

ICVrx, INC.

Private Company

Dan Abrams, M.D. Chief Executive Officer

www.icvrx.com

Healthcare – Drug Delivery

Highlights

- ▶ **\$3.9 billion combined market potential in three underserved initial target markets**
- ▶ **Unique drug/pump intellectual property serving high need patient populations**
- ▶ **4 drugs currently in IP pipeline for treatment of refractory epilepsy and depression Future pipeline: anxiety, PTSD, and brain cancer**
- ▶ **High-margin licensing revenue model**
- ▶ **Low risk development model:**
 - Requires less time to establish clinical utility AND generate revenue;
 - Requires less capital;
 - Employs *already-approved* drugs and devices;
 - Method of drug delivery is related to direct delivery to spine, which has been proven, safe, and effective;
 - Neurosurgeons already trained in implant procedure;
 - Reformulated drugs are State-regulated, not FDA regulated, reducing regulatory expenses and time.
- ▶ **Compounding pharmacies provide \$5 billion in off-label reformulations: perfect partners for distribution**

Financing

Founded in 2010, ICVrx builds on the intellectual property, under development for four years and purchased from Sierra Neuropharmaceuticals. Aggregate equity financing in ICVrx to date is approximately \$4.5 million.

*ICVrx is a clinical stage drug company focused on therapeutics for serious brain disorders. Using a combination of already approved pumps and off-patent drugs with administration directly to the brain, site specific drug therapy addresses targets key limitations of oral medications to improve patient lives. ICVrx represents a low-risk, high-return strategy for more effective treatment of patients currently underserved with existing drugs and conventional modes of administration. ICVrx has conducted preclinical work, has pump suppliers and compounding pharmacy distribution in place, and begins human clinical trials for its *Epilepsy Therapy in 2H11*. The company's unique drug/pump combination targets unmet needs in large markets with highly motivated patients and doctors given the few effective treatment options.*

ICVrx's mission is to improve treatment and outcomes for refractory CNS and systemic disease patients by enabling for selective brain administration of precise amounts of liquid drug formulations via implantable pumps for an extended period of time. The Company is creating a new treatment category for debilitating brain diseases by reformulating drugs for direct to brain delivery. This treatment strategy – site-specific delivery to the central nervous system – has already been **proven, safe, and effective** for neurological diseases in the spine.

Business Strategy

ICVrx's business strategy distinguishes it from traditional R&D pharmaceutical companies with its low-risk drug reformulation/compounding pharmacy approach, reducing costs and time-to-market.

ICVrx's business strategy is to deliver proprietary aqueous formulations of FDA-approved drugs via licensing agreements with compounding pharmacies. With its use of reformulated drugs and approved medical devices for their delivery, the company is able to rapidly progress in human clinical trials, significantly reducing the capital, risks, and time-to-market required for high-margin revenue generation. As with other reformulated FDA-approved drugs used in pump-based spinal delivery, management believes the Company's products will not require FDA approval. Human clinical trials will be undertaken to establish efficacy, safety and dosing ICVrx's product licensing strategy creates a partnership with compounding pharmacies, dramatically lowering marketing costs, shortening time to profitability, and lowering regulatory expenses and time. Compounding pharmacies will develop relationships with treating physicians for sales using their sales targeted sales force. The company is initially targeting medically refractory epilepsy, a large underserved market in need of effective treatment options.

Target Markets

ICVrx has four drug products covering two different diseases identified for development with a combined \$3.9 billion in market potential.

- **Refractory Epilepsy (\$2.4B market potential; 3 drugs)**
- **Refractory Depression (\$1.5B potential; 1 drug)**

Additional development candidates:

- Post-traumatic stress disorder (PTSD)
- Brain cancer
- Schizophrenia

Product Strategy

The Company is developing patented, improved-upon, commercially available off-patent medications administered by implanted medication pumps targeting large, underserved and highly-motivated patient populations with brain diseases that should benefit from site-specific delivery.

ICVrx has initially targeted refractory epilepsy:

- 1) clinically proving efficacy and safety of proprietary formulations of three known, available (off-patent) drugs, one of which is a common oral antiepileptic that has dose limitations because of systemic toxicity.;
- 2) determining effective dosing; and
- 3) using an established, available pump implanted at the abdomen as in spine delivery, but with output to spinal fluid adjacent to the epilepsy disease site in the brain. Compounding pharmacies will prepare drug formulations.

Delivery

CNS implantable pumps that can deliver drugs via catheter directly to the site of action have 22 years of proven safety and efficacy in spinal diseases where:

- 1) Lower doses (5% or less of oral dose) result in lower side-effects;
- 2) Computerized control achieves steady levels of drug over several weeks;
- 3) Pumps have consistently enabled patients to comply with medication therapy, improving patient outcomes.

Implantation surgery is 40 minutes and is easily reversible.

There are three pump manufacturers in the EU, 2 in the US and a fourth has raised funding on the assumption it will be on the market within 2 years. Management believes this dollar commitment in the industry provides an opportunity for significant strategic value creation.

Epilepsy Market Overview

Many people with serious CNS diseases suffer profoundly and have limited treatment options; many treatment options have serious and debilitating side-effects.

Epilepsy has an incidence of 1% of the population (approximately 3 million people). Medically refractory epilepsy (patients who cannot control their seizures effectively with medication) represents an approximate 20% of the overall incidence or 600,000 patients in 2011.

Management/Team Members

Dan Abrams, M.D. CEO; Former head of Department of Neurosurgery at St. Joseph's Hospital (Denver, Co.).

Stephen J. Farr, Ph.D. CEO Advisor/Board member; 25 years public & private management experience in pharmaceuticals; expert, CNS drug & device development.

Bill Poncy, MBA Adviser Commercialization. 25 years of experience in the pharmaceutical industry, VP Sales Accera Pharmaceuticals, Previous VP sales and marketing at Myogen, Inc. (now Gilead Sciences) & Pharmion Corp.

Larry Fenster, M.B.A. Manager; 20 years experience in early stage companies an 10 in Fortune 500, including M&A and turnaround.

Robert Fisher, M.D. Advisor; Director, Epilepsy Center, Stanford; Director, Neurological Teaching, Stanford; former President American Epilepsy Society.

Corporate Headquarters

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