



**BioPharmica Limited**  
*Bridging Biotechnology Borders*



# BioPharmica Limited

[ASX: BPH]

## Company Overview

July 2009



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# Executive Summary

BioPharmica Limited [ASX: BPH] is an Australian Securities Exchange listed company developing biomedical research and technologies within Australian Universities and Hospital Institutes.

BioPharmica provides early stage funding, project management and commercialisation strategies for proof of concept for a direct collaboration, a spin out company or to secure a license, whilst the institutional partner provides infrastructure and the core scientific expertise.

Three of BioPharmica's projects have advanced to a stage where we have been able to initiate discussions on commercialisation with domestic and international companies. The most recent development in the novel anti-mitotic cancer therapeutic area addresses a market valued at in excess of one billion dollars (US) per year.

BioPharmica currently partners with several academic institutions including University of Western Australia (UWA), Western Australian Institute for Medical Research (WAIMR), Swinburne University of Technology (SUT) and The Royal Melbourne Institute for Technology (RMIT) University.



**ASX**  
AUSTRALIAN SECURITIES EXCHANGE

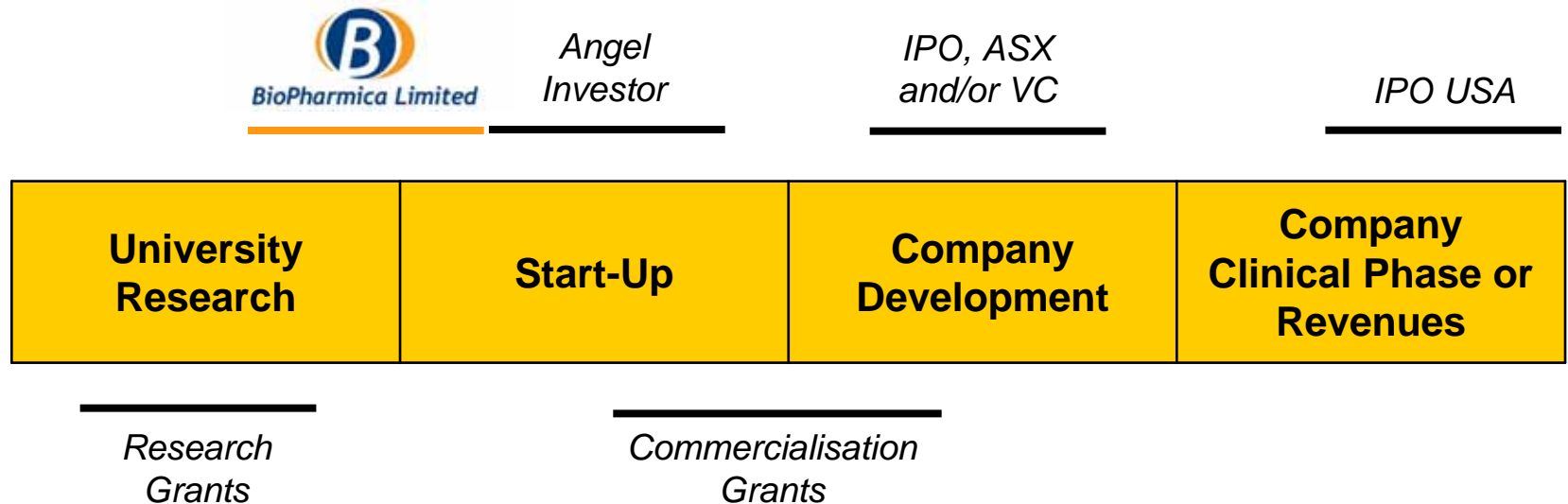


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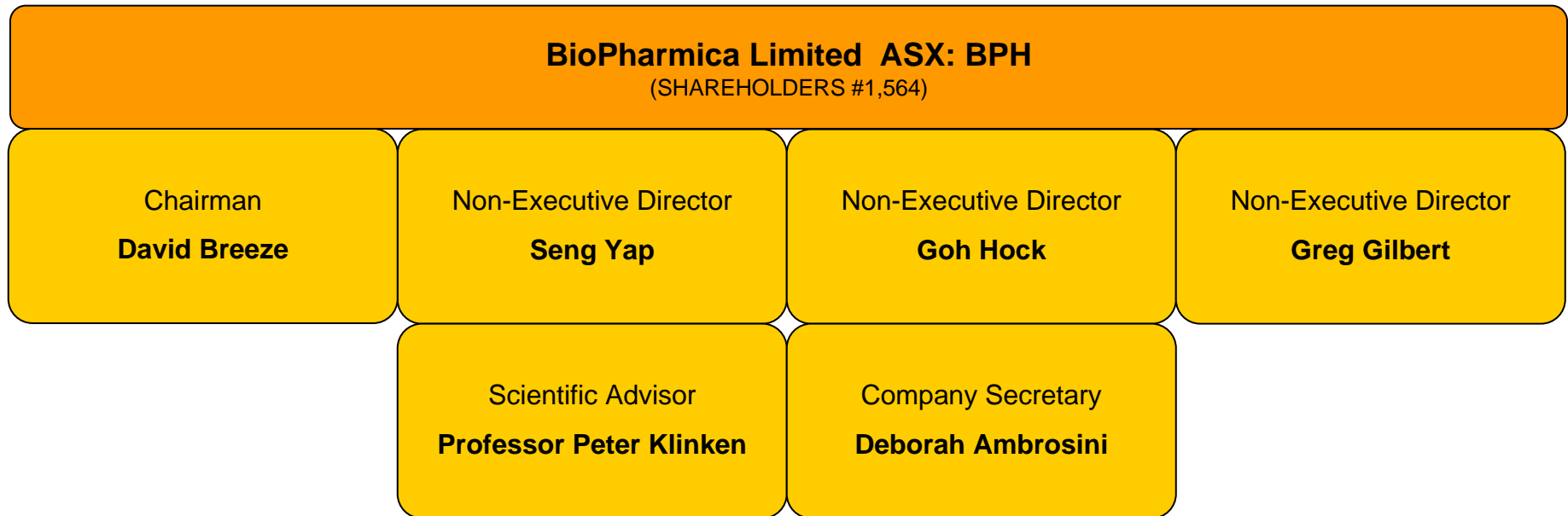
# Strategic Position

**BioPharmica** is an investor in early stage life sciences projects



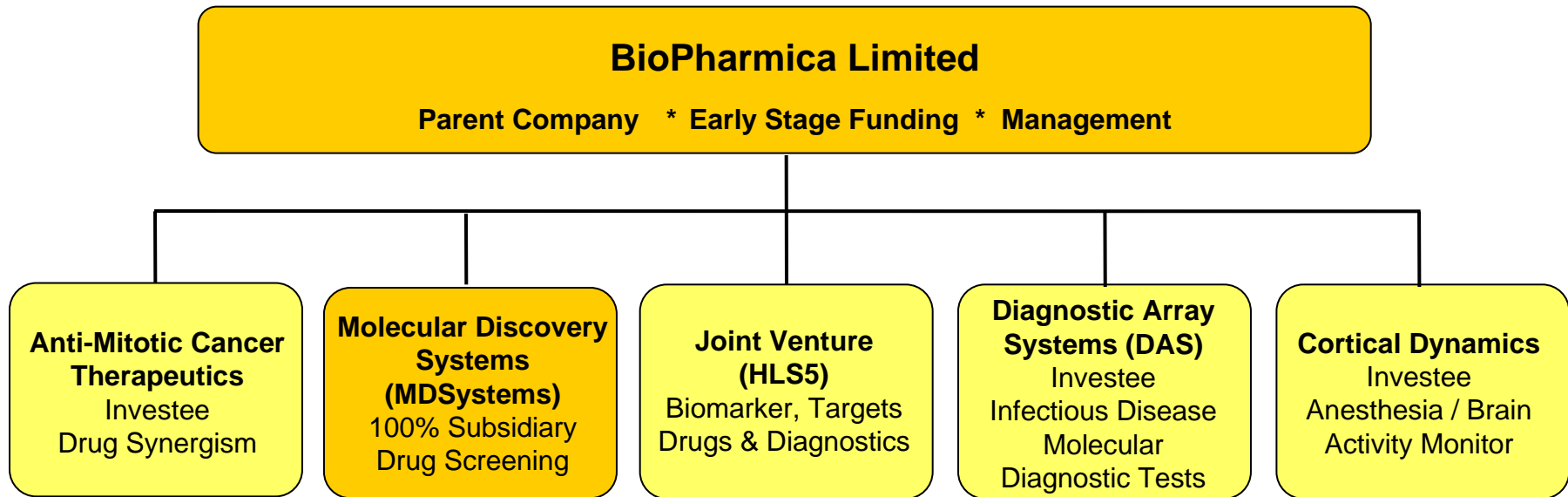


# Corporate Structure





# Project Structure





# Novel Anti-Mitotic Cancer Therapeutics

## Our Technology

Unregulated cell growth and evasion of cell death are two of the fundamental hallmarks of cancer.

BioPharmica has recently identified new anti-cancer agents that inhibit rapid cell growth and promote cell death.

In light of the clinical success of a similar drug, the anti-mitotic blockbuster drug Taxol®, the identification of new and improved anti-mitotic drugs remains one of the primary objectives of current oncology drug discovery. Anti-mitotic drugs are considered to be among the most clinically important cancer drugs discovered to date, generating revenue well in excess of one billion USD per year.

## Stage

Currently in the proof of concept stage, the project is utilising the MDSystems high content platform and *in vivo* trials.

In addition to defining the molecular and cellular modes of action of these compounds, BioPharmica is also actively pursuing hit optimization through *in silico* and *in vitro* medicinal chemistry.



# Novel Anti-Mitotic Cancer Therapeutics

## Data

The exceptional tumour inhibitory activity of anti-mitotic drugs is due to their unique ability to inhibit cell proliferation and promote cell death (Figure 1).

Our data supports this mechanism of action.

## Intellectual Property

The compounds isolated in the drug development program are novel and protected via provisional patent application.

## Potential

BioPharmica aims to progress the research program through to selecting a preclinical drug candidate at which point a co-development partner will be sought to progress the compound through to clinical trials.

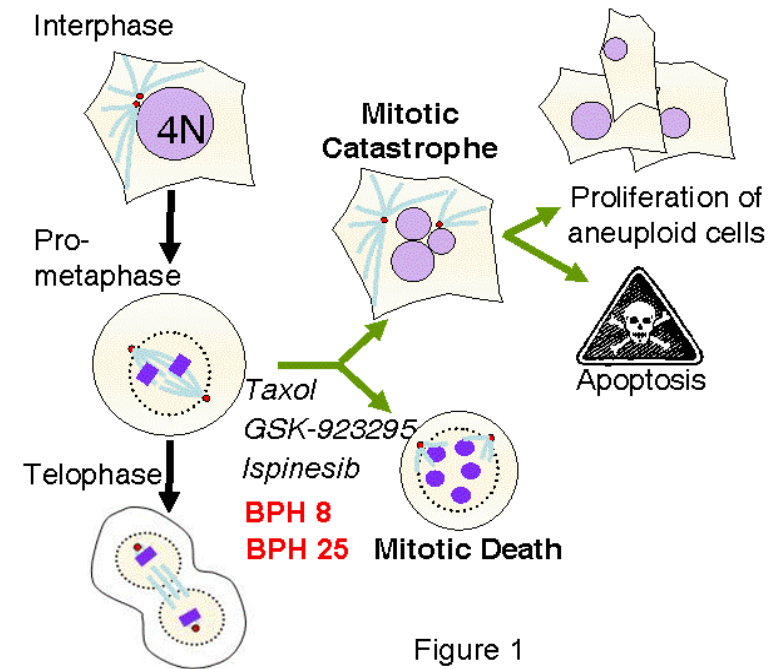


Figure 1



# Molecular Discovery Systems

Molecular Discovery Systems (MDSYSTEMS) is a 100% owned subsidiary of BioPharmica Limited.

The main business is drug discovery and the validation of biomarkers for disease, therapy and diagnostics.

MDSYSTEMS also provides screening services using the core expertise in high content analysis for researchers world-wide.

The MDSYSTEMS owned InCell Analyser 1000 combines high resolution imaging and high-content analysis to provide a technology that rapidly detects and quantifies components of the cell much faster than conventional methods.

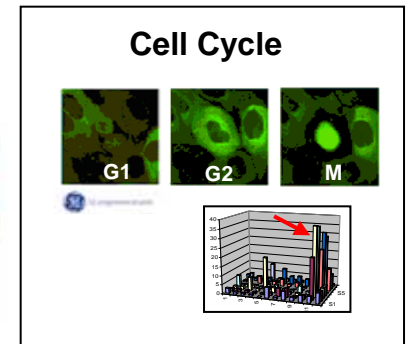
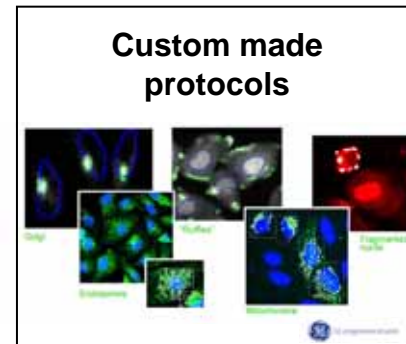
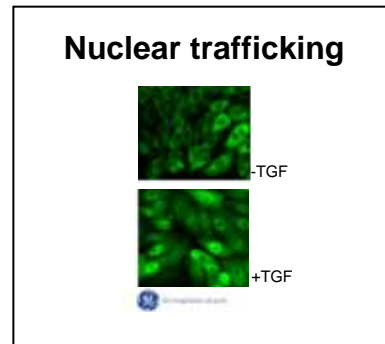




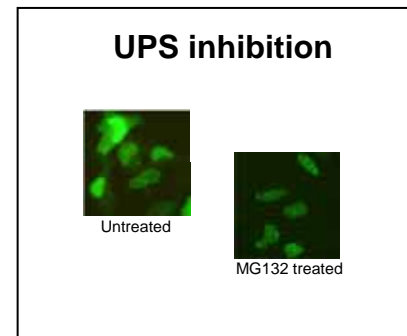
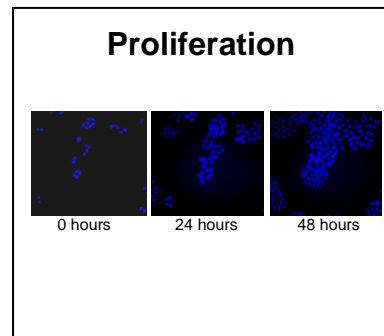
# Molecular Discovery Systems

High content analysis utilises high-resolution fluorescence imaging and advanced image analysis to visualise cell based assays. It is a technique used by pharmaceutical and biotech industries in their drug development process for mechanism of action studies, target identification, and can unveil potential toxicities not detected in other assays. This technique can visualise the effects of drug compounds on multiple biological pathways simultaneously. The effects of a drug compound on a particular protein(s) can be visualised and quantitated. Here are some examples:

## High-Content Analysis



## High-Throughput Screening

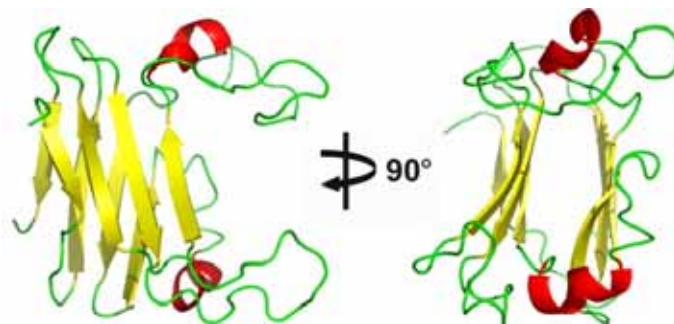




# Tumour Suppressor Gene HLS5

BioPharmica's tumour suppressor gene project was reported by Professor Klinken's team in 2004. In conjunction with BioPharmica the expert team at The West Australian Institute for Medical Research (WAIMR) led by Director Professor Peter Klinken are continuing with the research.

Currently the team is investigating the tumor suppressor gene HLS5 and its potential influence in Cancer. However, the concerted research efforts previously undertaken reveal that HLS5 works through multiple pathways that may target cancer as well as a range of other diseases.





# Tumour Suppressor Gene HLS5

BioPharmica has developed an extensive patent portfolio and has exclusive rights to the tumor suppressor gene HLS5 both as a potential therapeutic target and also underpinning its involvement in a variety of disease pathways. The patent portfolio of technology surrounding HLS5 is currently going through National Phase filings in Australia, US and Europe. The Tumor Suppressor Gene HLS5 has a large amount of data gathered with the continued support of the Western Australian Institute for Medical Research.

BioPharmica is seeking out-licensing or co-development opportunities with large pharma / biotech.

## Therapeutic Target

Tumour Suppressor Gene

Regulates transcription / signaling pathways

## Anti-Cancer Therapy

Gene Therapy

Small molecules

## Biomarker / Diagnostic Assays

Detect presence and severity of disease

Determine types of cancer and patients to target

## Screening Assays / Research Tools

To find compounds for anti-cancer therapy

To determine MoA and relevance to disease



# Diagnostic Array Systems (DAS)

## Technology

The BacTrak System is a diagnostic test for the detection of respiratory infections (e.g. diagnosis of pneumonia, Tuberculosis (TB) and Legionella disease). Our system identifies the cause of disease by testing for multiple bacteria in a single sputum sample quickly, efficiently and more accurately than current techniques.

## Current Status

The research has been completed with in-house validation and we have now initiated discussions with third parties to license the technology and progress the product to market.

## Intellectual Property

The IP (PCT WO 2007/012131 A1) relates generally to a method of identifying micro-organisms in a sample using a *tuf* gene variable region. Currently going through national phase in Australia, China, Europe, Japan and the US.





# Diagnostic Array Systems (DAS)

<p><b>Conventional Method</b></p> <ul style="list-style-type: none"><li>• Not automated</li><li>• Requires 2-3 days or several weeks for some bacteria</li><li>• Single test at a time</li><li>• Uncertain results</li><li>• Success rate 20%</li><li>• Requires bacterial targeting</li><li>• Disposal of tests require additional safety procedures as bacteria remain infective</li></ul>	<p><b>BacTrak Method</b></p> <ul style="list-style-type: none"><li>• Most of the procedure automated</li><li>• Requires only 4-5 hours for all bacteria</li><li>• Multiple tests done simultaneously</li><li>• Accurate results</li><li>• Success rate 90-100%</li><li>• Does not require bacterial targeting</li><li>• Disposal of tests does not require additional safety procedures as no live organisms used</li></ul>
<p><b>BacTrak Data</b></p> <ul style="list-style-type: none"><li>• Assay validated for 16 pathogens</li><li>• SOP's in place</li><li>• Software in development</li><li>• <i>Tuf</i> gene exemplified as gene of choice</li><li>• Success rate 90-100%</li></ul>	<p><b>BacTrak Process</b></p> <pre>graph TD; A["Sputum DNA extraction QIAamp DNA kit 30 mins"] --&gt; B["PCR Amplification Standard equipment 2 hours"]; B --&gt; C["Microarray hybridization Pre-prepared arrays 1 hour"]; C --&gt; D["Image capture and analysis Affymetrix array scanner 15 mins"];</pre>

**The objective is for a diagnostic company to license the BacTrak technology in the field of respiratory infection diagnosis.**



# Cortical Dynamics

## Technology

- Brain activity monitor that measures EEG
- Algorithm based on physiology underlying the EEG signal

## Product

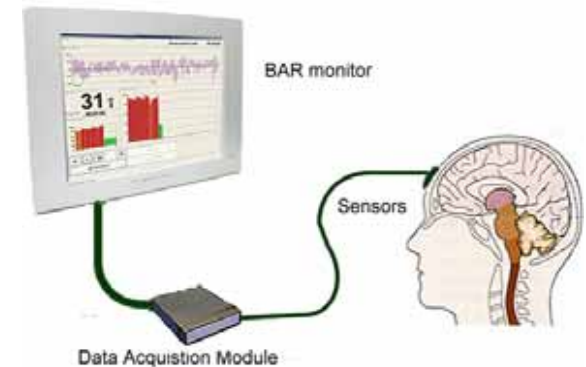
- Brain Anaesthesia Response (BAR) Monitor
- Other potential uses: Neurodiagnostics and drug monitoring. The market for depth of anaesthesia monitoring and Neurodiagnostics is expected to reach around US\$1 billion by 2010.

## Current Status

- Prototype monitor developed and built
- Clinical trials of algorithm in progress

## Intellectual Property

Cortical Dynamics patent portfolio is currently going through national phase in Australia, Europe, China, New Zealand and the US.





# Cortical Dynamics

- The Cortical Dynamics BAR analysis is based on the physiological mechanisms that generate brain electrical activity allowing the BAR Monitor to be quicker, far more sensitive and accurate than existing monitors.
- The Cortical Dynamics team have completed two clinical trials both conducted at The Royal Melbourne Hospital.
- The trials proved scientific acceptance for the Brain Anaesthesia Response (BAR) analysis methodology and shows superiority over existing monitoring approaches.
- The current program is to trial the BAR's sensitivity with the most commonly used anaesthetic drugs.
- The team has published in the peer reviewed international journal *Computers in Biology and Medicine*.
- Cortical Dynamics has initiated discussions for the licensing of this technology with leading global companies in this sector.





# Competitive Advantages

- BioPharmica partners with academic institutions on projects that have excellent scientific merit, strong intellectual property position and commercial potential.
- Research is carried out by the acknowledged experts in the field while BioPharmica provides the commercial direction and focus.
- BioPharmica has a balanced management system combining corporate and scientific expertise.
- The company head office is based in Perth, Western Australia giving it an ideal position for interactions with Asia.
- BioPharmica facilitates the tech-transfer process from academia to the pharma / biotech industry and provides potential partners / licensees with attractive opportunities.



- Significant potential return for investors.
- Current license and commercial opportunities in three of its project portfolio.
- Anti-cancer therapeutic and the BAR monitor both address product areas which have \$1 billion US market size.
- The DAS BacTrak product has global market application.
- Commercial outcomes have capacity to significantly impact on the company in the near term.
- Current market capitalization of \$1.5 million with 74 million shares on issue.



**BioPharmica Limited**

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