

Zacks Small-Cap Research

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BioCorRx Inc

(BICX-OTCQCB)

BICX: New grant, patent filed

Our \$5.65 valuation for BioCorRx uses a sum-of-products NPV, less corporate overhead and a 15% discount rate. We've modeled for \$20 million of equity funding and \$10 million in research grants through 2024.

Current Price (09/24/21)	\$3.53
Valuation	\$5.65

OUTLOOK

BioCorRx, Inc. is at an early point in front of a vast market opportunity for medication assisted treatment (MAT) of opioid and alcohol use disorders. In September, the Company received a \$3.5 million grant to support further development and clinical trials of its subcutaneous pellet of naltrexone (BICX104). Trials are expected to commence later this year. While it may be 2024-25 to see significant revenues from its BICX104 development efforts, we believe that the Company is on the right long-term path for sustainable growth.

SUMMARY DATA

52-Week High	\$6.00	Risk Level	High,
52-Week Low	\$0.84	Type of Stock	N/A
One-Year Return (%)	82.20	Industry	Medical Service
Beta	1.05	Zacks Rank in Industry	N/A
Average Daily Volume (sh)	2,439		
Shares Outstanding (mil)	7	ZACKS ESTIMATES	
Market Capitalization (\$mil)	\$23	Revenue	
Short Interest Ratio (days)	N/A	(in thousands of \$)	
Institutional Ownership (%)	0	Q1	Q4
Insider Ownership (%)	21	(Mar)	Year
Annual Cash Dividend	\$0.00	2019	240.3 A
Dividend Yield (%)	0.00	2020	122.6 A
5-Yr. Historical Growth Rates		2021	188 E
Sales (%)	-37.0	2022	403 E
Earnings Per Share (%)	N/A	Earnings per share	
Dividend (%)	N/A	Q1	Q4
P/E using TTM EPS	N/A	(Mar)	Year
P/E using 2021 Estimate	-6.1	2019	-\$1.71 A
P/E using 2022 Estimate	-3.8	2020	-\$0.65 A
Zacks Rank	N/A	2021	-\$0.57 E
		2022	-\$0.92 E
			Zacks Projected EPS Growth Rate - Next 5 Years %
			N/A

COMPANY UPDATE

Since receiving US FDA IND approval for its subcutaneous naltrexone pellet, BICX104, for the treatment of opioid and alcohol use disorders, in May 2021, BioCorRx continues to move forward towards initiating clinical trials before the end of this year. September was particularly newsworthy, with BioCorRx receiving a new grant, filing a US patent and expanding its manufacturing arrangement.

BioCorRx, Inc. develops and markets medication-assisted treatment and behavioral therapy programs to treat opioid use disorder (OUD), alcohol use disorder (AUD), and weight-management. The Company's offerings combine proprietary cognitive-behavioral-therapy (CBT) and peer support with medications (primarily naltrexone) prescribed by a physician which can enable them to provide customizable solutions to their patients. BioCorRx has sold its *Beat Addiction Recovery* program for OUD and AUD since 2010.

On September 1, BioCorRx received a \$3.5 million grant from the National Institute on Drug Abuse (NIDA) to help fund its first clinical trial for BICX104. The new funding is in addition to two grants of \$2.8 million each received in 2019 and 2020. On September 22, BioCorRx announced it filed a patent application with the U.S. Patent and Trademark Office (USPTO) for a biodegradable implant including naltrexone.

BioCorRx is seeking approval for its subcutaneous naltrexone pellet (BICX104) for the treatment of opioid use (OUD) and alcohol use (AUD) disorders under the US FDA 505(b)(2) pathway. The upcoming clinical trial focuses on local safety and pharmacokinetics of BICX104. The phase 1, six-month open label trial will enroll 24 healthy volunteers. ([A Randomized, Open Label, Single Dose Pharmacokinetic and Safety Study of Implantable Long Acting 3-month Naltrexone Subcutaneous Pellets Compared to Naltrexone IM Injection \(Vivitrol\) in Healthy Volunteers](#)). Patients in the experimental arm will receive a single BICX104, subcutaneous naltrexone implant and monitored for 84 days. Patients in the active comparator arm will receive Vivitrol intramuscular injection containing 380 mg of naltrexone. Three consecutive doses will be administered once every 28 days for 84 days.

The trial will compare patients in both arms on pharmacokinetic parameters (drug and plasma levels of naltrexone over time) and safety (primarily incidence and severity of adverse events related to implantation).

On September 8, BioCorRx expanded its agreement with Recro Pharma (REPH – NASDAQ), to manufacture and validate batches of BICX104 for use in the clinical trials and approval process. The next step is to sign a clinical research organization (CRO) to oversee the trial. Management expects to complete that decision soon. Along with BioCorRx, Recro and the CRO will establish timelines for starting the trial. If all goes according to plan, the goal is to dose the first patient before the end of 2021 and submit its NDA application for approval in 2022.

BioCorRx will devote the next few years to seeking approval for BICX104, working to gain payer reimbursement for its addiction treatment program and building out sales of *UnCraveRx*, for weight management. During the next two years, we expect catalysts to come from several areas:

- Clinical milestones for BICX104 and progress towards filing for FDA approval.
- Public health and policymaker actions to educate the public and providers on the benefits of MAT.
- Expanded access to MAT in office-based settings.
- Fewer hurdles to insurance reimbursement for MAT in both private and public payer programs.

Our model is based on the BICX104 implant, addiction recovery program, and *UnCraveRx* weight management program in the US market. For 2024, we forecast product sales of \$3.9 million. We've modeled BICX104 product sales at \$57 million and *UnCraveRx* sales of \$7-8 million by 2031.

We assume a 2023 launch for BICX104 with an average product price of \$4,500. Our model includes 1% annual growth in patients treated for OUD, 4% growth in patients receiving MAT and 7-10% annual growth in patients receiving naltrexone through 2031. For now, we use a 10% naltrexone market share for BICX104 by 2031 to allow for competition. Our estimates use an 80% product gross margin after royalties and 35% operating margins before corporate overhead. Our model uses a 15% discount rate on assumptions, risk-adjusted to 75% for clinical risk.

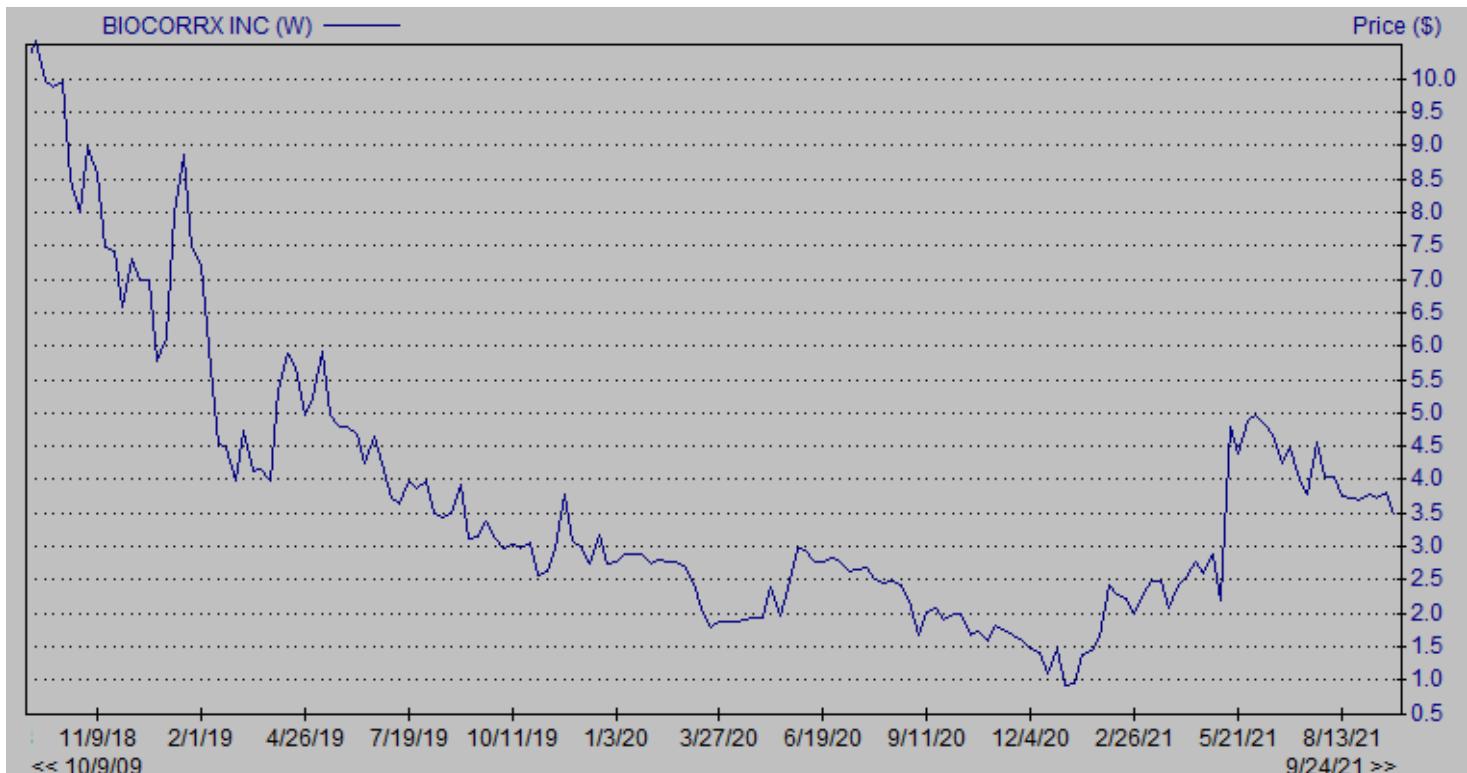
We assume that BioCorRx retains sales and marketing function and outsources manufacturing and distribution. Under this scenario results in an estimated gross profit margin of 80% and 45% operating margin (before corporate overhead) and mid-30s operating margin with corporate G&A in 2031 across all the businesses.

Factors that we believe may affect forecasts, results and valuation over the next several years include: regulatory and developmental, commercialization, competition, reimbursement and financing needs. Policymakers are focused on expanding types of MAT and accessibility, while lowering the hurdles that have limited broad clinical adoption for all types of MAT. While results will likely remain volatile for a few years as the Company invests in regulatory approval for its naltrexone implant for OUD and AUD, we expect this to stabilize as the business grows.

Our intrinsic value for BICX of \$5.65/share is based on an NPV for an FDA-approved naltrexone implant for OUD and AUD, the Company's addiction recovery program, and the *UnCraveRx* program for weight management. Our model assumes BICX carries all R&D costs through approval (estimated range of \$12-15 million) partially offset by research grants of nearly \$10 million through 2023.

Several factors provide upside to our valuation including: additional research funding beyond our \$10 million assumption, partnership that provides milestones and/or R&D cost sharing; a faster, or less-costly path to US approval; and the potential for sales in other geographies and indications as well as the possibility of additional approvals.

HISTORICAL STOCK PRICE



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