



## Options to acquire Depression Diagnostic Project

- **Unique quantitative test for depression & other debilitating mental health disorders**
- **Currently, there is no Quantitative test for clinical depression - all are Qualitative**
- **The test is simple, unobtrusive, and cost-effective.**
- **BPO to sole-fund independent validation trials upon exercise of its options.**
- **Depression is the leading cause of disability in the world <sup>(1)</sup>.**
- **Depression is estimated to cost the US economy alone US\$83 billion per annum <sup>(2)</sup>**

BioProspect Limited (ASX: BPO) is pleased to announce that it has entered into agreements which have allowed it to bring together a landmark Project for the quantitative diagnosis of depression and other mental health disorders. BPO has the option to acquire 80% of Invatec Health Pty Ltd (Invatec) by a 2 stage transaction. Invatec has developed a method for diagnosing Mental Health disorders including Depression, Generalised Anxiety Disorder, Acute Psychosis and Panic Disorder by monitoring a subject's heart rate data. The method has been developed from extensive research into the relationship between heart rate activity mediated by the autonomic nervous system and psychological state initiated at the University of Western Australia. The research, conducted over many years, involved the analysis of heart rate data from thousands of subjects covering all major psychiatric disorders which have been compared to traditional methods of clinical diagnosis.

In a separate agreement with Heartlink Limited (Heartlink), BPO has an option to acquire an exclusive licence to use and exploit Patents covering the project technology (stage 1 option) with a further option to acquire the entire patent suite and all associated IP (stage 2 option).

The World Health Organization estimates that depression is the leading cause of disability and that it afflicts 350 million people worldwide <sup>(1)</sup>. Depression can also adversely affect the course and outcome of common chronic conditions such as arthritis, asthma, cardiovascular disease, cancer, diabetes, and obesity. In the workplace, it can result in increased absenteeism and decreased productivity. For these reasons, depression is seen as a leading cause of disability. Consequently, the demand for curbing depression and other mental health conditions is on the rise globally.

The acquisition of rights over the Depression Diagnostic Project by the Invatec and Heartlink transactions occurred after BPO reviewed a number of projects so as to determine an appropriate complementary opportunity in the biotechnology sector.

In commenting on acquiring the project rights Mr Ben Cooper Executive Director of BPO said - ***“Invatec has developed an evidence based test for Depression. Their intellectual property is supported by a large body of empirical evidence and appears compelling. Should validation prove successful, we believe that it has major commercial appeal, especially in light of the formal announcement by the US National Institute of Mental Health earlier this year that they are actively seeking a diagnostic system that is evidence based as opposed to the traditional qualitative assessment.”***

### **Forward Plan**

In respect of the Invatec transaction, BPO has engaged a team of suitably qualified mental health professionals and medical researchers to undertake an independent Due Diligence on its behalf. It is anticipated that this Due Diligence upon the Project technology will be completed within 60 days.

Upon successful completion of Due Diligence, BPO will undertake a capital raising of at least \$1 million and exercise the option in respect of the Invatec transaction. Stage 1 of the Invatec transaction will involve funding trials to independently validate the technology. In this regard, Invatec management are in discussions with leading medical research institutions in Australia, the USA and Asia to establish independent validation trials over approximately a two year period. These validation trials will seek to confirm the effectiveness and clinical utility of the diagnostic method.

In respect of the Heartlink transaction, BPO will undertake Due Diligence on the intellectual property rights held by Heartlink within 60 days. Upon successful completion of Due Diligence, BPO will exercise the stage 1 option and obtain an exclusive 2 year licence to use and exploit the technology.

### **Current Diagnosis of Mental Health Disorders - and Associated Problems**

*“The need for screening for and early detection of depression in primary care services is unarguable”* - Depression A Global Crisis – World Mental Health Day, October 10, 2012 - World Federation for Mental Health.

Despite intensive research over many decades, there is still no reliable “Quantitative, evidence-based test” for mental illness. Diagnoses are still made by a physician based on experience and observed behaviour directed by a set of guidelines (predominantly DSM5). However, these subjective approaches may lead to inadequate or incorrect diagnosis, resulting in the potential for inappropriate or ineffective treatment. Furthermore, there is no reliable or effective way of assessing efficacy of treatment once depression is diagnosed.

There is a clear need for a diagnostic method that is objective, evidence based and can be administered early. This has recently been acknowledged by one peak US body “The US National Institute of Mental Health” earlier this year formally announced they will no longer endorse DSM5. Stating that, “they are actively seeking a diagnostic system that is evidence based”. They went further adding that “it is critical to realise that we cannot succeed if we use DSM categories as the gold standard.”

The method developed by Invatec is designed to enable earlier diagnosis and more effective treatment and follow-up, leading to better patient outcomes. This can make all the difference in the quality of life of affected individuals and their families as well as significantly reducing the burden on the healthcare system by reducing costs to payers.

### **Practical Application and Commercialisation**

The application of the technology is simple. Firstly, the heart rate data is collected using a heart rate monitor. In full commercial mode, the heart rate data will be transferred to a data centre via the internet where algorithms will analyse the data instantaneously. A Diagnostic Report is produced immediately and the medical practitioner and/or patient view the report.

Importantly with the advent of Blue Tooth enabled heart rate monitors, which can communicate directly with mobile phones and tablets, the technology is ideal for delivery via Android and iTunes Apps. Invatec envisages that ultimately this will form a core part of the commercial product offering. Inavtec believes that their technology has a number of compelling commercial advantages:

1. The simplicity of the diagnostic test will appeal to many general practitioners and specialist physicians. These professionals can use the test as an early screening tool to assist in diagnosis, assess the severity of symptoms, and by continuous testing, effectively measure response to treatment. Early detection as a result of this testing, will lead to timely intervention which is known to significantly improve outcomes.
2. Early identification, particularly in high risk occupations such as aviation, police & emergency services, has the potential to reduce the level of work related stress that results in absenteeism and lost productivity.
3. Insurance companies that assess a growing number of disability claims every year based on the diagnosis of a psychiatric disorder, will welcome the opportunity to utilize an objective, evidence-based diagnostic method to validate claims.
4. The test may also appeal to pharmaceutical companies as a useful research tool, particularly in drug efficacy trials to identify study candidates and assess therapeutic results.
5. Government and private health insurers who heavily subsidize expensive treatment for mental illness will benefit by better targeting of prescription drugs, which will lead to reduced costs to the health system.

### **About Depression**

Depression is a common and debilitating illness. It is a condition that causes impairment in many areas of functioning including school, work, family, and social life. It is treatable and successful depression treatment enables people to return to the level of functioning they had before becoming depressed. Despite the availability of treatment for depression, the majority of persons with depression do not receive even minimally adequate treatment. Depression is characterized by changes in mood, self-attitude, cognitive functioning, sleep, appetite, and energy level. The World Health Organization found that major depression was the leading

cause of disability worldwide<sup>1</sup>. Depression causes suffering, decreases quality of life, and causes impairment in social and occupational functioning. It is associated with increased health care costs as well as with higher rates of many chronic medical conditions. Studies have shown that a high number of depressive symptoms are associated with poor health and impaired functioning, whether or not the criteria for a diagnosis of major depression are met.

In 2008 a US Department of Health Study estimated the Annual Cost of Depression to the US in 2000 was US\$83 billion. The study went on to estimate that one in 20 Americans over the age of 12 has current depression and stated **“Depression is a major public health problem, and increasing the number of Americans with depression who receive treatment is an important public health goal and a national objective”**. In September 2011 in a Report titled “The Global Economic Burden of Non-communicable Diseases” the Harvard School of Public Health stated that **“Mental illness alone will account for more than half of the projected total economic burden over the next two decades.”**

### **Invatec Transaction Agreement**

BPO has entered into a deed of option with Invatec and key shareholders holding more than 94% of the shares in Invatec. The Invatec transaction is a 2 stage investment with a 6 month option term. Upon the exercise of the option, BPO will have a right to subscribe for a 35% interest in Invatec (stage 1 subscription) by sole funding Invatec and the independent validation trials. The investment to fund the Invatec and independent validation trials is capped to a maximum of \$3.5 million over 2 years. On completion of this investment, BPO will have a further option to acquire a further 45% interest in Invatec by way of a share sale from the existing shareholders (vendors) (stage 2 acquisition). If both stage 1 and stage 2 are completed, BPO will acquire an 80% interest in Invatec with the existing shareholders retaining a 20% interest.

By the option agreement, Invatec grants an exclusive option for a 6 month period. BPO has paid a non-refundable option fee of \$50,000 to Invatec. BPO anticipates completing due diligence investigations on Invatec and its technology within a 60 day period. Within this period the parties are to agree fuller form documents (anticipated to be a subscription agreement and shareholders agreement). Exercise of the option is subject to conditions precedent including that BPO raises at least \$1 million and obtains the agreement to the transaction of 100% of the Invatec shareholders (which may be waived by BPO). On exercise of the option, a binding agreement for the stage 1 subscription is formed.

On exercise of the stage 1 option, BPO will issue 150 million BPO shares to the shareholders of Invatec and pay \$50,000 to Invatec, which must be used to partly repay shareholder debt.

During stage 1, BPO has a right to subscribe for a 35% interest in Invatec within 2 years by sole funding Invatec. The funding is intended to be focused on independent validation trials. BPO must pay Invatec a minimum monthly amount to meet its corporate expenses (which amount is to be agreed). For every \$50,000 funded by BPO, it will be entitled to a 0.5% interest in Invatec. Thereby, a subscription of \$3.5 million will equal a 35% interest in Invatec.

BPO may cease funding at any time by providing 3 months written notice to Invatec.

BPO intends to appoint Dr Stephen Addis and (a key shareholder and executive of Invatec) as director of BPO after the exercise of the stage 1 option.

The key shareholders of Invatec have further granted BPO an option (stage 2 option) to acquire Invatec shares a further 45% of the shares in Invatec. On exercise of the stage 2 option, a binding agreement for stage 2 is formed.

By the stage 2 acquisition BPO may acquire up to an 80% interest in Invatec (the initial 35% interest plus a 45% interest).

Completion of the stage 2 acquisition is subject to conditions precedent including BPO raising a total of at least \$3.5 million since execution of the option agreement, BPO obtaining all necessary shareholder and regulatory approvals and the repayment by BPO of all moneys owing under the existing convertible notes.

On completion of the stage 2 acquisition, BPO must issue the number of shares to the vendors so that the total number of BPO shares held by the vendors (including the 150 million shares issued under stage 1) is equal to a 20% interest in the company on a fully diluted basis at that time. Additionally, BPO must pay \$250,000 to Invatec, which must be used to partly repay shareholder debt.

Following completion of stage 2, BPO has agreed to pay the sum of \$1.2 million to Invatec over a 4 year period, which funds will be used by Invatec to extinguish shareholder debt. The key vendors, Stephen Addis and Claude Solitario (as the people to whom the debt is owing), may elect to be issued with BPO shares in lieu of the cash repayment at any time prior to a repayment.

### **Heartlink Transaction Agreement**

Heartlink is an Australian public unlisted company which is the registered holder of patents in Australia, Canada, Israel, Singapore, the United States and New Zealand. The patents are in relation to technology that provides a method for diagnosing psychiatric disorders by the analysis of heart rate patterns. The ownership of patents in respect of this technology is relevant to the technology being developed by Invatec. By acquiring an exclusive licence to use and exploit the technology from Heartlink, it enables Invatec's technology to be developed without restriction.

BPO has entered into a licence and option deed with Heartlink. By this agreement Heartlink has granted an exclusive option to BPO in respect of the intellectual property rights. BPO has issued 25 million BPO shares to Heartlink as a non-refundable option fee. BPO has 60 days from execution of the agreement to exercise the option. During the option period, BPO may carry out due diligence investigations upon the intellectual property rights.

Upon the exercise of the option by BPO, Heartlink grants to BPO an exclusive licence to use the intellectual property rights and exploit the technology in the relevant territory for an initial period of 2 years (stage 1). The territory over which the licence is granted is Australia, Canada, Israel, Singapore, the United States and New Zealand, being the countries in which patents are held. BPO must issue 125 million BPO shares to Heartlink upon the exercise of the option. BPO

may sub-licence its rights to Invatec and BPO will be responsible for maintaining the registration and protection of the patents during the term of the licence.

At the end of the 2 year (stage 1) exclusive licence period, BPO may extend the exclusive use option for up to 25 years (stage 2). If the licence is extended, BPO must issue shares to Heartlink so that the total number of BPO shares held by Heartlink (including 150 million BPO shares already issued) is equal to a 10% interest in BPO on a fully diluted basis at that time. BPO must also pay a royalty to Heartlink. The royalty will be calculated as a percentage of the annual revenue generated by BPO or third parties that BPO has granted a right to use the technology. The royalty is 5% on the first \$20 million of annual revenue, 2.25% on between \$20 million and \$50 million of annual revenue, 1% between \$50 million and \$100 million of annual revenue and 0.5% over \$100 million of annual revenue.

At any time during the term of the licence, the Company has an option to acquire the intellectual property rights and the technology from Heartlink. If the option is exercised before the expiry of the initial 2 year term (during stage 1), BPO must pay the consideration set out above (as if it has extended the licence and entered stage 2). If the option is exercised during the extended term (stage 2), the consideration payable is \$1.

### **Current focus and projects**

Improvement in market sentiment towards the biotechnology sector coupled with progress by BPO in strengthening its cash position and balance sheet (see the ASX announcement of 7 August 2013 concerning the sale of a 25% holding in Frontier Oil Corporation and a debt restructure) has allowed BPO to direct greater resources towards its existing biotechnology assets.

BPO's biotechnology projects comprise AGRIPRO<sup>®</sup>, REGEN<sup>®</sup>, Qcide<sup>®</sup> and TERMILONE<sup>®</sup> which will each receive focus in the next 12 months. A new commercialisation strategy will be implemented for AGRIPRO<sup>®</sup> focusing on local product development and AGRIPRO<sup>®</sup> Topical Gel for horses and potentially other companion animals.

BPO retains a holding in Frontier Oil Corporation (Frontier), which will be subject to a 12 month escrow following Frontier's initial public offering and listing on the Philippine Stock Exchange. This listing has been rescheduled until early 2014 (see ASX announcement of 28 November 2013).

### **Shareholder and Regulatory approvals**

In undertaking stages 1 and 2 of each of the Invatec transaction and the Heartlink transaction, BPO will obtain any necessary shareholder and regulatory approvals.

BPO is seeking advice from ASX as to whether BPO will need to re-comply with Chapters 1 and 2 of the ASX Listing Rules in respect of the stages of the transaction.

<sup>1</sup> World Health Organisation Fact Sheet No. 369 of October 2012.

<sup>2</sup> NCHS Data Brief Number 7, September 2008, Depression in the United States Household Population, 2005-2006

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