Prana reports FY15 financial results

MELBOURNE, August 27, 2015: Prana Biotechnology Limited (ASX:PBT/NASDAQ:PRAN) yesterday announced its financial results for the 12 months to June 30, 2015.

Financial Results

- Full year revenue of $176,842, down 51% on prior corresponding period (pcp)
- Fully year loss after tax of $5,885,069, down 56% on pcp
- Cash position at June 30, 2015, of $34.9 million
- Cash receivable of $6.5 million for R&D tax incentive for eligible activities incurred in fiscal year 2015

Prana continues to focus on advancing the development of its therapies aimed at treating neurodegenerative conditions, such as Alzheimer's disease and Huntington disease, in fiscal year 2015.

A summary of events follows below:

Alzheimer's disease research and development

Prana announced that its lead drug in development, PBT2, was safe and well tolerated in a cohort of Alzheimer's disease patients over a two year period. Patients had taken part in a 12-month study known as the IMAGINE trial and were offered the opportunity to continue receiving PBT2 for a further 12 months through an Extension study.

The company is now preparing a manuscript for the IMAGINE and IMAGINE Extension studies.

While clinical safety has been demonstrated to date with PBT2, the US Food and Drug Administration has placed PBT2 on Partial Clinical Hold (PCH) based on particular non-clinical neurotoxicology findings in a dog study, which limit the dose of the drug that can be applied in future trials. Prana is working to have the PCH lifted and appointed third party experts to assemble a package of clinical and non-clinical data and its interpretation to address FDA concerns and facilitate clinical and commercial development of PBT2.

In November 2014, Massachusetts General Hospital researchers, Dr Doo Yeon Kim and Dr Rudolph Tanzi, Prana's Chief Scientific Advisor, published a novel model for Alzheimer's disease in the prestigious journal *Nature*.

The novel model strongly supports the central hypothesis that beta-amyloid is a key driver of brain cell tangles and neurodegeneration in Alzheimer's disease. For developing this revolutionary model, Drs Kim and Tanzi will receive the prestigious Smithsonian American Ingenuity Award (Natural Sciences) in November 2015.

Using this model, preliminary studies suggest PBT2 can prevent tangles in brain cells and increase neuronal cell viability.

Huntington disease research and development

Following last year's announcement of encouraging results from the Reach2HD trial in Huntington disease, Prana attracted one of the world's foremost experts in Huntington disease to the Board of Directors.

Professor Ira Shoulson has played a key role in planning Prana's next Huntington disease trial and in positioning PBT2 for successful commercialisation.

PBT2 was granted Orphan drug designation in United States and Europe. In the United States, Orphan drug designation entitles Prana to seven years of market exclusivity for the use of PBT2 in the treatment of Huntington disease; protocol assistance by the FDA to optimize drug development in the preparation of a dossier that will meet regulatory requirements; and reduced fees associated with applying for market approval. In Europe, 10 years of commercial protection is provided.

PBT2 has the potential to be the first drug approved to treat the cognitive problems of Huntington disease patients and to enjoy a substantial period of exclusive protection associated with Orphan disease designation.

Based on the emerging strong safety profile for PBT2, Prana is crafting a robust safety monitoring plan for future trials in Huntington disease. These plans will be submitted to the FDA as part of Prana's response to the PCH. The combined FDA safety and data information package will be used in submissions to European and other regulators to support global development plans and prospective marketing approvals.

Along with the assembly of safety analyses to the FDA, Prana is continuing to plan for the Phase 3 program for Huntington disease and, in particular, the design of the program to confirm clinical benefit with PBT2.

Movement Disorder research and development & Translational Biology programs

Prana has a library of more than 2000 Metal-Protein Attenuating Compounds (MPAC) which address Alzheimer's-like changes in the brain. MPACs do this by preventing a build-up of beta-amyloid deposits which destroy cognitive function.

Prana has continued to develop its 'two tier' research program structure, to (i) undertake new MPAC design and synthesis and (ii) undertake 'translational' animal modelling programs to test and validate new candidate MPACs as potential development leads.

Studies have shown lead MPAC PBT434 to be well tolerated with limited toxicity. It is anticipated that subject to regulatory approval, PBT434 will commence its Phase 1 program during 2016 in healthy volunteers to investigate safety, tolerability, pharmacokinetics, pharmacodynamics and putative biomarkers of PBT434.

Overall, Prana's MPAC pipeline, headed by lead compounds PBT2 and PBT434, is evolving rapidly to offer late and early stage disease modifying therapeutic strategies to treat the unmet medical needs in neurodegeneration.

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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 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.