

# Prana's Parkinson's drug meets Michael J. Fox Foundation development milestone

PBT434 advances through IND enabling studies -

MELBOURNE, Australia – August 30, 2012 – Prana Biotechnology Limited (NASDAQ: PRAN / ASX: PBT), announced today that its lead compound in development for Parkinson's disease (PD), PBT434, had progressed successfully through a series of preclinical development studies used to assess the suitability of a candidate compound for human clinical studies. The studies were funded by The Michael J. Fox Foundation (MJFF) 2011 Pipeline Program to support its 'Therapeutic Development Initiative'. The MJFF Program grant is milestone based. PBT434 achieved all of its milestones in preclinical toxicology studies, genotoxicity and safety pharmacology - allowing the compound to be positioned for larger scale animal toxicology studies prior to commencing clinical trials.

PBT434 is a novel, orally available compound that easily crosses into the brain and is able to exert potent neuroprotective properties. Most particularly, it preserves the brain tissue in PD that degenerates over time, the *substantia nigra*. By preserving this tissue, Prana's scientists have demonstrated significant restoration of motor coordination and strength in animal models. PBT434 has been shown that it is able to impede the iron-induced oxidative damage and neurotoxic cascade that kills the *substantia nigra*. As such, PBT434's mechanism of action offers a novel disease modifying therapeutic strategy in contrast to the currently marketed symptomatic agents that, at best, serve to reduce the side effects of the disease rather than alter its course.

"Based on these efficacy studies and now the completion of this suite of preclinical development assessments, Prana will look to move PBT434 into longer term toxicology studies in parallel to our scale up manufacturing plans for PBT434. All being well, we could file an IND by the end of next year and commence clinical trials in 2014" said Mr Geoffrey Kempler, Prana's Executive Chairman. "PBT434 also marks another product pipeline milestone for Prana to complement our two ongoing trials with PBT2 in Alzheimer's disease and Huntington disease" commented Mr Kempler.

Parkinson's disease is a devastating illness which can result in not only the loss of muscle control, speech, balance and digestive functions; it may also impair a patient's psychiatric and cognitive function. With 4 million people affected worldwide, Parkinson's disease is the second most common neurological indication behind Alzheimer's disease. The current market size for drugs to treat Parkinson's disease is approximately \$4 billion per year; however most currently available drugs primarily treat the symptoms and do not actually prevent the ongoing destruction of the *substantia nigra* in the brain and progression of the disease.

<sup>\*</sup> The program grant title is 'PBT434, a novel neuroprotective drug for Parkinson's Disease; completion of pre-clinical studies to enable human clinical trials'.

## **About Prana Biotechnology Limited**

Prana Biotechnology was established to commercialise research into Alzheimer's Disease and other major age-related neurodegenerative disorders. The Company was incorporated in 1997 and listed on the Australian Securities Exchange in March 2000 and listed on NASDAQ in September 2002. Researchers at prominent international institutions including The University of Melbourne, The Mental Health Research Institute (Melbourne) and Massachusetts General Hospital, a teaching hospital of Harvard Medical School, contributed to the discovery of Prana's technology.

#### About The Michael J. Fox Foundation for Parkinson's Research

As the world's largest private funder of Parkinson's research, The Michael J. Fox Foundation is dedicated to accelerating a cure for Parkinson's disease and improved therapies for those living with the condition today. The Foundation pursues its goals through an aggressively funded, highly targeted research program coupled with active global engagement of scientists, Parkinson's patients, business leaders, clinical trial participants, donors and volunteers. In addition to funding over \$250 million in research to date, the Foundation has fundamentally altered the trajectory of progress toward a cure. Operating at the hub of worldwide Parkinson's research, the Foundation forges groundbreaking collaborations with industry leaders, academic scientists and government research funders; increases Parkinson's awareness through high-profile advocacy, events and outreach; and coordinates the grassroots involvement of thousands of Team Fox members around the world.

For more information, visit: www.michaeljfox.org; www.facebook.com/michaeljfoxfoundation.

### **Forward Looking Statements**

This press release contains "forward-looking statements" within the meaning of section 27A of the Securities Act of 1933 and section 21E of the Securities Exchange Act of 1934. The Company has tried to identify such forward-looking statements by use of such words as "expects," "intends," "hopes," "anticipates," "believes," "could," "may," "evidences" and "estimates," and other similar expressions, but these words are not the exclusive means of identifying such statements. Such statements include, but are not limited to any statements relating to the Company's drug development program, including, but not limited to the initiation, progress and outcomes of clinical trials of the Company's drug development program, including, but not limited to, PBT2, and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to the difficulties or delays in financing, development, testing, regulatory approval, production and marketing of the Company's drug components, including, but not limited to, PBT2, the ability of the Company to procure additional future sources of financing, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug compounds, including, but not limited to, PBT2, that could slow or prevent products coming to market, the uncertainty of patent protection for the Company's intellectual property or trade secrets, including, but not limited to, the intellectual property relating to PBT2, and other risks detailed from time to time in the filings the Company makes with Securities and Exchange Commission including its annual reports on Form 20-F and its reports on Form 6-K. Such statements are based on management's current expectations, but actual results may differ materially due to various factions including those risks and uncertainties mentioned or referred to in this press release. Accordingly, you should not rely on those forward-looking statements as a prediction of actual future results.

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