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Propanc Biopharma Inc

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Propanc CEO looks to harness power of pancreatic enzymes in cancer fight

Propanc CEO James Nathanielsz was first introduced to the power of pancreatic enzymes while a post-graduate business student at Swinburne University of Technology in Melbourne, Australia. It was there that he got to know Propanc's original chairman Dr. Doug Mitchell and set about putting together a strategy to develop and commercialize Propanc's lead drug PRP as a proper pharmaceutical product. Together with Dr Mitchell and current chief scientific officer Dr Julian Kenyon, Nathanielsz launched Propanc in 2007 to develop new cancer treatments.

The company's thesis is that pancreatic enzymes can be used to halt the spread of cancer. And its lead drug candidate PRP is a solution of two proenzymes, trypsinogen and chymotrypsinogen, administered by I.V. injection, that take aim at solid tumors.

In a recent interview, Proactive Investors sat down with Nathanielsz to discuss the drug maker's latest advances.

Can you explain the science behind Propanc?

Pancreatic enzymes have been around nearly 100 years, so it's not something that's come out of the blue.

At the turn of the 19th century, Professor John Beard was doing this investigative work at the University of Edinburgh. What he did was look at the way proenzymes are secreted by the pancreas when embryos are developing in the mother. And what he recognized is that basically when these enzymes are secreted, it would prevent a very rare disease called trophoblastic disease - a form of cancer.

Recognizing that this might be a method of potentially stopping cancer from spreading, he started injecting the pancreatic enzyme trypsin into patients directly and found some amazing results. Years later, in the late nineties, at Bucknell University in Pennsylvania, a molecular biologist by the name of Josef Novak started to look at Beard's work again based on the advancement and understanding of looking at less toxic ways and more targeted treatments that can control the spread of cancer. He published a paper on the topic and went on to collaborate with a retired oncologist from the Czech Republic named Frantisek Trnka. Together, they published a paper and went on to administer the proenzymes to patients. One of Propanc's founders Dr Julian Kenyon reached out to them. He collaborated with them and he devised a formulation with a manufacturer in the UK to treat patients with pancreatic enzymes in his clinic by compassionate use.

Can you provide more detail about how these pancreatic enzymes curb cancer?

Price:	$0.80
Market Cap:	$676.02 k

1 Year Share Price Graph

Share Information

Code:		PPCB
Listing:		OTCQB
52 week	**High**	**Low**
	67	**0.06**
Sector:		**Pharma & Biotech**
Website:		**www.propanc.com**

Company Synopsis:

Propanc Biopharma, Inc. is a clinical stage biopharmaceutical company focused on developing new cancer treatments for patients suffering from pancreatic, ovarian and colorectal cancers. Together with our scientific and oncology consultants, we have developed a novel therapeutic approach based on 100 years of the scientific study of enzyme use.

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In the last ten years, we've uncovered that pancreatic enzymes basically assist with cell-to-cell contact and communication. What's very interesting is that cancerous cells or the ones that are malignant and spread, express certain proteins which in normal cells are turned off. When these proteins are expressed, cancerous cells become stem-cell like. For a cancer cell to spread, it needs to express these proteins. And when solid tumors start spreading, what the proenzyme markers do is they stop the expression of these mesenchymal markers and push the cells back to expressing epithelial markers.

To the best of our knowledge, there's no one out there who is really applying the same approach that we're doing where we're not directly killing the cancer stem cells, but forcing them to express proteins they normally wouldn't and they die naturally. This means it doesn't target the healthy cells. It leaves them alone. And that's what makes our approach quite exciting because it's a targeted therapy that doesn't have the side effects normally associated with standard therapies. There's no immune suppression, no hair loss and no nausea.

Can you describe your lead drug PRP?

PRP is a solution of two proenzymes, trypsinogen and chymotrypsinogen, administered by I.V. injection. We've just given it an acronym PRP, which doesn't stand for anything. The proenzymes are inactive and when they become activated at the tumor site, they become trypsin and chymotrypsin and the two activated enzymes assert their significance on the tumor of the cancer cell.

Can PRP be applied across a range of cancers?

Solid tumors are by their very nature, tumors that form in a particular organ. And solid tumors represent 80% of all cancers. The mechanism by which we target these cancer stem cells and the way solid tumors metastasize and spread is across the board for most common solid tumors. So, therefore we think our technology can be applied to most of the common solid tumors around. And that fundamental mechanism by which cancer spreads, we think we can halt. So, that's what is particularly exciting about our drug.

Discuss your compassionate use program for PRP

These proenzymes are naturally-derived and under our founder Dr Kenyon's supervision, we took a formula and delivered them to patients in the UK and Australia under a compassionate-use program. We treated up to 46 patients with metastatic cancer who had already failed conventional treatment. Of those patients, nineteen significantly exceeded their life expectancy and either double or quadrupled it based on the prognosis of the physician. They saw an average of about 9 months survival compared to a prognosis of about 5.6 months.

After summarizing and reviewing the data of the nearly 46 patients who took part in the trial and doing a couple of animal studies, we presented the data on the compassionate use trial to the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK way back in 2008. The MHRA agreed that we could initiate a patient trial with the same proenzyme suppository formulation which we have now discovered is less optimal than the IV formulation we've now uncovered and patented.

Since the compassionate use program, we've further refined the formula. We've optimized the ratio of the proenzymes and we've found a better impact at a ratio of one trypsinogen molecule to six chymotrypsinogen molecules. As part of the compassionate use program, the formula was administered by suppository so the patients could self-medicate in an outpatient setting because they were very sick. We're now looking to administer that formula at a much higher dose by IV injection in our first clinical trial.

Where are you on the trial front?

So far, we are right on the cusp of commencing our first trial. We're now about six months away from the stage where we're looking to file our first clinical trial application. We completed all of our pre-clinical development. We've done animal models, toxicology models. We've proved the concept in animals. We've done cell-line studies. We've filed patents on the mechanism of action.

Can you discuss your public debut?

We've been a public company on the OTCQB since 2011. We were fully audited from inception, so we were never a shell and we didn't stage a reverse merger. Propanc is a Delaware entity and domiciled in the US, so we've been raising money via hedge funds and institutional funding for some time.

We ended up taking a global view and listing on the OTC as a penny stock because we realized we needed to raise money to get the company to the next stage. Since setting up in 2007, we now have quite an extensive patent portfolio with further patents pending. We have achieved orphan drug status from the FDA for the treatment of pancreatic cancer. And after 10 years and close to nearly $20 million dollars raised, we're ready to proceed into our first trial.

Where are you planning to hold the clinical trial?

We're now thinking about undertaking a trial in Melbourne, Australia where I'm located. The interest in possibly doing it in Australia is two-fold. One is that Brexit and the unstable regulatory climate in the UK has meant that we feel there could be a considerable length of time waiting for the approval for the regulatory process in the UK. Australia, meanwhile, is still up to world standards in terms of clinical trials. So, we would undertake the trial for worldwide regulatory approval. And another added benefit is that companies who undertake their R&D in Australia are eligible for significant tax rebates on every dollar spent. You can also claim overseas expenditure in some cases under the tax refund. By doing the trial in Australia, our manufacturing and our expenditure could be claimed under this tax refund which could be quite attractive because we can then reinvest that money back into R&D.

Where will Propanc be in the coming years?

We are targeting a financing, a $5 million financing, to complete manufacturing and submit our first clinical trial application. From the commencement of our first trial, we are targeting over a three to four year period to achieve proof of concept in two target indications: pancreatic and ovarian cancers. If we do that, we would ideally like to license the drug, and potentially, if the results are good enough, we could file for fast-track designation, early conditional approval and so forth. So, potentially, within a five-year period, we could anticipate achieving proof of concept in one or two indications and hopefully, identifying a suitable licensing partner.

-- This article has been lightly edited --

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