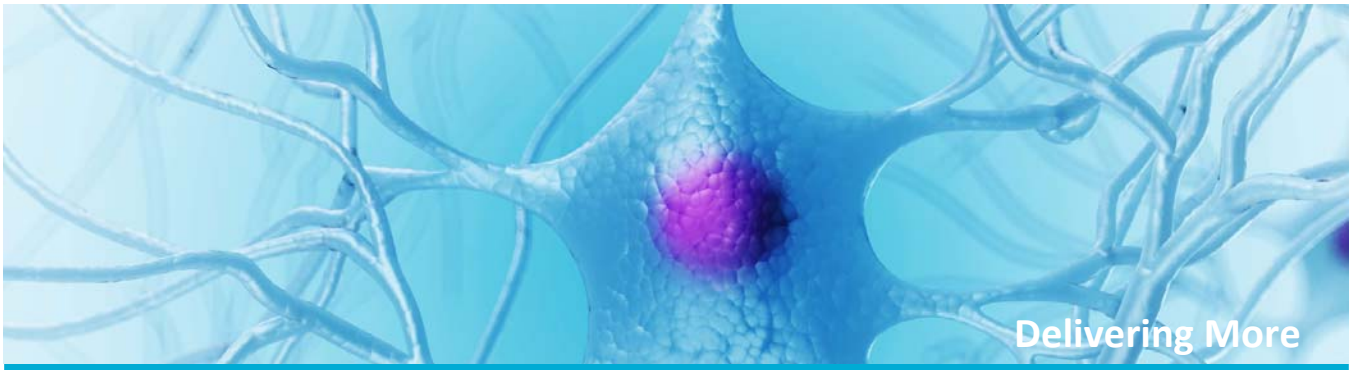
# Newsletter – May 2017




TPM® Drug Delivery Technology| Pharmaceuticals | Consumer Products | Animal Health

Welcome to our second investor newsletter for 2017. This issue has been jointly penned by our recently appointed Chairman, Dr Greg Collier, and myself, CEO, Dr Ross Murdoch. In response to feedback from our shareholders, and ahead of the upcoming AGM, we wanted to provide two key pieces of information requested repeatedly across our recent shareholder meetings:

1. an update on what has been achieved under the current plan, and an outlook for Phosphagenics across our three business areas, and
2. more information (including a timeline) to help shareholders better understand the Mylan arbitration, and by when we might expect a resolution. (*Now that the process is further advanced, we are at last able to provide this - a timelines is included later in this update)*.

## Strategic Plan: Progress Update and Outlook

At Phosphagenics our goal is to develop and commercialise our TPM® technology, and translate this into value growth for our shareholders. Over the past two years much has been done to improve the Company's operating efficiency, demonstrate our technology has published scientific rigour underpinning it and secure high quality partners whose goals are aligned with our own. This has not always been a straightforward or fast moving process, and it has required us to make some tough decisions along the way.

Although not always obvious, over the past two years, many aspects of the Company have improved dramatically, and the result is a leaner, more commercially focused organisation. Many of the legacy issues that complicated and slowed our Company's progress have now been resolved and we are now seeing definite progress: our key assets are moving forward through strategic partnerships and our own R&D and business development efforts are being rewarded with attention from strategic global partners for our human health as well as our animal health assets.

Over the past year, we have delivered improvements in our manufacturing processes which translate to significant reduction in the cost of manufacturing and greater capacity – all essential to convincing potential partners of the long-term viability and financial feasibility of the TPM® technology.

Over the past two years we have worked hard to extend our cash runway, through rationalising our operations in ways that do not diminishing our outputs. The headcount has reduced from 43 to 18 people and we have consolidated operations onto primarily one site, the latter reducing our yearly fixed costs by $200,000 per year.

Our focus is now on capitalising the progress made in the past 24 months, and translating this into deals across our three business units. The table below sets out the key pillars of our strategic plan and outlook for each.

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| Strategic Areas | Progress and Achievements to date | 12 month Outlook |
|---|---|---|
| **Human Health**<br><br>TPM®/Oxycodone Patch<br><br>TPM®/Oxymorphone Patch<br><br>TPM®/Diclofenac Gel<br><br>TPM®/Daptomycin Injectable<br><br>TPM® Injectable Portfolio<br><br>Scientific Publications | Consolidated portfolio to focus on key "partnerable" assets.<br><br>Ph2 Oxycodone PHN Trial completed on time – currently being assessed by Terumo.<br><br>Oxymorphone reformulation complete – Terumo Term Sheet signed and initial payment received. Licensing negotiations ongoing.<br><br>Diclofenac gel license extended from only India to 17 countries.<br><br>Mylan Arbitration case built and formal action now underway (see timeline following).<br><br>Propofol injectable moved from "on hold" status to multiple formulations developed and joint R&D development with Terumo signed.<br><br>10 publications produced and submitted for publication in 24 months. | • Extension of strong multiple partnerships with Terumo, bringing with it valuable data, expertise and possibly associated upfront milestone payments.<br><br>• Initial results expected from trials on a number of TPM® enhanced injectable formulations.<br><br>• Mylan Arbitration Hearing to be held in 2017, decision expected early 2018.<br><br>• Additional data driving further scientific publications. |
| **Animal Health** | Increased R&D and proof of concept data established – multiple trials initiated and completed showing efficacy/safety data in pigs and poultry. Two year Dairy trial initiated and ongoing.<br><br>Due Diligence initiated by multiple major global feed companies.<br><br>Legacy agreements dissolved – resulting in return of global rights, opening up ability to secure more effective partnerships. | Focus on securing partnership for TPM® as a feed efficiency enhancer in livestock – promising discussions based on strength of trial data.<br><br>Dairy cattle trial results expected Q4 2017 - designed to assess whether TPM® can as a feed additive promote improved fertility and milk quality. |
| **Personal Care** | ProPhase arbitration conducted and successfully completed, resulting in return of OTC rights and clearing path for BioElixia® sale.<br><br>Focus on better product and partner management with Vital ET® –multiple new products launched with Le Metier.<br><br>Due Diligence initiated by multiple major Personal Care companies.<br><br>New Vital ET® R&D initiated. | Sale of BioElixia®.<br><br>Relaunch of Vital ET® with global distribution partner Ashland.<br><br>Activities to secure partnerships for TPM® in broader Personal Care Products – promising discussions based on BioElixia® and other data. |

| Strategic Areas | Progress and Achievements to date | 12 month Outlook |
|---|---|---|
| **Production** | Significant improvements to processes and quality resulting in:<br>• Improved and updated manufacturing processes<br>• "10x" batch upscale - "20x" production capacity<br>• Capacity: 44kg/wk increased to over 1-2000kg/wk without need for increased CAPEX<br>• Fully implemented Quality Management System<br>• Improved data package – "US-FDA DMF" filed<br>• Production business profitable<br>• Multi-fold improvement in COGs and margin<br>• Significant TPM® process improvements. | |
| **Patents and IP** | Three new patent families added to the existing 14.<br><br>Overall increase in granted/active patents to 104. Extensive patent portfolio management resulting in 55 additional patent grants with 47 low value patents managed out of the portfolio. | New Intellectual Property submitted and approved.<br><br>Ongoing rationalisation of portfolio to maintain strong protection while containing costs. |
| **Regulatory** | US-FDA DMF extensively updated with new data supporting Mylan and other injectables.<br><br>Data packages assembled and filed in US for animal health regulatory campaign. Consultation meetings planned with FDA/EFSA. | Meetings with country specific regulatory Agencies around multiple products in 2017. |
| **Data Packages** | Data packages across all businesses now much more robust<br><br>• Manufacturing method dissected and critical process parameters now well understood and better protected<br>• Products well characterised with good supporting CMC data<br>• Data packs available for natural and synthetic TPM®. | Further enhancement of perceived TPM® advantages through increased data generation and publishing.<br><br>Ongoing generation of data supporting TPM® as a key injectable enhancement excipient. |

## Mylan Arbitration

The Mylan arbitration has been a substantial focus for Phosphagenics in 2016 and will remain a priority for 2017. Both the TPM®/Daptomycin product itself, and the damages Phosphagenics is seeking, represent significant potential value for the company and contribute to the ongoing protection of our Intellectual Property. Within the arbitration, Phosphagenics has lodged multiple individual damages claims, each of which carry the potential to recover significant quantums. Phosphagenics' Board and management remain convinced in the merits of pursuing this arbitration.

Arbitration like many legal processes can be long and complex. The table following attempts to provide shareholders with some transparency around the steps taken to date (in green) and the timeframe of the steps yet to be completed. The arbitration hearing is set for Q4 2017 and some more specific dates in the interim are listed. Based on this timetable we currently expect a final result in first quarter of 2018. Efforts are also underway in parallel to investigate if there is the potential for settlement discussions between the parties prior to the hearing. As the process advances and further information suitable for distribution becomes available, Phosphagenics will ensure that this is made available to shareholders.

| Task | Description | Deadline |
|---|---|---|
| Initiation Phase | • POH engages legal representation<br>• Notice of demand lodged<br>• Deposition and Pleadings developed<br>• Arbitration notices lodged<br>• Arbitrator mutually agreed<br>• Initial Arbitration Timetable set | 2015 - Dec 2016 |
| Evidence/Case Development Phase | • POH develops preliminary internal draft damages claims<br>• POH develops preliminary internal damages model for each claim<br>• Discovery and Fact Witness Statements developed and lodged | Sep 2016 - April 2017 |
| Expert Witness Evidence Phase | • POH engage independent subject matter experts who independently assess and provide input into claims and<br>• POH submits expert evidence to support claims<br>• Mylan submits expert witness evidence | Concludes Jun 2017 |
| | • POH and Mylan experts meet to establish points of agreement and identify matters still in issue.<br>• Reply expert evidence is filed<br>• Experts' agreed joint list of issues submitted (indicating areas of agreement and areas of disagreement) | Jun - Aug 2017 |
| "Pre-Evidentiary Hearing" Phase | • Submission of agreed final list of issues<br>• Pre-hearing conference b/w POH, Mylan and Arbitrator<br>• Submission of a composite agreed hearing bundle<br>• Filing of arguments for all claims, defences, etc for Evidentiary Hearing | Sep - Oct 2017 |
| Evidentiary Hearing | • Set down in Singapore<br>• Hearing estimate 10 days | Oct - Nov 2017 |
| Deliberation Phase | • Arbitrator considers all evidence<br>• Decision targeted approximately 2 – 6 months after Hearing concludes | Dec 2017 - Jan/Feb 2018 |

## Conclusion

As you can see, much has been progressed upon many areas of the business and we look forward to discussing this further at the AGM. We are excited about our future, and are encouraged by the response we are receiving in the industry and we look forward to keeping you updated on our progress in respect of our strategy and provide updates at the appropriate intervals in the Mylan arbitration.

## AGM

The Annual General Meeting will be held at 9:30 am on Wednesday, 31 May 2017 at the Oliphant Auditorium at the National Centre for Synchrotron Science, 800 Blackburn Road, Clayton, Victoria.

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