



Phosphagenics

news

JULY 2015



Welcome. It is an exciting time to be initiating this new line of communication with shareholders. I hope you find it a valuable way of keeping up-to-date with Phosphagenics' progress. My intent is to keep it regular, concise and informative.

This quarter has been all about rebuilding the foundation that supports shareholder value: a straight forward strategy in each business area and the complimentary skill set and internal structure to support it. We are focused on creating the type of short and medium term value that the markets can see, appreciate and, more appropriately reflect in share value. In line with the promises I made at the AGM, we have already begun to build-out the Company and the "businesses" within Phosphagenics with the explicit aim of improving business focus and accelerating progress.

In this Newsletter I would like to share with you some of the significant progress we have made over the past quarter towards this goal:

COMPANY STRUCTURE:

- We have **re-engineered the Board** of Directors - two members leaving and three joining.
- ◆ Over the past few months the Phosphagenics Board has been strengthened by the addition of new Directors: Mr Peter Lankau, Dr Greg Collier and myself. This injection of strong Biotechnology and Pharmaceutical experience and credentials to the Board has already begun to engender positive responses from existing and prospective partners. This renewed confidence in Phosphagenics has already had a positive impact in opening new doors.



In this issue

COMPANY STRUCTURE	1	OPERATIONS	4
THE NEW BOARD	2	FINANCE	5
THE BUSINESSES	2	PUBLICATION AND COMMUNICATION	5

THE NEW BOARD



Mr Peter Lankau
*Interim Chair &
Independent Director*



Dr Greg Collier
Independent Director



Dr Ross Murdoch
CEO & Managing Director



Dr Geert
Cauwenbergh
Independent Director



Mr Nathan Drona
Independent Director

- ◆ Both Lawrence Gozlan and Harry Rosen have recently decided to leave the Board. Harry Rosen has stepped down as President and a Director of the Company. I would like to take this opportunity to thank them for their considerable contributions to Phosphagenics and wish them well.

THE BUSINESSES:

- If we are to succeed we must drive business discipline and commercial focus into every aspect of Phosphagenics' activities. To this end I have set up four distinct business units within Phosphagenics. During this quarter we have **consolidated the leadership** and begun to build out the skill sets needed in each of these

business divisions. The following have been appointed to lead the businesses:

- ◆ Dr Roksan Libinaki - General Manager of Animal Health and Nutrition,
- ◆ Mr Greg Moses - General Manager of Operations and Production,
- ◆ Dr Paul Gavin - CSO will continue to lead the company's Strategy and Innovation, (supporting these functions across all business divisions), and
- ◆ Dr Ross Murdoch - CEO will continue as Head of Human Health.



- To support the new leaders and rapidly improve our skill set and access to potential partners, we have identified and appointed **expert consultants** to work with each business. The announcement of Dr Steve Meller in June 2015 demonstrates the calibre of the experts we are targeting. Dr Steve Meller, an ex-senior leader at Proctor and Gamble, has been appointed to assist us in licensing our technology into the human mass market.

- Over the past quarter we have consulted with a number of industry advisors in the core business areas to help consolidate a strategic path forward that will drive short and mid-term shareholder value. These strategic sessions reinforced that:

- ◆ the **human business** should continue to prioritise work on the existing patches and gel opportunities whilst assessing what potential exists for TPM® enhanced products in oral nutrition and injectables.
- ◆ the **Animal Health and Nutrition business** should be made a more important focus for Phosphagenics as there exists strong preliminary evidence and a strong value proposition for TPM® enhancing livestock performance and health.
- ◆ TPM® is a product with attributes far more valuable to partners and customers than simply a more efficient way to provide Vitamin E.

- Reformulation plans for the TPM®/Oxymorphone patch are well underway. Phosphagenics' lead scientists have identified and met with a number of specialist reformulation/manufacturing companies. We expect to have initiated formal reformulation activities within the current quarter.
- Recruitment into the TPM®/Oxycodone Phase 2a proof-of-concept clinical trial continues to progress – all sites are actively recruiting and we have added an additional site in June. Over half of the planned 28 Postherpetic neuralgia (PHN) patients have now initiated dosing. Progress remains on track to report results by the end of 2015.



- Work continues to formulate existing and new specific targets in the gel and injectable space. To ensure the optimal development approach for each of these we are in the process of building business cases that assess the trade-off between “speed to market” with minimal regulatory packages vs. a “more complete approach” incurring more cost, risk and time to undertake more complex development so as to support marketing claims and gain higher value. The right strategy will be essential to ensure we optimise the value of each of these assets for Phosphagenics.
- Phosphagenics has an existing commercial arrangement with Mylan in relation to an antibiotic injectable. In this case TPM® acts to enhance the solubilisation of the drug. Mylan inherited this arrangement in 2013 as a result of the takeover of Agila, the subsidiary of Indian company Strides. With Agila now well and truly part of the Mylan structure, we are hopeful that progress towards commercialisation of this product will accelerate this year. A successful commercialisation in this case would highlight the opportunity to exploit the use of TPM® for a whole range of other injectables.

- We recently announced a deal with Brinacombe/IAH to distribute TPM® animal products in the UK and Ireland. Regulatory work is ongoing and approval is expected to be some time in 2016. We believe that this work, and the subsequent approval, can open up further opportunities in Europe and beyond for TPM® animal products.
- We outlined in the 2014 Annual Report that Phosphagenics is in an arbitration process with a commercial partner relating to a dispute regarding claims for breach of operative agreements. The arbitration process is now in the discovery phase with the formal hearing set for December 2015. This arbitration is in regards to a joint venture (Phusion Laboratories LLC) developed in 2010 between Phosphagenics and ProPhase Labs. Inc. to develop a range of over the counter (OTC) remedies. Both Phosphagenics and ProPhase Inc. are preparing to defend claims seeking unspecified damages at that arbitration. This matter remains unresolved at this time, and no prediction as to the outcome of this action can be made.

OPERATIONS:

- I am pleased to say that the new “business” focus and structure already appears to be having a positive effect on Phosphagenics’ relationships with present and future potential partners. Interest in, and demand for, both TPM® and Vital ET® is increasing. Responsible expansion of our manufacturing capacity is needed to meet this demand, increase core revenues in the short term, reduce the cost of production, improve margins and enable us to be more successful in future deal making. Development of the business case and engineering activities to expand capacity has been initiated and will develop further over the next quarter. The capital costs associated with this expansion should be relatively modest and will provide considerable enhanced value to the Company.



FINANCE:

The half year financial results to June 2015 are due to be released towards the end of August 2015 and will provide a detailed financial account of our performance. Overall our revenues remain in line or slightly better than for the same period in 2014 and expenses are below that initially projected – primarily due to the change in development path for the TPM®/Oxymorphone patch. We remain in a strong cash position with around \$16 million cash with 2014 R&D refund of \$2.5 million expected in the near term.

PUBLICATION AND COMMUNICATION:

- A formal 2015/16 publication plan has now been put in place and outlines a strategy to produce a strong collection of publications to:
 - ◆ Educate on the technological, clinical & economic effectiveness of TPM® and TPM® products
 - ◆ Communicate the key data and key messages supporting TPM® and TPM® products.
- Phosphagenics' first publication for 2015
"Topical Application of a Novel Oxycodone Gel Formulation (Tocopheryl Phosphate Mixture)

in a Rat Model of Peripheral Inflammatory Pain Produces Localized Pain Relief Without Significant Systemic Exposure" was accepted in April and appeared in press in *"The Journal of Pharmaceutical Sciences"* in May 2015.

- A draft of the next publication is nearing completion and initial submission is expected during this quarter.
- As promised at the AGM, we have implemented a process of quarterly update communications through both a newsletter and conference calls. Each quarter we will release a newsletter to the market followed by a conference call. We are committed to continue to assess how we can further improve communication and if any shareholders have suggestions we would really like to hear their ideas.

RESEARCH ARTICLE – Pharmacokinetics, Pharmacodynamics and Drug Transport and Metabolism

Topical Application of a Novel Oxycodone Gel Formulation (Tocopheryl Phosphate Mixture) in a Rat Model of Peripheral Inflammatory Pain Produces Localized Pain Relief Without Significant Systemic Exposure

MAREE T. SMITH,^{1,2} BRUCE D. WYSE,^{1,2} STEPHEN R. EDWARDS,¹ MAHMOUD EL-TAMIMY,³ GIACINTO GAETANO,³ PAUL GAVIN¹

¹ Centre for Integrated Preclinical Drug Development, Faculty of Medicine and Biomedical Sciences, The University of Queensland, St Lucia Campus, Brisbane, Queensland 4072, Australia

² School of Pharmacy, Faculty of Medicine and Biomedical Sciences, The University of Queensland, St Lucia Campus, Brisbane, Queensland 4072, Australia

³ Phosphagenics Limited Australia, Clayton, Melbourne, Victoria 3168, Australia

Received 6 March 2015; revised 28 April 2015; accepted 28 April 2015

Published online 20 May 2015 in Wiley Online Library (wileyonlinelibrary.com). DOI 10.1002/jps.24502

Finally, let me emphasise that we remain committed to and focused on creating real short and medium term value for shareholders: value that markets can recognise and appropriately reflect. We are already revealing attractive shorter-term opportunities particularly in the “Production” and “Animal Health & Nutrition” businesses where a relatively modest investment has the potential to unlock a meaningful increase in their performance and associated revenues. We have had a busy quarter but there remains a lot to do. I believe with the new team and structure we are beginning to make real strides in the right direction.

Thank you for your support.

- Ross Murdoch CEO

If anyone has any enquiries, please contact:

David Segal, Investor Relations Manager

Email: dsegal@phosphagenics.com

Phone: +61 3 9565 1119



Phosphagenics Limited

11 Duerdin Street, Clayton VIC 3168

PO Box 1415, Clayton South

MDC VIC 3169 Australia

Ph: +61 3 9565 1119 Fax: +61 3 9565 1151

Security Codes: ASX(POH); OTCQX(PPGNY)

www.phosphagenics.com

email: info@phosphagenics.com

www.bioelixia.com

