMYRA® (lofexidine)	Commercial/ FDA Approved	Opioid withdrawal symptoms	First and only FDA- approved non-opioid for opioid withdrawal	Acquired March 2025, driving 9M revenues
BICX104	Phase I	Opioid & alcohol use disorders	Biodegradable naltrexone implant, 84- day duration	Phase I (OUD safety & PK) completed, Begin OUD Safety Assessment Study
BICX104	Phase 1b	Methamphetamine use disorder	Biodegradable naltrexone implant, 84- day duration	Begin Phase 1b
Beat Addiction Recovery	Commercial	Substance use disorders	CBT + peer support + medication program	Generating revenue from treatment centers
UnCraveRx®	Commercial	Weight loss	Medication-assisted weight loss program	Commercially available weight loss wellness program

Exhibit 2: BioCorRx® Product Pipeline. Source: Company Filings, Diamond Equity Research

LUCEMYRA® (lofexidine) represents the company's most significant near-term asset, acquired from USWM, LLC in March 2025. As the first and only FDA-approved non-opioid medication for mitigating opioid withdrawal symptoms, LUCEMYRA® addresses a critical need in addiction treatment. The acquisition immediately provided BioCorRx® with its first commercialized FDA-approved product and drove the substantial H1 2025 revenue increase. The product's established market position and proven efficacy provides a stable foundation for targeting revenue growth as the company scales its commercial operations.

BICX104 serves as the company's lead development candidate and represents a significant long-term potential value driver. This biodegradable naltrexone implant provides sustained drug release for approximately 84 days, offering three times the duration of currently marketed 28-day injection formulations. The Phase I clinical trial demonstrated encouraging safety and pharmacokinetic results, with therapeutic naltrexone levels maintained for a mean of 84 days and no serious adverse events reported.

Commercial programs include the **Beat Addiction Recovery Program** and **UnCraveRx®**, which generate immediate revenue while supporting the company's integrated treatment approach. The Beat Addiction Recovery Program combines cognitive behavioral therapy modules, peer support through mobile applications, and physician-prescribed medications. UnCraveRx® extends the company's platform into weight management, addressing the broader obesity epidemic through medication-assisted approaches.

LUCEMYRA® (Lofexidine): A Strategic Asset in BioCorRx®'s Addiction Treatment Portfolio

BioCorRx® completed the acquisition of LUCEMYRA® in March 2025 through its subsidiary BioCorRx® Pharmaceuticals Inc., under terms structured to minimize upfront capital requirements while providing ongoing financial benefits to both parties. Rather than a traditional upfront payment, the agreement stipulated that USWM, LLC would retain a portion of future sales up to a capped amount, with BioCorRx® Pharmaceuticals paying a low single-digit royalty to USWM, LLC. Additionally, USWM, LLC received shares of common stock and warrants from BioCorRx® Inc. as part of the transaction, aligning the former owner's interests with BioCorRx®'s future success. This structured approach allowed BioCorRx® to acquire an FDA-approved, revenue-generating asset without depleting its cash reserves, an important consideration given the company's status as a development-stage enterprise with limited liquidity.

In our view, LUCEMYRA® (lofexidine) represents a pivotal acquisition for BioCorRx®, positioning the company strategically within the growing opioid withdrawal treatment market, while providing immediate revenue generation and synergistic benefits across its addiction treatment portfolio. As the first and only non-opioid medication approved by the FDA specifically for mitigating opioid withdrawal symptoms, LUCEMYRA® addresses a critical unmet need in addiction treatment while complementing BioCorRx®'s development-stage naltrexone products. Furthermore, we note that the March 2025 acquisition from USWM, LLC has already delivered a substantial financial impact, with H1 2025 revenues increasing to \$313,137, representing a notable 3,985% increase compared to the same period in 2024.

BioCorRx® acquired LUCEMYRA® in March 2025 through a low-cash, royalty-based deal with USWM, LLC, gaining an FDA-approved, revenue-generating asset. The acquisition has already meaningfully increased H1 2025 revenue to \$313,137, while strengthening BioCorRx®'s position in the opioid withdrawal treatment market



Exhibit 3: Packaging and Bottle of LUCEMYRA® (Lofexidine) Tablets. Source: [LUCEMYRA.com](https://www.lucemyra.com)

Furthermore, beyond its immediate financial impact, the LUCEMYRA® acquisition holds significant strategic value for BioCorRx®'s overall business model and competitive positioning. The transaction provides BioCorRx® with its first FDA-approved, commercially available pharmaceutical product, transforming the company from a development-stage to a commercial-stage company with established market presence. This evolution substantially derisks the company's business model by providing near-term revenue generation, while its development-stage assets, particularly BICX104, continue advancing through the regulatory process. The acquisition also enhances BioCorRx®'s credibility within the addiction treatment space, demonstrating execution capability in building a comprehensive addiction treatment portfolio addressing multiple aspects of the recovery journey.

Historical Development and FDA Approval Timeline

LUCEMYRA®'s active ingredient, lofexidine hydrochloride, was initially studied in the 1980s as an antihypertensive medication but was subsequently repurposed for managing opioid withdrawal symptoms after researchers noted its effectiveness in this secondary application. The medication was first approved for treating opioid withdrawal in the United Kingdom in 1992, where it demonstrated clinical utility for over two decades before receiving FDA consideration in the United States. US WorldMeds LLC (USWM) acquired the rights to lofexidine and initiated the U.S. development program, recognizing the significant unmet need in the opioid crisis landscape. The compound's long history of international use provided valuable real-world evidence supporting its safety and efficacy profile prior to its FDA submission. The FDA approval of LUCEMYRA® was supported by two randomized, double-blind, placebo-controlled clinical trials³ enrolling 866 adults who were physically dependent on opioids. Study participants were evaluated using the Short Opiate Withdrawal Scale of Gossop (SOWS-Gossop), which assesses withdrawal symptoms based on patient-reported data across a range of physical and psychological manifestations. The trials demonstrated that LUCEMYRA® significantly reduced withdrawal symptom severity compared to placebo, with patients in the LUCEMYRA® group experiencing lower SOWS-Gossop scores and higher treatment completion rates. These

³ [U.S. FDA](https://www.fda.gov)

compelling results led to the drug receiving Priority Review designation from the FDA, reflecting the agency's recognition of the urgent need for non-opioid withdrawal management options.

LUCEMYRA® received historic FDA approval on May 16, 2018, becoming the first non-opioid medication specifically indicated for the mitigation of withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.⁴ The approval represented a significant milestone in addressing the opioid crisis, as withdrawal symptoms had long been recognized as one of the most powerful barriers preventing people from discontinuing opioids. Following approval, US WorldMeds partnered with Salix Pharmaceuticals (a division of Bausch Health) to enhance the market presence and commercialization efforts for LUCEMYRA®, with sales efforts targeting primary care physicians, pain management specialists, and addiction treatment centers. This strategic partnership expanded LUCEMYRA®'s reach within the healthcare community during its initial commercial phase between 2018 and its subsequent acquisition by BioCorRx® in 2025.

LUCEMYRA® Important Safety Information

LUCEMYRA is a non-opioid prescription medicine used in adults to help with the symptoms of opioid withdrawal that may happen when you stop taking an opioid suddenly. LUCEMYRA® will not completely prevent the symptoms of opioid withdrawal and is not a treatment for opioid use disorder.

LUCEMYRA® can cause serious side effects, including low blood pressure, slow heart rate, and fainting. Watch for symptoms of low blood pressure or heart rate, including dizziness, lightheadedness, or feeling faint at rest or when quickly standing up; if you experience these symptoms, call your healthcare provider right away and do not take your next dose of LUCEMYRA® until you have talked to your healthcare provider. Avoid becoming dehydrated or overheated and be careful not to stand up too suddenly from lying or sitting, as these may increase your risk of low blood pressure and fainting. When your treatment is complete, you will need to stop taking LUCEMYRA® gradually, or your blood pressure could increase. After a period of not using opioid drugs, you can become more sensitive to the effects of opioids if you start using them again. This may increase your risk of overdose and death. Before taking LUCEMYRA, tell your healthcare provider about all your medical conditions, including if you have low blood pressure, slow heart rate, any heart problems including history of heart attack or a condition called long QT syndrome, liver or kidney problems, or if you drink alcohol. Tell your healthcare provider if you are pregnant, plan on becoming pregnant, or are breastfeeding; it is not known if LUCEMYRA® can harm your unborn baby or whether LUCEMYRA passes into your breast milk. Especially tell your healthcare provider if you take benzodiazepines, barbiturates, tranquilizers, or sleeping pills, as taking these with LUCEMYRA can cause serious side effects. The most common side effects of LUCEMYRA® include low blood pressure or symptoms of low blood pressure such as lightheadedness, slow heart rate, dizziness, sleepiness, and dry mouth. To report SUSPECTED ADVERSE REACTIONS or product complaints, contact WorldMeds at 1-833-LUCEMYRA. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Click [here](#) to see full prescribing information.

⁴ clinicaltrialsarena.com

Clinical Profile, Mechanism of Action, and Demonstrated Safety and Efficacy

LUCEMYRA® functions as a selective alpha-2 adrenergic receptor agonist⁵, binding primarily to alpha-2A and alpha-2C receptors in the central nervous system with high affinity. The drug's therapeutic effect stems from its ability to reduce the release of norepinephrine, a neurotransmitter whose overactivity during opioid withdrawal drives many of the distressing physical and psychological symptoms. Long-term opioid use alters brain chemistry by suppressing norepinephrine production, and when opioids are suddenly discontinued, there is a surge in norepinephrine that triggers the withdrawal syndrome. LUCEMYRA® helps restore this neurochemical balance by activating alpha-2 receptors in the medulla oblongata, specifically within the lateral reticular nucleus, thereby moderating the sympathetic nervous system hyperactivity characteristic of

Clinical studies have shown that LUCEMYRA® effectively reduces a range of withdrawal symptoms, with the greatest improvements occurring on days 2 to 3 of treatment, when symptoms are typically at their peak severity

withdrawal. Clinical studies have demonstrated LUCEMYRA®'s efficacy in reducing multiple withdrawal symptoms, with the most significant improvements observed during days 2-3 of treatment when withdrawal symptoms typically peak in severity.

The medication does not completely eliminate withdrawal symptoms but substantially reduces their intensity, making the withdrawal process more tolerable and increasing the likelihood of successful opioid discontinuation. LUCEMYRA®'s safety profile is characterized by manageable adverse effects, with the most common being orthostatic hypotension, bradycardia, somnolence, sedation, and dry mouth. The incidence of hypotension is notably lower compared to clonidine (another alpha-2 agonist used off-label for withdrawal), which constitutes a key clinical advantage, particularly for outpatient management where blood pressure monitoring may be less frequent. The recommended starting dosage⁶ is three 0.18 mg tablets taken orally four times daily during the period of peak withdrawal symptoms (generally the first 5-7 days following last opioid use), with 5-6 hours between doses and treatment continuing for up to 14 days based on symptom severity. Dosage adjustments are recommended for patients with hepatic or renal impairment, with specific guidelines reducing the dose by 25-75%, depending on the degree of organ dysfunction.

LUCEMYRA® Uniquely Differentiates Itself in a Fast-Growing Opioid Withdrawal Treatment Market

The global opioid use disorder treatment market is projected to reach approximately \$10.24 billion by 2030, growing at a compound annual growth rate of 11.15%, driven by the persistent opioid crisis and expanding treatment infrastructure.⁷ Within this broader market, medications specifically targeting withdrawal management represent a critical segment addressing the initial phase of addiction treatment, with an estimated value of \$550 to \$650 million annually in the United States alone.⁸ The withdrawal management market has historically been dominated by methadone, buprenorphine, and off-label medications such as clonidine, with LUCEMYRA® representing a relatively new entrant with a differentiated non-opioid, FDA-approved profile. Market growth is supported by increasing government initiatives, expanding insurance

⁵ <https://pmc.ncbi.nlm.nih.gov/articles/PMC7377538/>

⁶ www.LUCEMYRA.com

⁷ Grand View Research

⁸ Verified Market Research

coverage for addiction treatment, and growing recognition of withdrawal management as a critical component of comprehensive addiction care.

Specialized Competitive Positioning as the Only FDA-Approved Non-Opioid Medication for Opioid Withdrawal

Within the withdrawal management landscape, LUCEMYRA® occupies a specialized niche as the only FDA-approved non-opioid medication specifically indicated for mitigating opioid withdrawal symptoms. The medication's primary competitors include off-label clonidine (another alpha-2 agonist), methadone taper protocols, buprenorphine induction, and various symptomatic treatments addressing specific withdrawal manifestations. LUCEMYRA®'s key competitive advantages include its FDA-approved status for withdrawal management, demonstrated efficacy in controlled clinical trials, and favorable safety profile compared to clonidine, particularly regarding hypotensive effects. However, the medication faces competitive challenges related to its premium pricing compared to generic alternatives, with LUCEMYRA® costing approximately \$1,800 for a seven-day treatment course compared to just \$10-100 for clonidine.

Attribute	LUCEMYRA® (lofexidine)	Clonidine
FDA Approval for Opioid Withdrawal	Yes (2018)	No (used off-label)
Mechanism of Action	Alpha-2 adrenergic agonist	Alpha-2 adrenergic agonist
Blood Pressure Effect	Mild to Moderate	Moderate to Severe
Sedation Level	Mild	Moderate
Typical Treatment Duration	7 – 14 days	7 – 14 days
Average Cost (7 days)	\$1,800	\$10 – 100
Insurance Coverage	Growing commercial coverage	Widely covered
Efficacy in Clinical Trials	Demonstrated efficacy in multiple controlled trials specifically for opioid withdrawal	Limited controlled trials specifically for opioid withdrawal
Safety Profile	Fewer hypotensive effects than clonidine; OT interval monitoring recommended	Great risk of significant hypotension; rebound hypertension upon discontinuation
Outpatient Suitability	Higher suitability due to lower hypotensive risk	Lower suitability due to hypotension risk

Exhibit 4: LUCEMYRA® vs. Clonidine Comparison for Opioid Withdrawal Management. Source: Diamond Equity Research

Several factors influence LUCEMYRA®'s market adoption trajectory, including prescriber awareness, reimbursement dynamics, and integration into withdrawal management protocols. The American Society of Addiction Medicine's 2020 National Practice Guideline specifically recommends lofexidine as the preferred alpha-2 agonist for outpatient withdrawal management due to its more favorable safety profile compared to clonidine.⁹ Market adoption is further supported by growing awareness of withdrawal as a critical barrier to addiction treatment and the recognition that non-opioid options may be preferable for certain patient populations. However, adoption barriers include the significant cost differential compared to generic alternatives, limited insurance coverage for some patients, and established prescriber habits favoring familiar medications. In our view, BioCorRx®'s acquisition presents an opportunity to address these barriers through targeted educational initiatives, expanded patient assistance programs, and integration with the company's existing addiction treatment infrastructure.

LUCEMYRA®'s Patient Access and Reimbursement Landscape

LUCEMYRA®'s price of approximately **\$1,800**¹⁰ for a supply of seven days represents a premium positioning within the opioid withdrawal medication landscape, substantially higher than non-FDA-approved alternatives such as clonidine. This pricing strategy reflects the medication's specialized FDA-approved status and demonstrated efficacy in controlled clinical trials, though it also creates potential access barriers for patients without adequate insurance coverage. Insurance coverage for LUCEMYRA® varies across plans, with many commercial insurers providing at least partial coverage, subject to prior authorization requirements and patient copayments. Government programs like Medicare Part D generally do not cover LUCEMYRA®, creating potential access challenges for this patient population. Medicaid coverage varies by state, with some programs including LUCEMYRA® on their preferred drug lists while others require prior authorization or step therapy protocols.

Following the acquisition, BioCorRx® has an opportunity to revisit and optimize LUCEMYRA®'s pricing and access strategy to align with the company's broader mission of expanding addiction treatment availability. Potential approaches could include enhanced patient assistance programs, innovative value-based contracting with payers, or strategic pricing adjustments based on competitive dynamics and patient population needs. BioCorRx®'s existing relationships with addiction treatment providers through its Beat Addiction Recovery Program could create synergistic opportunities to enhance LUCEMYRA® adoption within established treatment networks, potentially increasing patient access through integrated care models. Additionally, BioCorRx® may leverage data from real-world use to strengthen the medication's value proposition with payers, highlighting potential cost offsets through reduced hospitalization, emergency department visits, or improved recovery outcomes.

Strategic Growth Opportunities Can Broaden LUCEMYRA®'s Clinical and Commercial Impact

As BioCorRx® builds commercial momentum with LUCEMYRA®, we believe there are several forward-looking opportunities to expand its clinical relevance and market reach. These include developing new indications, pursuing international expansion, and leveraging digital health platforms to enhance patient access and outcomes.

⁹ [AAFP](#)

¹⁰ [AAFP](#)

Expanded Indications and Use Cases: LUCEMYRA®'s mechanism may support broader applications, such as withdrawal management from other substances, symptom-specific interventions, or adjunct use in tapering from methadone or buprenorphine.¹¹ Clinical expansion could unlock new market segments and strengthen its role across the addiction treatment spectrum.

International Market Expansion: LUCEMYRA® has commercial potential in opioid-impacted regions beyond the U.S., including Europe, Canada, Australia, and Asia.

Digital Health Integration: Integrating LUCEMYRA® with digital platforms, such as remote monitoring, telehealth services, or adherence-tracking apps, could enhance its therapeutic value. BioCorRx®'s existing digital tools from the Beat Addiction Recovery Program provide a ready framework to scale such services.

To summarise, the LUCEMYRA® acquisition positions BioCorRx® for significant near-term value creation through immediate revenue generation, operational synergies, and enhanced market positioning. Additional growth catalysts include potential expansion of LUCEMYRA®'s prescriber base, enhanced reimbursement coverage, and integration with BioCorRx®'s existing addiction treatment programs. The acquisition also strengthens BioCorRx®'s overall business profile, transforming the company from a development-stage to a commercial-stage company with established market presence and revenue generation. In our view, the evolution substantially derisks the company's investment profile while providing financial resources to support ongoing development programs.

BICX104: Next-Generation Naltrexone Implant Platform

BICX104 represents BioCorRx®'s lead development candidate, a biodegradable subcutaneous naltrexone implant designed to provide sustained drug release for approximately 84 days, specifically targeting both opioid use disorder and alcohol use disorder. The implantable pellet technology addresses one of the most significant challenges in addiction treatment: patient compliance with long-term medication regimens. Unlike existing naltrexone formulations that require daily oral administration or monthly injections, BICX104 eliminates the burden of frequent dosing through its innovative biodegradable platform that maintains therapeutic naltrexone levels for three months following a single implantation procedure.

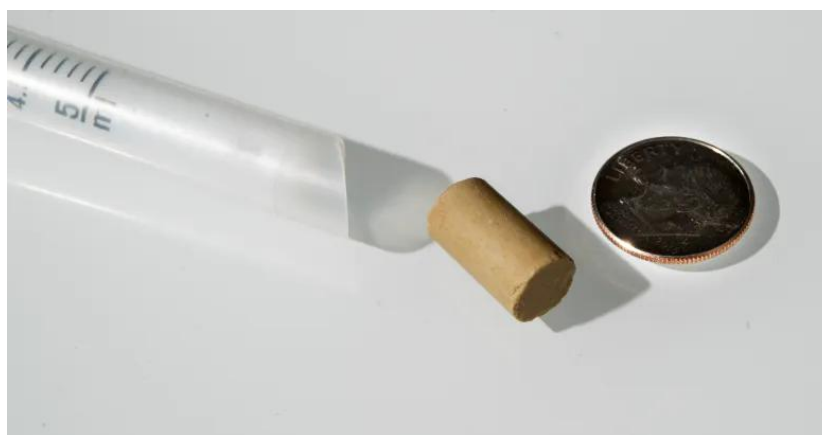


Exhibit 5: Representative Image of Naltrexone Implant. Source: Recovery Research Institute

¹¹ Urits I, Patel A, Zusman R, et al. Lofexidine for opioid withdrawal. *Psychopharmacol Bull.* 2020;50(3):76-96.

The development of BICX104 is being conducted under BioCorRx® Pharmaceuticals Inc., the company's majority-owned clinical-stage pharmaceutical subsidiary, with substantial support from the National Institute on Drug Abuse through the NIH HEAL Initiative. The program has received approximately \$19 million in non-dilutive federal funding, including a recent \$11 million grant specifically for investigating BICX104's potential in treating methamphetamine use disorder, either as a standalone therapy or in combination with bupropion.¹² This federal validation emphasizes the significant unmet medical need that BICX104 addresses and the program's scientific basis in combating the ongoing addiction crisis.

BICX104 utilizes a 505(b)(2) regulatory pathway, which allows the company to reference naltrexone's established 35-year safety profile, while focusing development efforts on demonstrating the implant's bioequivalence and delivery system performance. This strategic approach potentially reduces both development timelines and costs compared to traditional new drug applications, while enabling BioCorRx® to pursue dual indications for opioid use disorder and alcohol use disorder in a single regulatory submission. The company completed its Phase I clinical trial in March 2023, demonstrating that BICX104 was well-tolerated with no serious adverse events and provided therapeutic naltrexone levels for a mean of 84 days.

Advanced Technology Platform and Mechanism of Action

BICX104's technical design represents a significant advancement in sustained-release drug delivery technology, incorporating approximately 1,000 mg of naltrexone. The implant system is engineered to achieve complete biodegradation within 84 days post-implantation, eliminating the need for surgical removal while maintaining consistent therapeutic drug release throughout the treatment period.

Naltrexone functions as a pure opioid receptor antagonist, binding primarily to mu-opioid receptors with high affinity while also demonstrating activity at kappa and delta receptors to a lesser extent. The medication's mechanism involves blocking the euphoric effects associated with alcohol and opioid use, reducing cravings, and preventing the rewarding sensations that drive addictive behaviors. Unlike oral naltrexone, which suffers from poor bioavailability of only 5-40% due to extensive first-pass hepatic metabolism, the implantable delivery system provides sustained plasma concentrations that bypass hepatic metabolism and maintain therapeutic levels consistently.

The BICX104 implant procedure can be designed as a simple 15-minute outpatient procedure performed under local anesthesia, making it accessible in various clinical settings, including primary care practices and addiction treatment centers. The implant can be removed if narcotic pain relief becomes necessary due to injury or patient preference, providing flexibility that addresses physician and patient concerns about emergency medical situations. This removability feature distinguishes BICX104 from some competing implant technologies, while maintaining the compliance advantages of long-acting formulations.

BICX104 is a biodegradable, long-acting naltrexone implant delivering consistent therapeutic levels for up to 84 days, bypassing hepatic metabolism and eliminating the need for surgical removal. Designed for a simple outpatient procedure, it offers flexibility, clinical accessibility, and improved targeted compliance over oral or injectable alternatives

¹² [BioCorRx® News Release](#)

FDA 505(b)(2) Development Approach

BioCorRx® has strategically positioned BICX104 to leverage the FDA's 505(b)(2) regulatory pathway, which provides significant advantages for development companies by allowing reliance on existing safety and efficacy data for the active pharmaceutical ingredient.¹³ This pathway enables the company to reference naltrexone's established safety profile from over 35 years of clinical use across multiple formulations, potentially eliminating the need for extensive safety studies while focusing development efforts on demonstrating bioequivalence and delivery system performance. The FDA has indicated that they may rely on BioCorRx®'s proposed studies and existing data on BICX104 and its ingredients as the basis for 505(b)(2) approval, providing regulatory clarity that reduces development risk. The regulatory strategy includes the pursuit of dual indications for both opioid use disorder and alcohol use disorder within a single New Drug Application, leveraging naltrexone's established efficacy in both therapeutic areas. This approach maximizes the commercial opportunity while minimizing regulatory complexity, as both indications can be supported by the same bioequivalence data and safety profile. The company received FDA clearance for its Investigational New Drug application in May 2021, enabling progression to human clinical trials and validating the regulatory pathway.¹⁴

BioCorRx® is pursuing FDA approval for BICX104 via the 505(b)(2) pathway, leveraging naltrexone's established safety profile to reduce development time and risk while targeting dual indications for OUD and AUD

BICX104 can be a Potential Leader in Long-Acting Naltrexone Implants

The naltrexone market is dominated by Alkermes' Vivitrol®, an extended-release injection that generated projected net sales of \$457 million in 2024 and maintains a dominant position in the injectable naltrexone segment.¹⁵ Vivitrol®'s commercial success demonstrates strong market demand for extended-release naltrexone formulations, while its monthly injection requirement creates an opportunity for BICX104's three-month implant to capture market share through improved convenience and compliance. Alkermes' substantial commercial infrastructure and established prescriber relationships represent significant, competitive advantages, though the company's focus on monthly injections creates differentiation opportunities for implant-based approaches. The broader addiction treatment market includes competitors using different mechanisms of action, such as Indivior's buprenorphine-based products, including SUBLOCADE injections, and Orexo's ZUBSOLV sublingual formulations. These products serve somewhat different patient populations within the medication-assisted treatment spectrum, as buprenorphine functions as a partial opioid agonist compared to naltrexone's antagonist mechanism. Oral naltrexone represents approximately 56% of the naltrexone market but suffers from poor compliance rates that limit its clinical effectiveness. Studies comparing oral naltrexone to implant formulations consistently demonstrate superior abstinence rates and treatment retention for implant patients, with implant recipients showing much higher compliance with naltrexone therapy and attending more counseling sessions.¹⁶

¹³ [Grantome](#)

¹⁴ [BioSpace](#)

¹⁵ [Alkermes plc Press Release](#)

¹⁶ Colquhoun R et al. Oral vs. implant naltrexone outcomes at 12 months. J Opioid Manag. 2005;1(5):249–56.

Parameter	BICX104	Vivitrol®	Oral Naltrexone	Russian Naltrexone Implant
Duration of Action	84 days	28 days	24 hours	60-180 days
Dosing Frequency	Once every 3 months	Monthly injection	Daily pill	Variable
Administration Route	Subcutaneous Implant	Intramuscular injection	Oral tablet	Subcutaneous implant
Patient Compliance Mechanism	Passive (no patient action)	Monthly clinic visits	Daily adherence required	Passive
Peak Plasma Concentration (ng/ml)	19.91 ± 7.09	~15-20	~2-5	Variable
Removal Required	No (biodegradable)	N/A	N/A	No
FDA Approval Status	Phase I Complete	FDA Approved (2006)	FDA Approved (1984)	Russia only
Market Share	N/A (In development)	~34%	~56%	~10%

Exhibit 6: BICX104's Competitive Comparison. Source: Diamond Equity Research

The naltrexone implant segment represents a specialized but rapidly growing market niche, driven by increasing recognition of compliance advantages and expanding treatment access. BICX104's 84-day duration provides a significant competitive advantage over existing 28-day injection formulations, potentially capturing substantial market share through improved patient outcomes and reduced treatment burden.

First-Mover Advantages and Market Protection

BICX104's competitive positioning centers on its potential first-mover advantage in the 84-day naltrexone implant market, offering three times the therapeutic duration of market leader Vivitrol® while addressing key compliance challenges that limit existing treatment effectiveness. The company's intellectual property portfolio includes multiple pending patents covering implant design across the United States, Russia, and China, providing protection via formulation-specific patents.¹⁷

¹⁷ [BioCorRx® Press Release](#)

The regulatory strategy pursuing orphan drug designation for methamphetamine use disorder applications could provide additional market exclusivity and development incentives, particularly given the current

BICX104 offers a potential first-mover advantage in the naltrexone implant market, backed by strong IP protection and federal funding. With clinical validation, non-dilutive NIH support, and a growing \$19B addiction treatment market, BioCorRx® is well-positioned for durable competitive advantage and platform expansion

absence of approved medications for this indication.¹⁸ The NIH HEAL Initiative's substantial investment in BICX104 development provides federal validation of the technology's potential while reducing competitive threats from other development programs lacking similar government support. The company's platform technology approach creates defensive positioning, as successful development of BICX104 could establish foundational capabilities for rapid development of additional implant products across multiple therapeutic areas.¹⁹

The strategic positioning of BICX104 targets substantial market opportunities within the rapidly expanding drug addiction treatment market, which is projected to grow from \$18.6 billion in 2024 to \$36.8 billion by 2033 at a compound annual growth rate of 7.5%.²⁰ The US opioid use disorder treatment market specifically represents \$856.9 million in 2024 and is expected to reach \$1.75 billion by 2035, providing a large addressable market for BICX104's primary indication.²¹ In our view, BICX104 positions BioCorRx® as a potentially disruptive force in the \$19 billion drug addiction treatment market, with a potential first-mover advantage in extended-duration implant technology

supported by compelling clinical validation and substantial non-dilutive funding. The program's risk-reward profile appears favorable given successful Phase I proof-of-concept validation demonstrating 84-day efficacy and safety, capital efficiency achieved through a recent \$11 million in non-dilutive NIH funding, and strategic optionality for platform extension across methamphetamine use disorder and other addiction indications.

Commercial Programs: BEAT Addiction Recovery & UnCraveRx®

BioCorRx®'s B2B commercial programs represent the company's frontline engagement with providers, generating immediate revenue while supporting long-term pipeline development through real-world data collection and treatment ecosystem development. The BEAT Addiction Recovery Program and UnCraveRx® weight management platform collectively address substantial market opportunities across substance use disorders and obesity, leveraging proprietary behavioral health technologies and medication-assisted treatment protocols.

BEAT Addiction Recovery Program: Comprehensive Outpatient Treatment Ecosystem

The BEAT Addiction Recovery Program is BioCorRx®'s flagship commercial offering, combining three evidence-based treatment modalities in an integrated, intensive outpatient protocol designed to address both the physical and psychological aspects of addiction.

¹⁸ [BioCorRx® Press Release](#)

¹⁹ Song R et al. Biodegradable polymers for biomedical use. Drug Des Devel Ther. 2018;12:3117. doi:10.2147/DDDT.S165440

²⁰ [Custom Market Insights](#)

²¹ [Future Market Insights](#)

The program's foundation rests on medication-assisted treatment (MAT) utilizing FDA-approved medications, primarily naltrexone in various formulations, including oral, injectable, and implantable pellet forms, prescribed at the sole discretion of treating physicians in consultation with patients. This medication component addresses the neurobiological aspects of addiction by reducing cravings and blocking the euphoric effects of alcohol and opioids, providing patients with a physiological foundation for recovery.

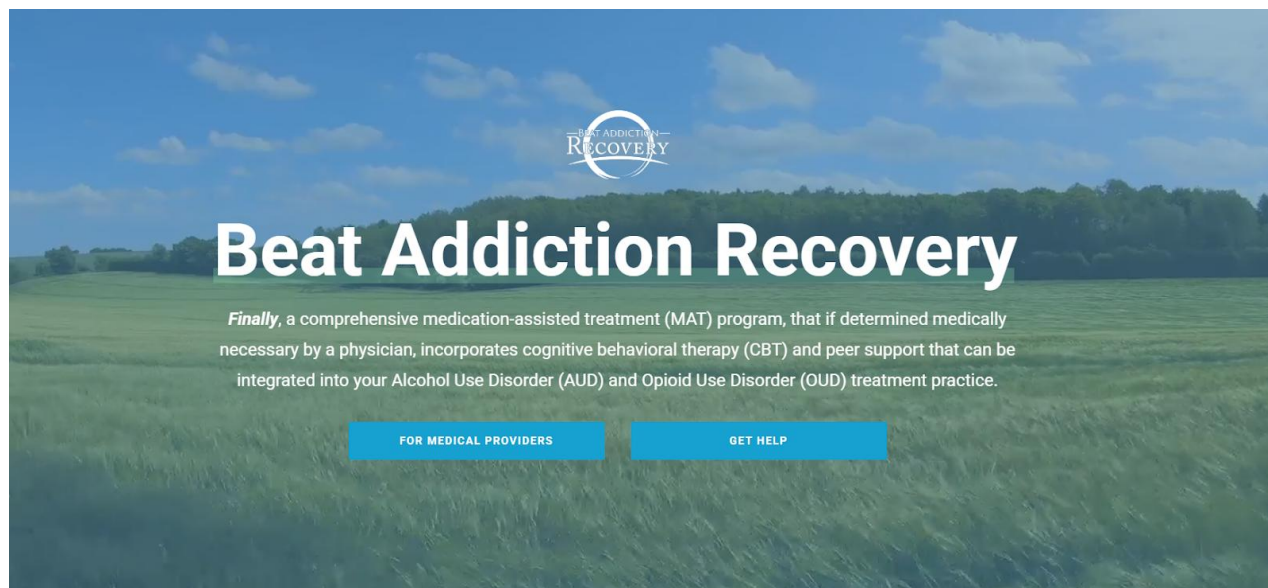


Exhibit 7: BEAT Addiction Recovery Program Landing Page. Source: beataddiction.com

The second core component consists of BioCorRx®'s proprietary cognitive behavioral therapy (CBT) modules specifically designed to address substance use disorders and prepare patients for sustained sobriety. These CBT protocols are delivered through a modular, tailored approach that can be customized to individual patient needs and addiction patterns, focusing on identifying triggers, developing coping strategies, and building long-term behavioral changes necessary for recovery. The program's behavioral component recognizes addiction as a complex condition requiring both pharmacological intervention and psychological support to achieve optimal outcomes.

The third element incorporates a peer recovery support mobile application that provides 24/7 access to recovery communities, counseling resources, and ongoing support throughout the treatment journey. This digital platform enables continuous engagement between formal treatment sessions while creating connections with peers who share similar recovery experiences, addressing the isolation and social disconnection often associated with addiction. The multi-tiered approach may result in lower patient dropout rates, possibly due to reduced cravings when physicians utilize anti-craving medications combined with comprehensive behavioral support.

Clinical Effectiveness and Patient Outcomes

The BEAT Addiction program's integrated approach addresses documented challenges in addiction treatment, where traditional methods often focus exclusively on behavioral interventions while underutilizing pharmacological solutions that address the neurobiological aspects of addiction.

BioCorRx® positions this medication-assisted approach as analogous to treating diabetes, where patients require both lifestyle modifications and appropriate medications to effectively manage their medical condition. This comprehensive approach recognizes addiction as a chronic medical condition requiring sustained intervention rather than acute treatment episodes. Program effectiveness is enhanced through the integration of multiple treatment modalities that address different aspects of the addiction process, from initial craving reduction through long-term relapse prevention. The proprietary CBT modules are designed to work synergistically with medication components, potentially improving treatment retention and outcomes compared to single-modality approaches.

The BEAT program combines medication-assisted treatment, proprietary CBT modules, and peer support to improve outcomes and retention in addiction care, recognizing addiction as a chronic condition requiring sustained intervention

The peer support mobile application component provides ongoing reinforcement and community connection that extends beyond formal treatment periods, addressing the chronic nature of addiction and the need for sustained support.

The program's discreet outpatient delivery model removes barriers to treatment access while minimizing disruptions to patients' daily lives, work schedules, and family responsibilities. This accessibility factor is particularly important given that over 75% of people with alcohol abuse or dependence currently go untreated, often due to concerns about stigma, cost, or treatment accessibility. The BEAT program's approach addresses these barriers while providing evidence-based treatment that combines the convenience of outpatient care with the comprehensive support necessary for sustained recovery.

UnCraveRx® Weight Management Platform: Pharmacobehavioral Approach to Obesity

UnCraveRx® represents BioCorRx®'s expansion into the obesity treatment market, utilizing the company's core expertise in medication-assisted therapies to address food cravings and compulsive eating behaviors. The program is designed as a comprehensive 3-month medically-assisted weight loss management system that combines sustained-release anti-craving medication with integrated digital health platforms providing nutritional coaching, fitness support, and lifestyle behavioral modification.

The therapeutic approach recognizes similarities between eating disorders and addictive conditions, particularly in terms of compulsive behaviors and difficulty controlling intake, making naltrexone's anti-craving properties applicable to weight management.

The digital platform provides 12 weeks of 24/7 access to virtual lifestyle, fitness, and nutrition support through an easy-to-navigate mobile application. Program participants receive personalized nutrition plans, fitness class access covering various exercise styles, and behavioral lifestyle group support designed to create sustainable healthy habits rather than temporary dietary changes. The virtual platform includes tools for tracking calorie intake and expenditure, physical activity monitoring, and progress measurement, providing comprehensive support for behavioral modification and lifestyle change.

BICX104 and Outpatient MAT Strategy Unlock Long-Term Value in Addiction and Behavioral Health Markets

At its core, BioCorRx® Inc. addresses the unmet needs of individuals facing behavioral health challenges, particularly those struggling with substance use disorders, weight management issues, and withdrawal-related complications. The company's primary target market consists of adults in the United States dealing with opioid and alcohol disorders, a population often underserved by traditional systems and constrained by stigma, limited access to care, and high relapse rates. Approximately 28.9 million Americans aged 12 and above suffered from Alcohol Use Disorder (AUD), yet less than 2% receive any form of medication-assisted treatment.²² Excessive alcohol use contributes to about 178,000 deaths annually and leads to nearly 4 million years of potential life lost.²³ Meanwhile, an estimated 9.4 million adults required treatment for Opioid Use Disorder, but only 25% could access comprehensive medication-assisted therapy (MAT).²⁴ Although opioid-involved overdose deaths declined to 54,743 in 2024 from a peak of 83,140 in 2023, the situation still remains alarmingly severe, with opioid misuse still representing an ongoing and pressing public health crisis, highlighting the urgent need for expanded and improved treatment strategies.

Moreover, the recent proposed federal budget cuts to critical public initiatives, including naloxone distribution and addiction treatment infrastructure, risk undermining any recent progress and exacerbating the ongoing crisis, underscoring the need for continued urgency and resource allocation to address OUD comprehensively.²⁵ The economic impact of these conditions remains substantial, with excessive alcohol use costing the U.S. economy an estimated \$249 billion annually.²⁶ In comparison, the opioid epidemic accounted for a financial burden of nearly \$1.5 trillion in 2020, rising to approximately \$2.7 trillion by 2023.²⁷ Additionally, relapse remains a significant challenge, with up to 60% of individuals relapsing within the first year post-treatment for both AUD and OUD, underlining critical shortcomings in existing interventions and highlighting the urgent need for enhanced treatment approaches, better pain management, and innovative care models.²⁸ These figures reflect the scale of public health challenges and reinforce the relevance of BioCorRx®'s therapeutics offerings within these critical markets.

BioCorRx® addresses critical gaps in addiction treatment, targeting over 28.9 million Americans with alcohol use disorder and 9.4 million needing opioid use disorder care. With addiction costing the U.S. trillions of dollars annually and relapse rates up to 60%, BioCorRx® seeks to provide solutions for an underserved

²² [National Institute on Alcohol Abuse and Alcoholism](#)

²³ [CDC.gov](#)

²⁴ [CDC.gov](#)

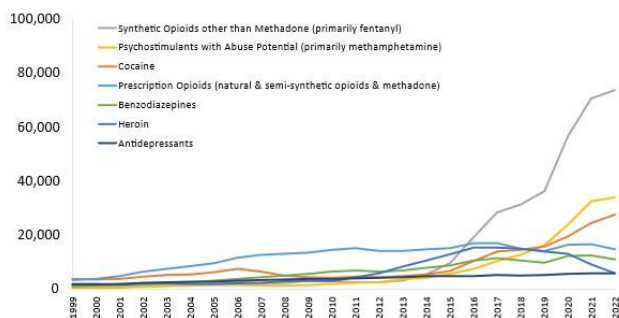
²⁵ [American Addiction Centers](#)

²⁶ [National Institute on Alcohol Abuse and Alcoholism](#)

²⁷ [Congress Joint Economic Committee](#)

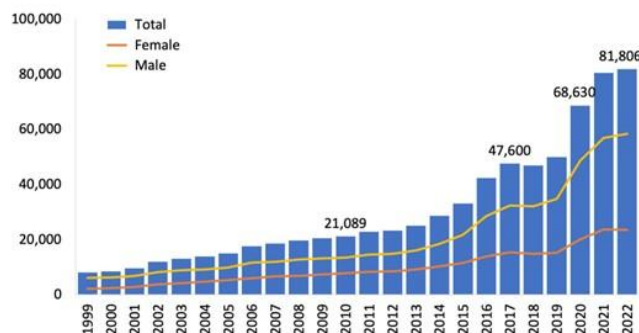
²⁸ [National Institute on Drug Abuse](#)

Figure 2. U.S. Overdose Deaths*, Select Drugs or Drug Categories, 1999-2022



*Includes deaths with underlying causes of unintentional drug poisoning (X400-44), suicide drug poisoning (X60-X64), homicide drug poisoning (X85), or drug poisoning of undetermined intent (Y40-Y44), as coded in the International Classification of Diseases, 10th Revision. Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2022 on CDC WONDER Online Database, released 4/2024.

Figure 3. U.S. Overdose Deaths Involving Any Opioid* by Sex, 1999-2022



*Among deaths with drug overdose as the underlying cause, the "any opioid" subcategory was determined by the following ICD-10 multiple cause-of-death codes: natural and semi-synthetic opioids (T40.2), methadone (T40.3), other synthetic opioids (other than methadone) (T40.4), or heroin (T40.1). Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2022 on CDC WONDER Online Database, released 4/2024.

Exhibit 8: U.S. Overdose Deaths. Source: American Psychiatric Association

U.S. Medication-Assisted Treatment (MAT) Market: Expanding Amid Policy Reforms and Underserved Demand

Medication-Assisted Treatment (MAT) is an evidence-based approach to treating substance use disorders through the combination of FDA-approved medications with counseling and behavioral therapies. MAT aims to stabilize brain chemistry, reduce cravings and withdrawal symptoms, block the euphoric effects of drugs or alcohol, and support long-term recovery. Unlike abstinence-only approaches, MAT is clinically proven to reduce relapse, improve treatment retention, and lower overdose mortality. Recovery success rates for individuals undergoing MAT frequently exceed 60%, far surpassing the 5-15% rates observed in medication-free detoxification approaches.²⁹ Treatment retention is also significantly higher, with one real-world trial showing average retention of 438 days on MAT versus 174 days in abstinence-only programs.³⁰ These outcomes emphasize MAT's potential clinical superiority and cost-effectiveness as a public health intervention.

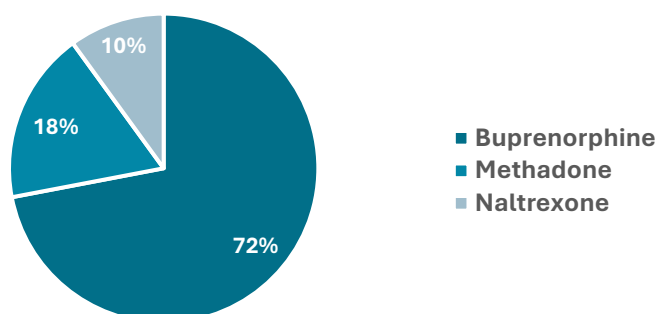


Exhibit 9: U.S. Overdose Deaths. Source: American Psychiatric Association

²⁹ [Colorado Department of Human Services](#)

³⁰ [JON Recovery Center](#)

The global Medication-Assisted Treatment (MAT) market is a rapidly growing segment within the substance abuse treatment landscape. As of 2021, it was valued at approximately \$8.19 billion and is estimated to grow at a Compound Annual Growth Rate (CAGR) of 9.4% from 2022 to 2029.³¹ The North American market alone is expected to reach \$8.84 billion by 2029, growing at a CAGR of 9.7%.³¹ The U.S. medication-assisted treatment (MAT) market is anchored by three FDA-approved medications, buprenorphine, methadone, and naltrexone, each with distinct delivery models, reimbursement challenges, and regulatory oversight. Approximately 60% of MAT revenue is generated by buprenorphine-based therapies, driven by office-based flexibility and relaxed prescribing rules, especially after the 2023 elimination of the federal X-waiver requirement.³²

Methadone, although clinically effective, remains tightly regulated, with dispensing restricted to certified opioid treatment programs (OTPs). However, recent federal reforms now allow up to 28-day take-home doses for stable patients, a significant shift from pre-pandemic rules and a potential inflection point in expanding access. Extended-release naltrexone, particularly the extended-release injectable form (Vivitrol®), is valued for its non-opioid profile but sees constrained uptake due to high costs and adherence challenges. Medicaid finances about 40% of all MAT treatments, yet access remains uneven across states due to variable prior authorization policies and pharmacy availability.

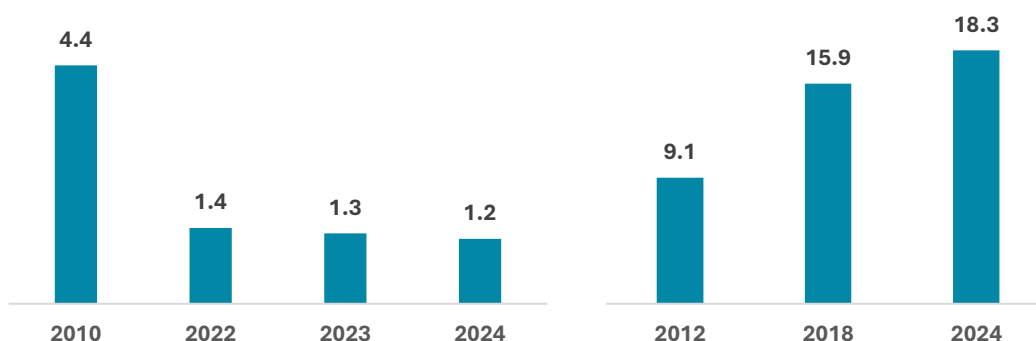


Exhibit 10: Methadone (left) and Buprenorphine (right) Prescriptions (in millions). Data Source: IQVIA National Prescription Audit™, Diamond Equity Research

Despite these structural challenges, the U.S. MAT market is transitioning toward more patient-centric, decentralized care models, strengthened by telehealth expansion, payer reform, and rising investment in long-acting formulation, positioning it for sustained growth and greater integration into mainstream behavioral healthcare. Nationwide networks such as BayMark Health Services, CleanSlate Centers, Pinnacle Treatment Centers, and Acadia Healthcare operate outpatient MAT clinics, while digital-first platforms like Bicycle Health and Workit Health are pioneering virtual MAT delivery models, contributing to broader access and innovation.

Naltrexone Market: BICX104's Market Positioning, Generic Penetration, and Competitive Pressures

Naltrexone is an FDA-approved opioid receptor antagonist indicated for the treatment of opioid use disorder (OUD) and alcohol use disorder (AUD). Unlike opioid agonist therapies such as methadone and

³¹ [Data Market Research](#)

³² [Global Growth Insights](#)

buprenorphine, naltrexone exerts its therapeutic effect by competitively inhibiting opioid receptors, thereby blocking the euphoric and reinforcing effects of opioids and alcohol without activating the receptors themselves. It is non-addictive, non-scheduled by the DEA, and lacks abuse potential, characteristics that make it an appealing therapeutic option in criminal justice systems, abstinence-based programs, and primary care settings seeking non-opioid pharmacologic alternatives. However, despite these pharmacological advantages, its widespread applicability remains limited due to the complete detox requirement before treatment initiation, which creates a significant barrier to timely treatment, especially in acute care settings or early recovery phases. Moreover, naltrexone does not relieve opioid withdrawal symptoms, reducing its effectiveness in early-stage treatment when physiological dependence is high. Comparative studies have consistently shown that buprenorphine leads to superior outcomes in treatment retention and relapse prevention, making it the preferred agent in most MAT protocols.³³ As a result, while naltrexone serves a valuable role in specific populations, particularly those who are already detoxified and seeking abstinence-based approaches, its overall market penetration remains modest relative to opioid agonist therapies. Aside from its pharmacokinetic properties, structural and systemic barriers further impede the broader clinical adoption of naltrexone. A 2022 survey of 770 prescribers across internal medicine, family medicine, and psychiatry departments revealed substantial challenges to its routine use.³⁴ Only 23.3% of respondents reported prescribing naltrexone within the previous three months, underscoring its limited integration into everyday clinical practice. The predominant barrier cited by 52.8% of non-prescribers was unfamiliarity with naltrexone as a treatment option for alcohol use disorder (AUD), highlighting a persistent gap in provider education and awareness. These findings reflect a considerable potential for improvement through focused educational initiatives, clinical training, and systemic support aimed at increasing the use of naltrexone in routine practice.

Brand Name	Generic Name	Indication	Dosage Form	Patient Status	Est. Annual Revenue (USD)
Vivitrol®	Extended-release Naltrexone	AUD, OUD	Monthly IM injection	Patent expiry ~ 2029 (U.S.)	~\$457 million (2024)
Sublocade	Buprenorphine (XR injection)	OUD	Monthly SC injection	Key patents to ~ 2030	~\$756 million (2024)
Brixadi	Buprenorphine XR (weekly/monthly)	OUD	Weekly & monthly SC injection	Patented; launched 2023 (U.S.)	~\$22.27 million (2024)
Suboxone	Buprenorphine + Naloxone	OUD	Sublingual film	Patent expired - 2023	n.a.

Exhibit 11: Select Patented OUD/AUD Drugs Annual Revenue. Source: Company Filings, Diamond Equity Research

*Camurus receives mid-teen percent royalties on Brixadi sales in North America

³³ Lee JD et al. XR-naltrexone vs. buprenorphine for opioid relapse. Lancet. 2018;391:309–18.

³⁴ Leung JG et al. Barriers to naltrexone for AUD. Front Psychiatry. 2022;13:856938.

Naltrexone is available in two primary forms, oral tablets (generic, 50 mg daily) and extended-release injectable naltrexone (Vivitrol®). However, clinical use is often challenged by adherence issues with oral formulations and the high cost and logistical burdens of injectables. The introduction of BICX104 aims to fill the gap between low-cost oral generics and high-cost injectables. Designed to last up to 90 days, BICX104 is a biodegradable pellet composed almost entirely of naltrexone, requiring only a brief outpatient procedure under local anesthesia for insertion, with no removal required. BICX104's unique value proposition lies in its improved adherence profile, non-injectable nature, and potential for cost-effectiveness. In terms of market dynamics, general oral naltrexone remains dominant in terms of prescription volume but weak in terms of long-term retention. Vivitrol®, despite commanding over \$450 million in annual revenue, is constrained by delivery, adherence, and convenience. Meanwhile, buprenorphine and methadone continue to dominate MAT in terms of efficacy and patient volume, but both are opioid-based and controlled substances, thus limiting their suitability in abstinence-based programs or correctional systems. BICX104 enters this landscape with the potential to establish a new treatment modality, a long-acting, non-opioid, office-based MAT with minimal compliance burden and broader accessibility.

BICX104's distinction to Vivitrol® is in its terms of ease of administration, patient compliance, and long-term adherence. Its subcutaneous, biodegradable implant design eliminates the need for monthly clinic visits, offering a more convenient and sustained delivery mechanism. If BioCorRx® can strategically price BICX104 to reflect its differentiated value, while maintaining commercial viability, the product could capture a meaningful share of the OUD niche, particularly in criminal justice programs, drug courts, and abstinence-focused treatment settings where Vivitrol® has historically been strong. However, BICX104's pricing power may face headwinds as the competitive landscape evolves. Vivitrol®'s patent expiration in 2029, coupled with anticipated early generic entry from Teva by 2027, could lead to price erosion in the extended-release naltrexone space. To sustain its competitive edge, BICX104 will need to demonstrate clear clinical and economic advantages while targeting segments where convenience, adherence, and continuity of care are prioritized over price alone.

Appendix

Income Statement	FY2023 A	FY2024 A	FY2025 E	FY2026 E	FY2027 E
Net sales	89,160.0	7,665.0	1,652,001.1	2,978,721.7	3,303,422.0
Cost of sales	(35,986.0)	(1,667.0)	(660,800.4)	(1,135,060.1)	(1,009,459.7)
Gross profit	53,174.0	5,998.0	991,200.7	1,843,661.7	2,293,962.4
Operating expenses					
Research & development expense	(891,063.0)	(1,482,877.0)	(2,224,315.5)	(3,892,552.1)	(4,087,179.7)
Selling, general and administrative	(2,875,119.0)	(3,612,481.0)	(4,515,601.3)	(4,967,161.4)	(5,215,519.4)
Depreciation and amortization	(26,808.0)	(33,145.0)	(221,643.2)	(36,250.7)	(43,318.1)
Income from Operations	(3,739,816.0)	(5,122,505.0)	(5,970,359.2)	(7,052,302.6)	(7,052,054.9)
Interest expense - related parties	(692,586.0)	(750,773.0)	(750,308.3)	(750,308.3)	(750,308.3)
Interest expense, net	(194,041.0)	(776,780.0)	(771,890.7)	(771,890.7)	(771,890.7)
Loss on settlement of debt	(34,338.0)	(164,602.0)	(187,514.0)	-	-
Grant income	932,996.0	1,473,276.0	1,620,603.6	1,458,543.2	1,385,616.1
Other miscellaneous income	5,275.0	129,282.0	685,901.0	-	-
Profit before exceptional items, extraordinary items and tax	(3,722,510.0)	(5,212,102.0)	(5,373,567.7)	(7,115,958.3)	(7,188,637.9)
Impairment of intellectual property	(47,980.0)	-	-	-	-
Employee separation cost	-	-	-	-	-
Profit before tax from continuing operations	(3,770,490.0)	(5,212,102.0)	(5,373,567.7)	(7,115,958.3)	(7,188,637.9)
Income tax (expense) benefit	-	-	-	-	-
Net earnings including noncontrolling interests	(3,770,490.0)	(5,212,102.0)	(5,373,567.7)	(7,115,958.3)	(7,188,637.9)

Exhibit 12: Income Statement Snapshot.
Source: Diamond Equity Research

Risk Profile

BioCorRx® Inc. operates in a complex and capital-intensive segment of the healthcare industry. As a clinical-stage company with limited revenue history, it faces several operational and financial risks that investors should carefully consider.

- **Going Concern Uncertainty and History of Operating Losses:** BioCorRx®'s independent auditors have issued a “going concern” opinion, reflecting doubt about the company’s ability to sustain operations without additional funding. As of the FY 2024, BioCorRx® reported an operating loss and negative cash flows from operations exceeding \$1 million. While management has outlined plans to secure funding and reduce expenses, there is no assurance these efforts will enable sustainable or profitable operations.
- **Uncertain Market Acceptance of Products and Programs:** The success of BioCorRx®'s treatment programs and pharmaceutical products hinges on acceptance by physicians, hospitals, and third-party payors. Even with regulatory approval, factors such as perceived efficacy, pricing competitiveness, patient willingness, and marketing strength will heavily influence adoption.
- **Limited Provider Adoption May Hinder Commercial Growth:** As of March 2025, only a small number of licensed providers have agreed to offer BioCorRx®'s BEAT programs. Broader adoption is essential for market traction, and provider hesitation due to a lack of peer endorsements or insurance reimbursement could delay patient uptake and limit revenue potential.
- **Dependence on Government Grants Poses Revenue Sustainability Risk:** A significant portion of BioCorRx®'s non-operating income comes from government grants, including a multi-year \$11 million award from NIDA supporting BICX104 development. If such funding is reduced, delayed, or discontinued due to policy shifts or unmet grant conditions, the company’s ability to fund R&D activities and maintain financial stability could be materially affected.
- **Regulatory, Development, and Competition Risks Surround the BICX104 Program:** Despite promising Phase I results and a pending FDA Fast Track application, clinical development inherently carries risks related to safety, efficacy, and regulatory delays that could significantly impact valuation. The 505(b)(2) pathway, while potentially expedited, still demands substantial clinical data and FDA approval. Additionally, competition from established naltrexone products and emerging entrants may limit the program’s market potential.
- **Low Stock Price and Penny Stock Status May Impede Capital Access:** BioCorRx®'s relatively low share price and historical classification as a “penny stock” pose challenges to raising capital and maintaining liquidity. Declines in stock price can deter new investment, limit broker-dealer participation due to regulatory restrictions, and negatively impact the company’s ability to finance operations through equity sales, potentially jeopardizing ongoing development efforts and business continuity.

This list of risk factors is not comprehensive. For a full list, please refer to BioCorRx® Inc.'s latest prospectus and/or annual filings.

Disclosures

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