

# Investment Overview

**BioPharmica intends to seek an IPO for investee Molecular Discovery Systems on the Australian Securities Exchange. Molecular Discovery Systems will be a company dedicated to the Anti-Mitotic Drug Discovery Development Program and the tumour suppressor gene HLS5 along with its current high content screening facility. Under a planned 'spin off' process, BioPharmica (ASX: BPH) shareholders would receive a share at no cost in Molecular Discovery Systems for every listed BioPharmica share that they hold five days after the date of the shareholder approval of the spin off.**



BioPharmica Limited 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 commercial strategies, whilst the institutional partner provides the potential opportunity, the majority of the infrastructure and the core research expertise.

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

New commercially targeted projects have been spun out of the original BioPharmica portfolio of research which includes a possible new anti-cancer therapeutic and a new anti-cancer strategy. The most recent development in the novel anti-mitotic cancer therapeutic area addresses a market which

is one of the primary objectives of current oncology drug discovery. Clinically approved anti-mitotic drugs (e.g. Taxol® and Velban®) currently attract in excess of one billion dollars (US) in revenue per year. Since new and improved anti-mitotic drugs can be expected to have a similar revenue potential, they are actively being sought by most pharmaceutical companies.

BPH Chairman, Mr David Breeze said "We are excited about the new research being undertaken as it has excellent commercial development opportunities. Discussions have already been initiated with international companies with the objective of licensing the development of these projects. It is anticipated that the research program will enable developments in this area within this financial year".

**Please see following an update on business activities, technologies being developed and media coverage.**

## BioPharmica Exploration Update

[www.wotnews.com.au](http://www.wotnews.com.au)

10 August 2009

### BioPharmica (ASX: BPH) ASX Announcement New Anti-Mitotic Drug Development for Pre-Clinical Testing.

A new class of anti-mitotic drugs, discovered by BioPharmica's cancer cell biology researcher Dr Robin Scaife, has undergone extensive development toward pre-clinical testing of anti-cancer activity. Detailed analysis of chemical analogues of the new drug have yielded a new drug that exhibits nearly 1000 times the biological activity of the initial compound derived by screening of a chemical library. This new drug has also recently undergone testing in animals to rule out adverse toxic side-effects.

Animals exposed to very high levels of the new drug exhibited no signs of acute toxicity. BioPharmica's new anti-mitotic drug is, therefore, primed for pre-clinical testing of anti-tumour activity, and it is anticipated that the research program may enable commercial development within this financial year.

The inhibition of cell proliferation and induction of cancer cell death is due to the anti-mitotic activity of these potential new drugs.

Anti-mitotic drugs, such as the blockbuster anti-cancer drug Taxol®, are considered to be among the most clinically important cancer drugs discovered to date, generating revenue well in excess of one billion USD/yr. Taxol® has become one of the most valuable cytotoxic chemotherapeutic agents we have in clinical oncology. It has proven effective in ovarian, breast, lung and head and neck cancer and it has contributed immensely to the quality of life of cancer patients ([www.medicalnewstoday.com/articles/26471.php](http://www.medicalnewstoday.com/articles/26471.php)). In 2000, BMS reported its annual sales of Taxol® was \$1,592 billion – equal to excess \$4.3 million per day ([www.21cecpharm.com/px](http://www.21cecpharm.com/px)). A taxane is a type of chemotherapy that stops living cell division in order to fight tumors.

## Molecular Discovery Systems (MDSys) High Content Imaging Technology

MDSys is located in the Western Australian Institute for Medical Research and has core expertise in high content and high throughput imaging and analysis. Services are able to be provided to researchers utilizing the InCell Analyser 1000 and is currently undertaking works for the Lung Institute of Western Australia (LIWA). Also continuing collaboration with the Laing Group screening to help find a cure to Floppy Baby Syndrome.



**Rachel Ramsdale**  
Research Scientist

### Molecular Discovery Systems

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## THE WEST AUSTRALIAN Business

[thewest.com.au/business](http://thewest.com.au/business)

Wednesday, August 12, 2009

### BioPharmica rises after drug trials

VIVIENNE RYAN

BioPharmica is closer to commercializing its anti-cancer drug after completing successful medical trials, sparking a share price rally. The company's shares have rallied from Friday's close of 2.6 cents to 12 cents yesterday on news its anti-mitotic drug had passed animal trials. Chairman David Breeze declined to comment on whether BioPharmica had been approached by a pharmaceutical company interested in commercializing the drug but said the company was focused on achieving milestones required to take the drug to a commercial partner. The drug has been developed in collaboration with the University of WA.

Friday, August 14, 2009

### BioPharmica drug plan

BioPharmica is planning to spin off its anti-cancer drug into a separate listed company called Molecular Discovery Systems. The local biotechnology player has launched its share purchase plan for the new company that will be dedicated to its anti-mitotic drug which boasted successful animal trials this week. BioPharmica shares have soared 1130 per cent this week, from its 2.6 cent close last Friday to 32 cents.

## Anti-Mitotic Cancer Therapeutics



**Dr Robin Scaife**  
Principal Scientist

A new class of anti-mitotic drugs, discovered by BioPharmica's cancer cell biology researcher Dr Robin Scaife, has undergone extensive development toward pre-clinical testing of anti-cancer activity.

Detailed analyses of chemical analogues of the new drug have yielded a new drug that exhibits nearly 1000 times the biological activity of the initial compound derived by screening of a chemical library. This new drug has also recently undergone testing in animals to rule out adverse toxic side-effects. Animals exposed to very high levels of the new drug exhibited no signs of acute toxicity.

We expect to shortly commence testing of the anti-tumour activity in vivo using a variety of animal models of tumour growth. In light of the anti-tumour activities of other anti-mitotic drugs, we expect our pre-clinical/animal testing of anti-tumour activity to be successful.

The inhibition of cell proliferation and induction of cancer cell death is due to the anti-mitotic activity of these potential new drugs. Anti-mitotic drugs, such as the blockbuster anti-cancer drug Taxol®, are considered to be among the most clinically important cancer drugs discovered to date[1], generating revenue well in excess of one billion USD/yr[2],[3]. In light of the clinical success of the anti-mitotic microtubule drug Taxol®, the identification of new and improved anti-mitotic pharmacophores remains one of the primary objectives of current oncology drug discovery.

We are actively undertaking the research along with seeking co-development. The outcomes for this project will be: New anti-cancer drug; characterized anti-cancer drug and validated anti-cancer drug / characterisation of drug synergy at a cellular level, molecular level and validated new anti-cancer strategy.

Unregulated cell proliferation and evasion of cell death (apoptosis) are two of the fundamental hallmarks of cancer. While a number of pharmacological agents can target cell proliferation or apoptosis, anti-mitotic agents have proven to be among the most clinically effective anti-cancer drugs. The exceptional tumour inhibitory activity of anti-mitotic drugs is due to their unique ability to link perturbation of cell

proliferation (metaphase arrest) with apoptosis (mitotic death and/or catastrophe) (Figure 1).

Given that pharmaceutical industry has invested billions of dollars in anti-mitotic drug research and development, a new drug candidate can generate a lot of interest. Several dozen pharmaceutical companies (i.e. nearly all of those that we have approached) have expressed interest in our anti-mitotic drug. Co-development will, however, first require completion of the testing with animals.

It is likely that, similar to other mitotic drugs, our new compounds will exhibit anti-tumour activity in animal models. We expect to be able to validate the in vivo anti-tumour activity in about 6 months, and this will pave the way to commercialisation. When one considers the revenue generated by Taxol® and other microtubule drugs, the potential financial windfall is enormous.

- [1] "Taxol has become one of the most valuable cytotoxic chemotherapeutic agents we have in clinical oncology. It has proven effective in ovarian, breast, lung, and head and neck cancer and it has contributed immensely to the quality of life of cancer patients," ([www.medicalnewstoday.com/articles/26471.php](http://www.medicalnewstoday.com/articles/26471.php))
- [2] "In 2000, BMS reported its annual sales of Taxol® was \$1.592 billion - equal to excess \$4.3 million per day" ([www.21cecpharm.com/px](http://www.21cecpharm.com/px))
- [3] "A taxane is a type of chemotherapy that stops cell division in order to fight tumors. Sales of taxanes were approximately \$2 billion in 2007," ([www.wikinest.com/stock/Abraxis\\_BioScience\\_\(ABII\)](http://www.wikinest.com/stock/Abraxis_BioScience_(ABII)))

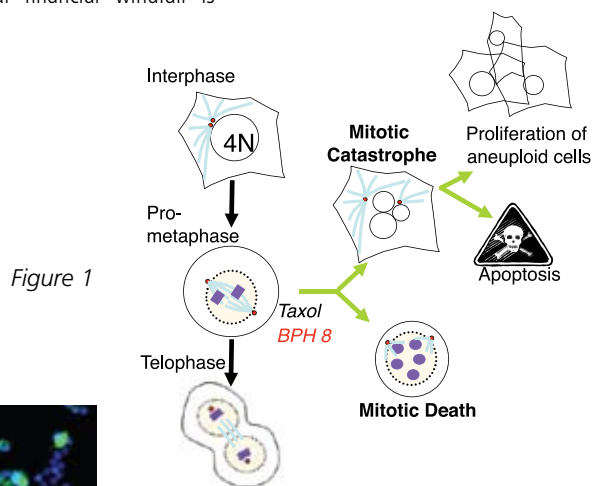
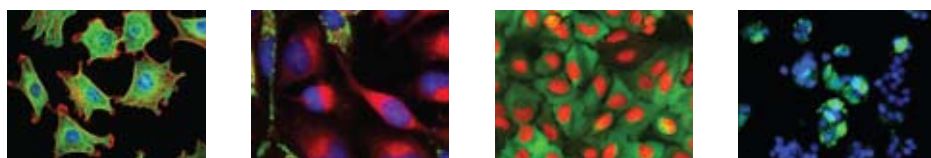


Figure 1



**BioSpectrum**  
ASIA EDITION

Singapore, Aug 10, 2009

### BioPharmica's anti-mitotic drug for pre-clinical testing

A new class of anti-mitotic drugs, discovered by BioPharmica's cancer cell biology researcher Dr Robin Scaife, is said to have undergone extensive development toward pre-clinical testing of anti-cancer activity. Detailed analysis of chemical analogues of the new drug have yielded, according to the company, a new drug that exhibits nearly 1000 times the biological activity of the initial compound derived by screening of a chemical library.

This new drug recently underwent testing in animals to rule out adverse toxic side-effects. Animals exposed to very high levels of the new drug is said to have exhibited no signs of acute toxicity. BioPharmica's new anti-mitotic drug is, therefore, primed for pre-clinical testing of anti-tumor activity, and it is anticipated that the research program may enable commercial development within this financial year.

The inhibition of cell proliferation and induction of cancer cell death is due to the anti-mitotic activity of these potential new drugs. According to BioPharmica, anti-mitotic drugs, such as the blockbuster anti-cancer drug Taxol, are considered to be among the most clinically important cancer drugs discovered to date, generating revenue well in excess of \$1 billion per year.

BioPharmica has also announced that a new agreement between the University of Western Australia (UWA) and BPH has been finalized to replace the HLS5 Collaborative Research and Technology Farmin Agreement.

Under the new agreement BPH will own 100% of the intellectual property of the HLS5 project and its derivatives developed during the research and development. BPH will also continue to sole fund the development of the projects. In exchange for the ownership of the intellectual property BPH

will pay the UWA an agreed net royalty upon commercialization.

As part of the new agreement the company has appointed Dr Robin Scaife as the lead scientist on the project. Dr Scaife who was previously employed by the University of Western Australia will now continue his research as a full time employee of BPH. Dr Scaife will head up the BPH Laboratory located at the Western Australian Institute for Medical Research (WAIMR).

BPH's chairman, Mr David Breeze said "We are excited about the new research being undertaken as it has excellent commercial development possibilities. Discussions have already been initiated with international companies with the objective of licensing and development of these projects. It is anticipated that the research program will enable developments in this area within this financial year".



## BioPharmica progresses toward cancer treatment

Written by Laura Glitsos Friday, 21 August 2009

BIOPHARMICA Ltd (BPH) is sailing toward pre-clinical testing of a new class of anti-cancer drugs, with Dr Robin Scaife at the helm.

The progress coincides with the announcement of BPH's new agreement with the University of Western Australia, which stipulates BPH will now own 100 percent of the intellectual property of the HLS5 project and derivatives, including the anti-cancer agents.

The research has profound implications, considering current approved anti-mitotic drugs such as Taxol® and Velban® attract more than US\$1 billion in revenue per year, according to BPH.

Project leader Dr Robin Scaife says this new class of anti-mitotic drugs represent an important category of anti-neoplastic cancer therapeutics.

"By blocking cell division (mitosis), they can profoundly inhibit tumour growth and even cause tumour shrinkage," he says.

"The new growth inhibitory drug that I have discovered is an anti-mitotic drug, therefore, it directly inhibits cell division, thereby killing most human cancer cells tested to date."

Mitosis requires the assembly of a highly complex and tightly regulated cellular structure, known as the mitotic spindle, which orchestrates the chromosome segregation that is required for cells to divide and proliferate.

According to Dr Scaife, the new drug perturbs the spatial/3D organisation of the mitotic spindle, thereby preventing the chromosome segregation and cell division/proliferation.

Dr Scaife says his anti-mitotic drug discovery may represent a new, or third, class of mitotic spindle inhibitors.

"Its mode of action appears to be quite distinct from the effects of mitotic kinase and mitotic kinesin inhibitors on dividing cells," he says.

"The first generation of anti-mitotics like Taxol® affect the assembly of the protein fibres (microtubules) that form the mitotic spindle.

"While these drugs block cell division and are effective at inhibiting the proliferation of cancerous cells, they also tend to cause undesirable side-effects such as neuropathy.

"These side-effects are largely due to inhibition of other important microtubule functions and these microtubule drugs also suffer from the ability of most cancerous cells to develop resistance to them."

BPH chairman Mr David Breeze says detailed analyses of chemical analogues of the new drug have yielded a new drug that exhibits nearly 1000 times the biological activity of the initial compound derived by screening of a chemical library.

"This new drug has also recently undergone testing in animals to rule out adverse toxic side-effects and animals exposed to very high levels of the new drug exhibited no signs of acute toxicity," Mr Breeze says.

Dr Scaife says the next step will be testing the anti-tumour activity in vivo using a variety of animal models of tumour growth.

"In light of the anti-tumour activities of other anti-mitotic drugs, we expect our pre-clinical/animal testing of anti-tumour activity to be successful," he says.

## HLS5 Tumour Suppressor Gene Biomarkers and Therapeutics



**Professor Peter Klinken**

Director, WAIMR



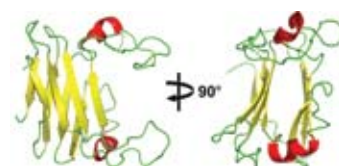
Professor Klinken and his team's discovery of a tumour suppressor gene called HLS5 is providing fresh hope of tackling a number of cancers. The gene may be able to be used to slow the rate of some cancers. In effect, HLS5 acts in much the same way as a brake cable in a car – if the cable is cut, then the gene can't do its job and cell growth can't be controlled, leading to cancer. The research could lead to the development of a drug that mimics HLS5 to slow and even stop the growth of cancer cells. The team is also working to produce a test for the gene which could indicate a person's risk of developing breast, prostate, liver, ovarian and colon cancer. BioPharmica has been working with the Western Australian Institute for Medical Research (WAIMR) since 2004 to develop and validate HLS5 as a novel tumour suppressor gene.

BioPharmica's representatives attended BIO2008 in San Diego to discuss with international pharma groups potential licensing opportunities for HLS5. Professor Klinken and his team at the MRF Laboratory are currently working on a number of milestones that will help carry the research through to a commercial point.

The team presented at ComBio Signalling and Cancer Symposium in Canberra, the American Society of Hematology (ASH) and presented a poster at the Lorne Cancer Conference in Victoria.

The team has also been awarded a grant from the Scott Kirkbride Melanoma Research Centre (SKMRC). Thanks to the grant Dr Winteringham will now lead a team at WAIMR investigating the tumour suppressor gene HLS5 and its potential influence in Melanoma.

BioPharmica has developed an extensive patent portfolio around HLS5 both as a potential therapeutic target and underpinning its involvement in a variety of disease pathways. BioPharmica has exclusive rights to the tumour suppressor gene 'HLS5'. The Tumour Suppressor Factor patent has been granted in Australia and more recently in the United States of America.



## proactiveinvestors

Tuesday, August 11, 2009

### BioPharmica receives U.S. Patent for exciting tumour suppressor gene in cancer fight

Recent investors in BioPharmica (ASX: BPH) would have done a jig today, as the share price shot up over 140% to 12 cents.

On news, that the patent "Tumour Suppressor Factor" No.7560253 has been issued as a patent in the United States. The HLS5 tumour suppressor gene was reported by Professor Klinken's team in 2004.

Potentially, the gene could have a significant part to play in the fight against cancer. Currently, BioPharmica 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.

It 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.

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.

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

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 acquires all of HLS5; develops anti-mitotic drug

Monday, August 10, 2009

Biopharmica has acquired all rights to anti-cancer compound HLS5 from the University of Western Australia and has appointed Dr Robin Scaife to develop anti-mitotic cancer drugs.

Biopharmica said an agreement with the University replaced the HLS5 collaborative research and technology farm-in agreement giving Biopharmica the outstanding 16 percent of the intellectual property held by the University in the HLS5 project and its derivatives in exchange for a royalty on commercialization.

Biopharmica said it alone would fund the development of the projects. The company said new commercially targeted projects had been spun-out of the original program as a result of the last four years of research which included a possible new anticancer therapeutic and a new anti-cancer strategy.

Biopharmica said the most recent development in the anti-mitotic cancer therapeutic area addressed a market in which current clinically approved anti-mitotic drugs such as Taxol and Velban had revenue of more than \$US1 billion a year. As part of the agreement cancer cell biology researcher Dr Robin Scaife has been

appointed lead scientist on the anti-mitotic project.

The company said Dr Scaife was previously employed by the University of Western Australia and would continue his research as a full time employee and would be in charge of the Biopharmica laboratory at the Western Australian Institute for Medical Research.

Biopharmica chairman David Breeze said discussions had been "initiated with international companies with the objective of licencing and development of these projects ... within this financial year".

The company said a new class of anti-mitotic drugs, discovered by Dr Scaife had undergone "extensive development toward pre-clinical testing of anti-cancer activity".

Detailed analyses of chemical analogues yielded a new drug that exhibited nearly 1000 times the biological activity of the initial compound derived by screening of a chemical library, Biopharmica said.

The company said the new drug had recently undergone testing in animals to rule out adverse toxic side-effects and animals exposed to very high levels of the drug exhibited no signs of acute toxicity and the anti-mitotic drug was "primed for pre-clinical testing of anti-tumor activity".

Biopharmica was as high as 5.5 cents, closing up 2.4 cents or 92.3 percent at five cents.

## BioPharmica up 10-fold in 3 days; share plan; spin-out

Wednesday, August 12, 2009

Biopharmica jumped a further 187.5 percent today on news of a share plan to spin-out Molecular Discovery Systems as stand-alone cancer drug company.

Biopharmica's share price peaked at 32.5 cents, a 22.5 cents or 187.5 percent increase above yesterday's close of 12 cents, itself a 140 percent rise on the previous day's five cent close.

According to data from Commonwealth Securities, Biopharmica's shares traded at a high of 32.5 cents at 10.19am.

Biopharmica closed at five cents on August 10, having closed on Friday August 7, 2009 at 2.6 cents. Over the past 12 months the company has traded between 1.8 cents and 4.5 cents.

Today, Biopharmica said it intended to seek an ASX initial public offering for investee company Molecular Discovery Systems, dedicated to the anti-mitotic drug discovery development program and the tumor suppressor gene HLS5 (BD: Aug 10, 2009).

Under the share plan and spin-off, Biopharmica would retain an interest in the company and its shareholders would receive a share at no cost in Molecular Discovery Systems for

every listed Biopharmica share that they hold five days after the date of shareholder approval of the spin off.

The company said that an eligible Biopharmica shareholder can participate in the share purchase plan and receive the same number of shares at no cost in the Molecular Discovery Systems IPO.

The spin off and listing is subject to approval from shareholders and regulatory bodies.

Biopharmica said the funds raised from the share plan would be used for continuing research and development, commercialization, additional working capital, funding the IPO and to meet anticipated expenses of the issue.

Eligible shareholders can purchase shares, at a 20 percent discount to the weighted average price of the last five days prior to the day on which the issue is made.

The plan offers a minimum of \$1000 and a maximum of \$15,000 worth of shares per shareholder and is limited to 30 percent of the existing share capital with applications "accepted on a first received basis".

Biopharmica said the record date for the share plan was August 21, 2009 with a document dispatch date of August 24 and a closing date of September 24, 2009.

Biopharmica closed up 14 cents or 116.7 percent at 26 cents with 7.3 million shares traded.

## Life Sciences West

Western Australian BioTechnology Update - Issue 3

June 2009

## Screening to help find a cure to Floppy Baby Syndrome

Molecular Discovery Systems (MDSys) research scientist Rachel Ramsdale is currently collaborating with the Laing Neuromuscular Diseases Group to screen medications that might increase heart actin in skeletal muscles. This screening could potentially offer a treatment for many patients born with Floppy Baby Syndrome.

In a world first, Western Australian scientists have recently cured mice of a devastating muscle disease that causes Floppy Baby Syndrome, a congenital myopathy disorder that causes babies to be born without the

ability to properly use their muscles. The research has been published online in the journal of Cell Biology and reveals how the team's efforts have cured mice born with the condition.

Lead author of the publication Dr Kristen Nowak said this was 'proof of principle' towards one day hopefully being able to better the lives of human patients.

The collaboration with MDSys allows the screening of more than a thousand already approved medications. They are looking for

one that might increase heart actin in skeletal muscles that could ultimately help thousands of families across the globe. The currently incurable genetic disease renders most of the affected children severely paralysed and takes the lives of many of these children before the age of one.

Both MDSys and the Laing Neuromuscular Diseases Group are located at the Western Australian Institute for Medical Research and have been collaborating on the French Muscular Dystrophy Association Grant since 2008. The grant will be brought to fruition by

the involvement of the MDSys sophisticated high-content screening and development facility.



InCell Analyser 1000



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