

The Essential CNS Business Development Tool: Private CNS Company Review: 2010

The completely revised and updated 2010 edition provides a unique database of information about the private companies specializing in the development of novel therapeutics for neurological/psychiatric disorders.

PCNS describes and appraises scientific platforms; clinical/preclinical activity; contact information; alliances; financing; prospects, and licensing opportunities.

Produced in pdf form for easy searchability.

102 companies, 146 pages.
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2010

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CeNeRx BioPharma

270 Cornerstone Drive Ste. 103 Cary NC 27519 866.287.2622
Key Contacts: Barry Brand, CEO
Founded: 2005
Financing: US\$42.5 million to date.
Investors: Aisling, Perseus-Soros, L Capital Partners, A.M. Pappas, Wistar Morris
Number of Employees: 12
Summary: Developing drugs for psychiatric disorders

Platform/Programs

TriRima (CX157)/Depression: This reversible MAO-A inhibitor (RIMA) is the chiral progeny of their original lead, CX2614. The basic platform was developed from an earlier compound, CX1370. CX1370 had been developed by **Burroughs-Wellcome**, but they found elevated liver enzymes in Phl. It was acquired by **Krenitzky Pharmaceuticals**, which then developed three variants. A Phase II trial, aiming to enroll 270 patients, used six tablets (TID), which led to considerable noncompliance. A treatment effect was seen in compliant patients, and a noteworthy magnitude of effect was observed in a subset with severe depression (MADRS-24). They are thus going ahead with Phase IIb early in 2010, in severe depression, using a reformulation which permits BID single tablet dosing. An independent researcher (Meyer) has reported that patients who are nonresponders to the first antidepressant trial have elevated MAO-A levels, lending indirect support to this as a potential option for TRD. CeNeRx reports that no tyramine-based blood pressure effects are seen unless one goes 2.5X beyond the FDA's outlier tyramine dose-level.

CX722,724/Anxiety, PTSD: CeNeRx licensed the CRF-1 antagonist CXB-722, for which there is a human safety base of over 800 individuals, from an undisclosed source. CeNeRx ran a social stress study wherein CXB-722 produced desired shifts in ACTH, cortisol, and cardiac rate, matching the results achieved in a similar study run by the licensor. The produg Ayrenis/CXB724 reportedly has 10X better bioavailability, and much longer patent exclusivity. No cardiovascular or liver toxicity issues have been seen with either of these molecules. CeNeRx is evaluating whether to advance both molecules, or just CXB724.

Cannabinoid Platform: Licensed from **PharmaNess**, this includes fifteen CB-1 modulating compounds, with potential uses in pain, glaucoma, and obesity (the latter will not be pursued, given the rimonabant side effect issue). Preclinical POC has been obtained in all three, but the intraocular pressure effects were apparently particularly compelling. Composition-of-matter protection was obtained in 2009. They are still choosing a lead candidate.

CXB909/Neurodegeneration, neuropathic pain: Licensed from **Krenitzky Pharmaceuticals** in late 2009, this is described as a 'NGF' enhancer. It is a small molecule which enhances neurite growth and neuronal differentiation, and reduces glutamate toxicity in one model. They are going to prioritize neuropathic pain (as did Pfizer/Rinat), rather than pursuing the more difficult neurodegenerative possibilities. Since it protected neurons from Taxol toxicity in an animal model, they will begin with chemotherapy-induced neuropathic pain. They are in Phase I.

Partners
None

Prospects

Reversible MAO-A inhibitors have long been available in Europe and Canada. Those are losing their patent protection, which makes them not worth the trouble of passing US regulatory muster. CeNeRx believes that the clinical efficacy of RIMAs, plus a better side effect profile (little or no sexual dysfunction), has already been proven by moclobemide et al. TriRIMA could be a useful new antidepressant option for TRD, as a second-line option for nonresponders, or for a yet-to-be defined atypical depression subcategory. CeNeRx has also shown a willingness to take on platforms with more risk, and potential, including both the CRF-1 and CB-1 licensings. They have an unusually broad array of clinical data for the CRF-1 program, although the many failures in that category warrants caution. With management featuring BP experience at **GSK** and **Pfizer**, this virtual company has better development credentials than many of its start-up competitors.

Opportunities

Given that they have a new formulation and spotty Phase II TriRima data, they may well have to run Phase IIb in order to maximize their leverage in partnering TriRima. The CRF-1 program has attracted some partnering interest given that it has some POC in humans, while the NGF and cannabinoid programs may be too early on to partner.

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*Private Company Fates/Casualties
2003-9*

Private CNS Company Funding 2009

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AC Immune

Acumen Pharmaceuticals

Adamas Pharmaceuticals

Affectis Pharmaceuticals

Affiris

Afraxis

AgeneBio

Alzhyme

American Life Science Pharmaceuticals

Archer Pharmaceuticals

Arcion Therapeutics

ArmaGen Technologies

AurimMed Pharma

Axon-Neuroscience

Axxonis Pharma AG

Azevan Pharmaceuticals

Bayhill Therapeutics

BioArctic Neuroscience

BioChromix Pharma

BrainCells

BrainTact

Cambria Pharmaceuticals

Cara Therapeutics

Cellzome

CeNeRx BioPharma

Ceregene

Clera

Cognition Pharmaceuticals

Cognition Therapeutics

Cognosci

CoLucid

CoMentis

Embera Neurotherapeutics

ENKAM Pharmaceuticals

EnVivo Pharmaceuticals

Galantos Pharma

Galenea

GliaMed

**Helicon Therapeutics/
Dart Neuroscience**

Intra-Cellular Therapies

KeyNeurotek

Kinexis

Knopp Neurosciences

Link Medicine

Maas Biolab

Maprég

Marinus Pharmaceuticals

Medeia Therapeutics

MedGenesis

MediProPharma

Mithridion

M's Science

Naurex

Neuraltus

NeurAxon

Neuréva

Neurim

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NuPathe

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PharmaNeuroBoost

Pharmaxon

Pharnext

Probiodrug

ProMentis Pharmaceuticals

Proneuron Biotechnologies

Proteostasis Therapeutics

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RemeGenix

SanBio

Satori Pharmaceuticals

SCT Spinal Cord Therapeutics

Seaside Therapeutics

Senexis

Solace Pharmaceuticals

Solstice Neurosciences

Sonexa Therapeutics

Spinifex

Stealth Peptides

Synosia Therapeutics

TauRx

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TheraQuest Biosciences

to-BBB

Trophos

Xenome Ltd

Yaupon Therapeutics

Zenobia

Zogenix

Programs by Company, Indication, Stage

Company Funding

VC Funding Roster