20 March 2014

Successful Completion of Technical Due Diligence Points to Breakthrough Diagnostic Tool for Mental Illness

- **BioProspect is pleased to announce the successful completion of Technical Due Diligence on Invatec/Heartlink's Diagnostic Heart Rate Variability (HRV) technology. The results of which provide us with confidence that mental health disorders can be diagnosed using heart rate data.**

- **The due diligence program was conducted by two independent groups of industry experts. Due Diligence confirmed that:**
    - **In a blinded test of patients with a range of mental health disorders and healthy controls (98 case files), the HRV technology demonstrated a successful diagnosis rate in excess of 80% in comparison to clinician diagnoses.**
    - **The technology has the potential to be used as a diagnostic tool for a wide range of mental health disorders; and**
    - **No single competing evidence-based test for a wide range of mental health disorders currently exists.**

- **The Diagnostic Heart Rate method has been in development for 10 years and involves over 6,000 test cases. The present Due Diligence is the first independent, quantitative review to confirm that the technology is ground breaking and has the potential to revolutionise mental health diagnosis.**

- **To date, diagnosis of mental health disorders has relied on the informed and expert, but subjective opinion of mental health practitioners. BioProspect's Due Diligence results suggest that in the future, mental health and mental illness can be medically diagnosed via heart rate patterns with a high degree of accuracy.**

- **A number of outside institutions have already approached Invatec for further development and trials, which will be explored immediately, post the acquisition. BioProspect will work with Invatec to implement pathways to commercialisation in both the medical and consumer fields.**

BioProspect Limited (ASX: BPO or the company) is pleased to announce that it has received reports from both sets of experts retained to undertake Technical Due Diligence on the patented Invatec/Heartlink technology. Both reports confirm the potential viability of the technology. BPO is currently awaiting the final report on Corporate/Legal Due Diligence, which is expected shortly. Pending acceptable results of Corporate/Legal Due Diligence, the Board of BPO has resolved to proceed with the Invatec/Heartlink transaction.

In commenting on the Due Diligence the Chairman of BioProspect Mr Peter May said, ***"We are confident that we have conducted a rigorous Due Diligence process with independent experts retained to evaluate the technology, its theoretical background, past clinical research, diagnostic performance, and competing technologies.***

"We are pleased that both reports independently confirm the view that the Invatec technology is a breakthrough innovation in the diagnosis of mental health disorders, and appears to have excellent

potential as the world's first objective and quantitative tool for diagnosing a wide range of mental health disorders.

"We are excited about the path to commercialisation of the technology, especially given the size of the market with depression alone estimated to cost the US economy some US$83 billion per annum." he said.

University Research Team Due Diligence

The Research team included experienced Research Psychologists from a number of leading Universities and was led by a Research Psychologist with a PhD focused on Major Depressive Disorder. A detailed literature review was undertaken to evaluate: competing technologies, other potential biomarkers of Major Depression, and other analyses of heart rate variability in psychopathologies. The key findings were that:

1) Historical research supports the use of Heart Rate Variability (HRV) as a biomarker for Major Depression and other mental health disorders.
2) Longer periods of HRV measurement may provide greater diagnostic capabilities for mental health disorders in at risk patients.
3) The majority of research on Heart Rate Variability (HRV) focused on much shorter time intervals, while Invatec has focused on 24 hour (circadian) periods.

The University Research team concluded, ***"Results from this review can only suggest that HRV measurement may be a useful means to diagnose psychopathology within a patient. HRV measurement appears to be a relatively non-invasive, portable, and inexpensive measure to assist in determining health from disease. It therefore seems appropriate to further investigate this candidate biomarker in an independent, appropriately controlled prospective trial to validate the claims of Invatec."***

Independent Consultant Psychiatrist Due Diligence

BPO retained an independent Consultant Psychiatrist who is Head of Psychiatry at one of Perth's largest Private Hospitals as part of its Due Diligence. The scope was to provide confirmation that Invatec's clinical investigations have been undertaken, and whether there is reliable evidence underpinning the technology, as well as applicability of technology for the broader population. The key findings of this report were:

1) Confirmation that Invatec has undertaken systematic clinical investigations conducted over an extended period and that the standard of work is at an acceptable level and comparable to a typical investigator-initiated clinical study.
2) Confirmation that results from clinical studies undertaken consistently supports the diagnostic value of circadian HRV measurement. In fact the Consultant Psychiatrist commented, "***The correlation results of the blinded validation study are impressive, reaching statistical significance. And importantly it demonstrates in a convincing fashion the link between certain diagnostic categories and recognisable changes in heart rate pattern."***
3) Confirmation that the numbers of participants in the Invatec clinical research program are sufficiently large to be statistically meaningful and composed of real life clinical cases submitted by competent and experienced clinicians.
4) On the question of generalisability, the report confirmed it reasonable to expect that the research findings are generalisable to a broader population. There is no reason to think that the diagnostic potential of this technique would be restricted to a particular ethnic or other subset of the population, while the number of participants tested is sufficient to suggest generalisability.
5) Confirmation that based on the research literature, there appears to be a high probability that 24 hour heart rate data has diagnostic potential for mental health disorders. Invatec research rests on the foundation of this well-established body of international, peer-reviewed literature.

6) Confirmation that the patient records reviewed included many individual longitudinal case studies. These case studies demonstrated that as the patient's mental health disorder improved, the heart rate pattern normalised. This opens the possibility of the technology being used as a monitoring tool to evaluate the effectiveness of various treatments such as medication and/or psychotherapy.

Additionally, as part of the Due Diligence, a number of local clinicians participated in a survey, which invited them to provide their opinion on the heart rate monitoring procedure. The group included Psychiatrists, GP.s and non-medical clinicians, all of whom were highly experienced clinicians with knowledge of the use of heart rate monitoring in the field of mental health. The results of this survey were highly encouraging. It is apparent that there is a high level of interest in heart rate monitoring amongst clinicians with knowledge of the technology. Comments made by participants in the survey included;

- "There are no known psychiatric screening, diagnostic or monitoring technologies of this nature available"
- "Provides useful confirmation of diagnosis and/or can assist the clinician when difficulties arise in the diagnostic process / diagnostic dilemmas which may occur in complex psychiatric presentations."
- "Very helpful to use serial heart rate monitoring to help determine the efficacy of the treatment protocol in recovery."

Overall, the group surveyed is keen to see further research and development in the area, as they require a standardised diagnostic procedure that is both reliable and valid.

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