Prana provides regulatory update for PBT2 for the treatment of Huntington disease

MELBOURNE, Thursday 3rd November, 2016: Prana Biotechnology Ltd (ASX PBT: NASDAQ PRAN) today announced that is has received further advice from the US Food and Drug Administration (FDA) on the steps necessary to remove the Partial Clinical Hold (PCH) on PBT2, including the requirement to undertake further non-clinical studies.

The PCH limits the dosage of PBT2 that can be used in clinical trials in the USA. As part of Prana's global clinical development strategy, the Company has now prioritised clinical development of PBT2 in Europe. Later this month the Company is scheduled to meet with the Medical and Healthcare Regulatory Agency in London and the Medical Products Agency in Stockholm to receive formal scientific advice on how to best proceed to a Phase 3 trial in Huntington disease.

There is increasing non-clinical evidence that PBT2 protects brain cells from decay and death. PBT2 has been shown to improve aspects of cognitive function in two clinical trials, one in Alzheimer's disease and one in Huntington disease (HD). These data supported the grant of Orphan drug designation for PBT2 in Europe for the treatment of HD.

Recently, Defined Health, a US based leading consultancy in therapeutic opportunity evaluation, has conducted research in Europe on Prana's behalf and reported that cognitive decline in Huntington disease remains a significant unmet medical need, with no approved treatments. Whilst pursuing this significant commercial opportunity to develop PBT2 for HD in Europe, Prana is in parallel undertaking a review of all available options to improve shareholder value.

Prana has commenced a process of reviewing other potentially suitable opportunities that may be highly attractive and have the ability to add shareholder value in the medium to longer term. The Company currently has cash reserves of approximately A$30 million. Further updates will be provided at Company's the AGM to be held on Thursday 17th November 2016.

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About Prana Biotechnology Limited

Prana Biotechnology was established to commercialise research into Alzheimer's disease, Huntington 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 www.pranabio.com.

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.