



Partnering in Neuroscience

Sharing a Vision to Help Improve Patients' Lives

Janssen Research & Development, LLC





Yvonne Ford, *Untitled Artwork*
Artwork from Reflections Art in Health,
a user-led charity that promotes positive
mental health through the creative arts.

Partnering to Build Neuroscience Solutions of Tomorrow

The impact of neuropsychiatric diseases and pain conditions on our society is staggering. An estimated 44 million people worldwide have dementia;¹ schizophrenia affects approximately 24 million people globally;² more than 350 million people around the world have depression,³ and 1.5 billion people in the world suffer from chronic pain.⁴ At Janssen, we are deeply committed to these patients and to the health care professionals who care for them. Our goal is to enhance a culture of innovation and bring forth new treatments for those in need.

We are united and energized by one mission—discovering, developing and delivering differentiated medicines that address the most serious unmet medical needs of our time.

Our strategy is to harness the best science in the world, whether from our own laboratories or through strategic relationships and collaborations with academia, biotech and other pharmaceutical companies.

Our priorities are Alzheimer’s disease and mood disorders, and we continue our legacy work in schizophrenia and pain. In order to succeed in these areas, we recognize that innovation cannot be limited to our scientists and technology experts alone. Collaboration with scientists around the globe will drive the types of discoveries that will ultimately improve the prevention, diagnosis and treatment of neuropsychiatric diseases and pain conditions for generations to come, while helping us to achieve our business goals.

Across neuroscience, our researchers are exploring the emerging science in synaptic plasticity and cellular resilience, with an emphasis on developing novel therapeutics for the treatment of severe mood disorders and neurodegenerative dementias. Our goal is to leverage breakthrough technologies in imaging, genomics and associated biomarkers to provide early disease diagnostics and patient management programs.

Along with a strong commitment to our internal research groups, we are dedicated to partnering with individuals and companies that share our vision and want to work together to build the neuroscience solutions of tomorrow. We believe that partnerships are essential to drive change, innovation and transformation, and we are committed to ensuring the success of our collaborations.

Whether you are an academic scientist working on an innovative concept, or a biotechnology or pharmaceutical company in search of a development partner, we welcome your inquiries. We look forward to learning more about your interests and opportunities for collaboration.



Husseini Manji, M.D., F.R.C.P.C.

Global Head, Neuroscience
Janssen Research & Development, LLC

¹ World Alzheimer Report 2013, Alzheimer’s Disease International. <http://www.alz.co.uk/research/statistics>

² World Health Organization. http://www.who.int/mental_health/management/schizophrenia/en/

³ “Depression, A Global Public Health Concern,” M. Marcus, M. Yasamy, M. Vanommeren, WHO, 2012

⁴ American Academy of Pain Medicine. http://www.painmed.org/patientcenter/facts_on_pain.aspx

Partnering with the Neuroscience Team

Janssen's Neuroscience organization provides comprehensive scientific and wide business expertise. We have successfully established many partnerships through creative and innovative deal structures, and we are continuously seeking new ways to collaborate in our core areas of interest, including:

- **Licensing and acquisition** opportunities for therapeutics against novel targets.
- **Academic partnerships** where novel discoveries have revealed high potential targets for therapeutic or diagnostic development.
- **Public-private partnerships** and collaborations to advance therapeutics, clinical trials and biomarker programs.
- **Opportunities to license out and reposition** selected compounds in our neuroscience pipeline.
- **Other innovative business structures**, such as venture investments, startup companies, option deals and risk-sharing partnerships.

Our global presence and cross-business portfolio provide us with the flexibility to build strong relationships for many collaborative opportunities in both established and emerging markets. Janssen is committed to making these relationships work for the benefit of patients around the world.

Growth in Emerging Markets

In emerging markets, our vision is to harness growth, expand businesses and enable the delivery of quality medicines.

We continue to build our presence in Asia Pacific, Latin America, Eastern Europe, new Europe and the Middle East by establishing R&D activities and expanding our sales and marketing

The Johnson & Johnson Innovation Centers

Strategically Located to Foster Collaboration

As part of the Johnson & Johnson Family of Companies, we believe that the best way to move innovative solutions forward is through collaboration and idea exchange. To advance this belief, Johnson & Johnson opened Innovation Centers in major science and technology hubs throughout the world to focus on early-stage partnerships. By putting ourselves in key locations with thriving life science and entrepreneurial communities, the world becomes our laboratory to support and accelerate the best science.



Our Innovation Centers in Boston, California, London and Asia Pacific house science and technology experts—including senior, experienced neuroscientists—who are active members of their scientific communities. They are working to identify and bring forward early-stage collaborations on a local basis in areas that are of interest to our company.

Each regional center also has broad capabilities and flexibility to negotiate and customize partnership structures to meet the needs of each collaboration opportunity.

If you have an opportunity that you feel may be of interest to the Johnson & Johnson Family of Companies, we invite you to submit it to ijninnovation@its.jnj.com.

operations. We welcome opportunities to develop partnerships with companies in emerging markets that want to leverage their innovative products and technologies.

Our capabilities include global development programs, world-class manufacturing of biologics and small molecules, and strong commercialization entities that market our products in more than 175 countries. We are part of the most broadly based health care company in the world, yet our decentralized structure assures that we remain focused on the markets in

every therapeutic and geographic area that we serve.

Each year, the Johnson & Johnson Family of Companies enter into more than 150 collaborations with outside organizations. On average, Janssen Pharmaceutical Companies license more than 50 products and platform technologies each year.

Janssen's collaborative work involves research agreements, product licenses, joint ventures, co-marketing arrangements and venture investments. Staff from our Johnson & Johnson Innovation teams lead these efforts.

Evolving Strategies

Recent research has linked neuronal plasticity and cellular resilience to learning, memory, cognition and mood. We know that neuropsychiatric disorders arise from abnormalities in neuronal plasticity and cellular resilience cascades. Consequently, we are increasingly focused in this area because understanding how to control and augment this ability for the brain and central nervous system to adapt may lead to the development of novel treatments for Alzheimer's disease and mood disorders.

Our Neuroscience team is also pioneering holistic "predict and pre-empt" paradigms that involve:

- Early Diagnostics
- Patient Adherence Tools
- Digital Therapy for Cognitive Remediation
- Remote Monitoring for Relapse Prediction
- Patient Management Programs



Identifying New Targets

To execute our overarching strategy, the Janssen Research & Development Neuroscience team is focused on Alzheimer's disease and mood disorders, and we continue our legacy work in schizophrenia and chronic pain. While our primary interest is in programs aimed at the discovery and development of novel medicines, we are also interested in new biomarkers and

companion diagnostics to drive earlier and more accurate diagnosis, treatment response, and outcome prediction and measurement in these core focus areas.

We have a strong interest in biological molecules and in developing novel strategies to address blood-brain barrier challenges to improve CNS penetration of large-molecule medicines; for example, through receptor-mediated

transcytosis and intra-nasal delivery methods.

We seek integrative solutions to achieve earlier intervention and adherence, and prevent relapse. Examples include non-pharmaceutical cognitive enhancing therapies and compliance technologies. Following are our core areas of interest:

Alzheimer's Disease

Disease-modifying Activity

- Agents in preclinical stage or later should have preclinical validated *in-vivo*, proof-of-concept data
 - ApoE modulators
 - Disease interception
 - Genetic risk factors
 - Neuroimmune modulators
 - O-GlcNAcase modulators
 - Synaptic plasticity modulators
 - Targets associated with known co-morbidities with the disease
 - Tau modulators

Symptomatic Treatment of Cognitive Impairment and Neuropsychiatric Conditions

- Novel agents with Phase 2 proof-of-concept in neuropsychiatric symptoms or neuropsychiatric symptoms with cognitive impairment that exhibit superior efficacy to standard of care (e.g., antipsychotics, acetylcholinesterase inhibitors) as monotherapy or adjunctive therapy with synergistic efficacy
- Examples include:
 - GABA-A alpha 5 inverse agonist
 - mGluR2 antagonist/NAM

Biomarkers and Diagnostics

- Prognostic, diagnostic and disease progression biomarkers
- Diagnostic imaging agents, including imaging of disease pathology (A β , tau), structural and functional MRI
- Improved CSF and blood biomarker assays
- Novel animal models for target evaluation

Identifying New Targets (continued)

Mood Disorders

Depression and Treatment-resistant Depression

- Novel therapeutic agents that have fast onset of action, good safety and tolerability profiles and that address common co-morbidities (e.g., anxiety, insomnia and substance abuse)
 - Glutamatergic modulators
 - Neuroactive cytokines
 - Molecules that positively impact synaptic plasticity and cellular resilience
- Phase 2 and later stage opportunities with defined mechanism of action and superior efficacy over standard of care

Bipolar Depression

- Novel therapeutic agents that provide rapid improvement in bipolar depression and in suicidal patients and that produce long-term stabilization of mood and prevent recurrences

Biomarkers and Integrated Solutions

- Predictive biomarkers of response to antidepressants
- Biomarkers for relapse prediction
- Diagnostic biomarkers to identify subgroups with different etiologies

Schizophrenia

Novel therapies in Phase 2b or later for symptomatic treatment of the underlying symptoms of schizophrenia

with special emphasis on treatment of cognitive impairment and negative symptoms

Biomarkers and Integrated Solutions

- Prognostic biomarkers to identify patients at risk for disease
- Predictive biomarkers for treatment response
- Integrated solutions for patient diagnosis or treatment assessment
- Cognitive tests for measuring disease progression

Pain (chronic neuropathic and non-neuropathic)

Novel therapeutic agents in Phase 2b or later for moderate-to-severe chronic and neuropathic pain

- Preventive or disease modifying agents for pain chronification
- Novel therapeutic agents and compounds with proof-of-concept data (Phase 2 or later) that are significantly differentiated from standard of care in safety and efficacy

Biomarkers and Diagnostics

- Biomarkers and genetic markers for pain chronification
- Diagnostic tools of placebo responders
- Companion diagnostics

Janssen is also interested in pursuing external licensing opportunities in other complementary disease areas within neurodegeneration and neuroplasticity, niche indications and orphan drugs. Opportunities of interest in this area

include those for neurological diseases where there is significant unmet medical need and where robust clinical proof-of-concept has been established relative to standard of care. We welcome and appreciate your interest

in Janssen Research & Development Neuroscience Therapeutic Area. We look forward to learning more about the innovative work that you bring to the study and treatment of neuropsychiatric diseases and pain conditions.

Guidance Regarding Areas of Interest

Janssen Research & Development, LLC, Neuroscience Therapeutic Area has focused research interests in Alzheimer's disease, mood disorders, schizophrenia and pain. **For complete information on our areas of interest, please review pages 5 and 6 of this brochure.** We are eager to learn about a variety of opportunities from possible scientific and business partners.

At the current time, however, we are not considering opportunities in the following areas:

Alzheimer's Disease

- Compounds with unknown mechanism of action
- Acetylcholinesterase inhibitors
- Amyloid or tau aggregation inhibitors
- Caspase inhibitors
- GABA modulators
- Gamma secretase inhibitors
- Insulin modulators
- Metal chelators
- Muscarinic agonists
- Nutritional/antioxidants
- RAGE antagonists
- Sigma agonists

Mood Disorders

- Compounds with unknown mechanism of action
- Lithium formulations
- Adenosine modulators
- MAO inhibitors
- Monoaminergic modulators
- Monoaminergic reuptake inhibitors
- Non-selective ion channel modulators
- Opioid agonists (mu, delta)
- Sigma agonist

Schizophrenia

- Compounds with unknown mechanism of action
- CB modulators
- Monoaminergic modulators

Pain

- Compounds with unknown mechanism of action
- Compounds for mild to moderate pain without **significant clinical differentiation**
- Compounds for migraine or migraine prevention
- Monoaminergic reuptake inhibitors
- Non-selective ion channel modulators
- Opioids or opioid receptor modulators without **robust clinical efficacy and significant differentiation in safety as it relates to classical opioid side effects**
- NSAIDs/COX2s
- Reformulations of known or combinations of **marketed drugs**

Contacts

Representatives of established pharmaceutical companies, mid-sized and large biotechnology companies, individuals with opportunities that have achieved clinical proof-of-concept, and those with interests in licensing and acquisition activities, contact:

Mark Nuttall

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For CNS and Pain licensing opportunities, please contact:

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Universities, small biotechnology companies, venture capital firms, and individuals with early stage opportunities prior to clinical proof-of-concept, contact:

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Ramón Losa, *Untitled Artwork*

Artwork from National Art Exhibitions of the Mentally Ill, Inc (NAEMI), an organization dedicated to discovering and preserving the art of people with mental illness.

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