

## FDA End of Phase 2 Status Update

**MELBOURNE, Friday February 13th, 2015:** Prana Biotechnology (ASX: PBT/NASDAQ:PRAN) has today announced the status of its End of Phase 2 discussions with the US Food and Drug Administration (FDA).

At the End of Phase 2 meeting for its Reach2HD clinical trial, and following subsequent correspondence, Prana presented its plans and information package to initiate a Phase 3 trial in Huntington Disease.

Upon review, the FDA has issued a Partial Clinical Hold letter based on non-clinical (animal) findings which currently limits the dose of PBT2 that can be given to patients with Huntington disease. Under Prana's open Investigational New Drug application, Prana is able to continue clinical trials but at a dose that is not considered clinically relevant by the Company.

The FDA has provided Prana with options to remove the Partial Clinical Hold. To support moving forward with clinical trials of PBT2 at a clinically relevant dosage in humans, Prana would conduct additional animal neurotoxicity studies or identify a strategy for safely using a clinically relevant dosage in humans in the planned Phase 3 trial in Huntington disease. The FDA has not raised any concerns about PBT2 safety data in human trials conducted to date.

The company is continuing discussions with the FDA in addressing these issues.

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## **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 Stock 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.



For further information please visit the Company's web site at <a href="https://www.pranabio.com">www.pranabio.com</a>

## **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 forwardlooking 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.