



18 May 2015

**ASX Limited**

**Market Announcement Office**

**Phosphagenics Limited**

**2015 Annual General Meeting ("AGM")**

**Addresses/Presentations**

At the Annual General Meeting ("AGM") of the shareholders of Phosphagenics Limited which is to be held in Melbourne, Victoria, this afternoon the following addresses/presentations will be made:

- Chairman – Mr P Lankau
- Executive Director CEO – Dr R Murdoch

A copy of each document is attached for release to the market.

**END**

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**Phosphagenics Limited – 2015 Annual General Meeting  
Chairman’s Address – Mr Peter Lankau**

*18 May 2015*

Good afternoon and welcome again to the Phosphagenics Ltd Annual General Meeting. On behalf of the board, our executive leadership team and all of our dedicated employees, we are here to conduct the business of the company before us on this agenda, and to present today, to you our shareholders, a realistic perspective on the status of the Phosphagenics business in 2015. We will provide you with sufficient detail about the future prospects for the TPM platform, the status of product development, and what we expect to do to re-invigorate our ambition to achieve the value that you, as shareholders, expect.

I want to first start out by acknowledging the retirement of Lawrence Gozlan the previous interim chairman. Lawrence worked tirelessly on behalf of the company during his tenure, and was instrumental in securing increased funding for the company over the last year in order to fuel its continued operations. We wish him well in his future endeavors. At the same time, I believe that the new members who have joined your board have clearly enhanced the capabilities of this company to be a successful, development stage biopharmaceutical company. They all bring significant expertise in selected areas that will contribute tremendously to the future business prospects of this company. We expect to provide you with the leadership, the expertise, the fair and balanced assessment of our prospects that you expect. For many of us on this board, it is a new day and we look forward to unlocking the value that this technology holds. We will be looking to further enhance that oversight and guidance capability in time as well, with additional board appointments.

A little later in this meeting, Dr Collier will provide you with insights with regards to his qualifications and his decision to join Phosphagenics’ board. I would now like to give you a brief background regarding my qualifications and how I came about to be associated with the company and why I believe it has the potential to be a successful developer of novel pharmaceutical products, and other potential uses of its proprietary intellectual property. As you may know, I was recently appointed to the board of Phosphagenics a little over a month ago. Six days ago, I was elected as interim chairman of the company by your board to help guide the development of a new and purposeful strategy to optimize the TPM platform and its current portfolio of products. As you can see from my biography, I have many years experience in the industry developing and commercializing pharmaceutical products, some innovative, and some not so much. I have been a CEO of a fully integrated pharma company, Endo Pharmaceuticals, where I personally oversaw the development, regulatory approval and commercialization of the oral opioid analgesic, oxycodone, a dodgy little molecule branded in the USA as Opana which at its peak, achieved over half a billion dollars in annual revenue. Also while at Endo, we developed an oxycodone oral formulation to compete with the market leader OxyContin. Several other pain products were brought to market as well with combined sales approaching a billion US dollars. I have been the chairman and CEO of a biotech company in Boston, which was developing novel anti-inflammatory agents to challenge the notorious gastrointestinal effects of major NSAIDs, such as naproxen, ibuprofen and diclofenac. And most recently, I was Executive Chairman of a commercial stage company, Nautilus Neurosciences, marketing a unique

formulation of diclofenac for acute migraine. We sold the business to the specialty pain company, Depomed.

I tell you this because my experience, and hopefully expertise, is in diagnosing drug development candidates, putting them to the test in clinical and non-clinical settings, getting the manufacturing right (especially the real challenges in scale-up), getting regulatory approvals, and bringing them to market successfully, rewarding shareholders and employees with enhanced value. But what I have learned over that extensive period of time, is that nothing is assured. You already know this as you've endured a recent path of disappointments and value erosion. There is risk at every stage of a product's lifecycle, with many ups and downs, and re-do's, in order to optimize the chances for success. I've killed many more projects than I've completed. But my history, I believe, is quite relevant to Phosphagenics, now, at this stage in its lifecycle, to reevaluate the opportunities before it, recalibrate, and recommit to delivering shareholder value. That would be the reward.

In a few moments, you will hear from your new Chief Executive Officer, Dr Ross Murdoch, about how he has spent his first 100 days assessing the business, and how he plans to address the opportunities, and effectively manage the company's resources and assets through trying time, to ultimately achieve a reversal in valuation for our shareholders. You'll hear about how we need to rethink our business strategies, our core competencies, and recommit our energies to doing what's in the best near term and medium term interests of all stakeholders. You, as investors, need to have confidence that we have the expertise to shift the odds just a little more in our favor. We get that. I think we can.

But let me return to the reason I agreed to join this organization of dedicated individuals. It is because of my belief in the TPM technology as a mechanism to enhance drug delivery that is unsurpassed. I did the diligence on TPM and its current products. From the ability to deliver therapeutic doses of drug that were previously undeliverable through the skin, to the ability to positively affect dissolution profiles and absorption characteristics of various uncooperative molecules, the potential of TPM is much more than applying it to patches. And yes, we've had recent disappointment with the delay in the OxyM program, which we will address with efficiency and resolve. But we've yet to discover all the potential uses for formulating TPM with other molecules to improve their delivery and acceptability to end users. Some of this detailed work Phosphagenics will do on its own, some will require outside expertise, to be directed and guided by us. But all of our activities will be done with the promise to be opportunistic, engaging with potential partners, and to leverage our expertise as best we can.

So what's going to be different? As I indicated earlier, we've begun to assemble a new board of directors with additional, and significant pharmaceutical expertise, that can provide appropriate guidance to the executive team, and ensure that the opportunities for TPM's potential use are identified quickly, assessed rapidly, tested thoroughly, and offered for partnering with as much retained value as possible. And we expect to employ that best and most effective talent internally and through partnerships, to unlock the potential product opportunities TPM can exploit.

That is our commitment to you from this day forward. And we'll keep you regularly apprised of our progress.

Although I do not yet know many of you, I do want to thank all of you for your continued support, your challenges to us, and your loyalty and belief in this company's potential through all its been through these past several years. And of course, I'd like to thank once

again all the company's employees for their past efforts and their future endeavors to deliver for you as well.

Thank you, and I'll now turn over the podium to Dr Ross Murdoch, your CEO, for his address.

END.



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## **CEO AGM Address**

**18 May 2015, Melbourne:**

Good afternoon, my name is Dr Ross Murdoch and as of today I have now been CEO of your company for just under four months. Like several people up here, I am relatively new and therefore have not had an opportunity to meet with many of you. I am looking forward to changing that in the very near future. Before starting the formal presentation, let me first say thank you to you for coming today. I hope you find it informative and that it rejuvenates your enthusiasm in Phosphagenics.

### **Slide 1:**

The most common questions I have been asked over my first few months is, "Why did you decide to come to Phosphagenics?" My answer has always been, "I like the technology and think I can really add significantly to the business". When first approached, Phosphagenics was described to me as an Australian company with a platform technology, multiple projects, a product sold in India, a turbulent history culminating in a dramatic loss of shareholder value due to fraud, and a real need for someone with strong business, commercial and development experience to come in and help it realise value out of its growing pipeline. I truly believe that the skill set I have developed over my 25 year career in the Healthcare Industry puts me in an ideal position to help Phosphagenics deliver for shareholders.

### **Slide 2:**

My formal qualification is a PhD in Clinical Pharmacology. But really I learnt my trade (the business of drug development and commercialisation) over the last 25 years working across the Pharmaceutical industry. I have worked in big Pharma and small Biotechs, across the USA, Europe, Asia and Australia, and have managed everything from early research, development, FDA filings to commercialisation, sales and generic and OTC switches – over 100 programs in all. I have managed several drugs onto the market and have been involved in over 20 significant deals. Over the past 7-8 years however my work has turned to building and rebuilding businesses.

### **Slide 3:**

Developing a successful drug is like putting together a complex jigsaw. In drug development the end picture is not always immediately clear. Only some of the pieces are visible, some are not and some may be missing. Sometimes all the pieces fit and sometimes they just don't. Regardless, optimising the chances of putting it together, solving the challenges that come along and making the decisions that ultimately shape the end result need experienced hands. Ultimately our customers and partners don't need the jigsaw put together but they do need to see that it can be. They want to know how much risk we have eliminated for them. To market our technology successfully, there are ultimately five questions we need to answer:

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- What evidence is there that the tech works?
- What evidence removes the risk that it does something bad?
- What is the evidence that the tech can be a commercial product?
- What is the relevance to customers?
- How does the evidence stack up relative to competition?

Phosphagenics is at a stage where it can really benefit from experienced leadership helping it to decide how it answers these. This is why I am very pleased that the Board has brought on two distinguished new directors in Greg Collier and Peter Lankau with an abundance of this experience. It is for this same reason that I believe my experience will really enhance the Phosphagenics team.

#### **Slide 4:**

I have approached Phosphagenics in the same way that I have approached other companies I have joined to lead or manage. I gave myself 100 days to fully assess the strategy, people, assets, structure, processes and opportunities. During this time I try not to speculate or make major changes, unless they are absolutely obvious and needed. My 100 days finished late April. My aim is always to re-evaluate a company's strategy and find ways to drive to a more focused, results oriented approach to drug development and business development.

#### **Slide 5:**

Phosphagenics is a company with a lot of research, history, options and promise. My overwhelming impression remains that Phosphagenics has at its core strong fundamentals. Two years of cash, the ability to generate revenues, and a pipeline of R&D programs across a large number of products is a nice position to be in for any small company in this industry. It has an established research team, with a long history working with the technology and a flexible technology surrounded by an abundance of data and patents.

Having said this, Phosphagenics clearly has its challenges:

- One that is very evident to shareholders is that publications and public validation of the technology is thin on the ground – the focus to date has been to concentrate on patents. I am pleased to say that this has already begun to change with the first paper being accepted into the “Journal of Pharmaceutical Sciences” this month. Our intent is to make publications a much more important part of our value enhancing strategy moving forward.
- Secondly, the Company needs to strengthen its commercial approach to research - We have been “Broad rather than deep”. Much of Phosphagenics’ 14 years of research focuses on demonstrating the breadth and possibilities of the technology rather than proving it can be commercialised. TPM<sup>®</sup> has been shown to provide benefit across a huge array of molecules: from small, to big, to huge - from opioids, to insulin, to vaccines, and across just about all modes of delivery: oral, injectable, gels, creams, patches. The utility of TPM<sup>®</sup> has been demonstrated in cosmetics, veterinary and animal nutrition, human nutrition, human prescription and human generic and OTC products. While this suggests a platform with almost infinite potential, the Company has yet to harness this in a convincing way to ensure partners that it can be used to produce commercial products.

- Thirdly, having been able to generate a lot of interest with a lot of potential partners, for one reason or another we have not been able to get many of these across the “partnership” line. Whilst of course I was not there, I have spent considerable time on the “other side” of the deal table, and I believe that this may be a result of potential partners seeing broad possibilities but, in the end, not finding the depth to satisfactorily reduce the risk for any investment, and
- Finally, and most obvious to shareholders, Phosphagenics has missed many of its deliverables, which in turn has led to disappointment and nervousness amongst investors and a lack of enthusiasm on the “buy side”. This, in my experience, can in turn amplify the effect of any decision to sell. I believe this is what we have seen this year.

#### **Slide 6:**

I have also been listening to shareholders. My take-aways are that you have been very patient but are also very disappointed. I find that shareholders are really demanding four things:

- More reliable promises - promises we CAN and DO deliver on!
- Improved communication, not simply more announcements but more regular communication that allows shareholders to understand better what is progressing inside the Company;
- More validation, particularly through publications; and ultimately
- Some deals and partnerships.

Only then will the trust begin to come back. Shareholders have made it clear that they certainly do not want more of the same.

#### **Slide 7:**

So, armed with all of this, we are making a number of changes moving forward. I believe these are sensible, achievable and will fundamentally change the Company for the better. These changes will allow us to achieve balance between the short, medium and long term objectives needed to develop real shareholder value.

- Firstly, change the Company’s structure from a single “department” to individual Business Units that can focus on very defined deliverables. By clearly defining those deliverables we will be able to better plan, better predict when deliverables can be achieved, and more accurately tailor the spend and personnel to maximise “return on investment”.
- We need to re-evaluate where we look for our next internal research targets. We need to pick targets that have nearer term benefit and are less technically challenging than patches. Nearer term, less complex targets will allow a more predictable development path, and more assets to be developed, making our business less binary by reducing the impact of any singular delay on the overall performance of the Company.

- We need to up-skill the Company's expertise. This has already happened at the Board and senior level, but there remains some key skill gaps. Where appropriate, these skills will be sourced outside the Company rather than adding to the headcount.
- We are actively re-reviewing all the data we have with a focus on identifying "low hanging fruit". We must focus on what we CAN deliver rather than what would be really impressive to prove. Ultimately, our focus needs to be on shorter-term delivery of products and deals.
- Finally, together with my leadership team, we have already moved towards a more fiscally responsible organisation. You are aware of the ongoing sale of the BioElixia<sup>®</sup> brand which lost \$1.3M last year. In addition, I have also initiated the closure of our New York office to save further money. My aim is to drive a culture with improved planning and rigour around our costs and deliverables.

My vision is a simple one – a lean, business focussed company with the expertise to extract the most value we can from the TPM<sup>®</sup> platform whilst maximising the financial runway we have today. A company with a balance between short, medium and longer-term deliverables.

So over the next few slides I would like to provide you with a little more detail around these changes.

#### **Slide 8:**

To ensure the new company is driven to optimise "the return to shareholders" on any investment we make and to ensure we focus on commercial outcomes, I have started from the bottom up and changed the Company's core structure, setting up three key commercially focused Business Units supported by an additional minimal infrastructure. Not long into my 100 day review it appeared clear to me that today's company logically splits into three businesses – with each having:

- revenues,
- commercialised products,
- programs for growth in 2015 with focused, commercially attractive short to medium term deliverables,
- prospects to improve existing partnership outcomes and develop new partnerships from already ongoing discussions within their focused area.

Early research as well as work required to support validation, publication, IP, etc will be handled by the CSO, Dr Paul Gavin, and his team under the banner of our "strategy and innovation" group.

#### **Slide 9:**

I have mentioned previously that I am keen to reduce technical risk across our portfolio. What options do we have?

As I said earlier, the research behind TPM<sup>®</sup> has shown that it not only enhances delivery of molecules across the skin but also may benefit problematic injectables, enhance oral absorption and, at its most simple, is a better absorbed source of Vitamin E. While patches have been, and remain, at the forefront of our portfolio, patches are time and resource intensive to develop and at the most complex end of this spectrum. We have considerable data around what I believe are easier nearer term opportunities: we need to also begin to exploit these so as to expand our options and accelerate shorter-term revenue growth.



**Slide 10:**

From now on we will refocus some of the internal resources previously required on the TPM<sup>®</sup>/Oxymorphone patch towards targets with nearer term commercial outcomes: targets with less technical risk. I believe we have clear opportunity in the Injectable and Gel space. We intend to enhance our pain portfolio further by exploiting the considerable existing data we have in both these areas. Both our R&D agreement with Mylan for injectables and our commercial agreement around Novartis in India for Voveran<sup>®</sup> 1% Diclofenac Gel validate these areas and give me great hope that we can move more rapidly here. Our focus within the animal health arena will remain on oral nutrition and vitamin E exchange.

**Slide 11:**

I would now like to focus your attention on our key pipeline assets.

Having shown that the TPM<sup>®</sup>/Oxycodone patch can deliver drug in humans and deliver pain relief in race horses, it is now in a Phase 2 trial targeting the pain associated with PHN (postherpatic neuralgia – shingles). This trial started in January and results are expected in the 4<sup>th</sup> quarter of this year. The opioid regulatory landscape is forever shifting and this is a risk for us so, to ensure that we understand the changing regulatory imperatives for this program and the oxymorphone patch, we are also planning to approach the FDA this year for a Type C meeting.

As I stated earlier, patches are complex, really challenging and opioid patches have an added layer of complication, and as we have announced Thursday the issues with the oxymorphone patch have now gone beyond our capabilities internally. So let me now take a little time to give you an update on the status of the TPM<sup>®</sup>/Oxymorphone patch and also provide some additional background on the recent oxymorphone patch decision to reformulate. As we have previously announced, in 2014 we took the TPM<sup>®</sup>/Oxymorphone patch to a manufacturer in the USA with the intention of moving towards a finalised formulation and scale-up in manufacture. This activity proved much more difficult and time consuming than anyone could have anticipated. The patches we have developed are complex and the process of Technology Transfer was complicated. In the end they were able to produce patches and we received them in early 2015. We immediately started the key preclinical testing required to assure ourselves that it was reasonable for us to spend considerable shareholder money to move the patch into further clinical work. Stability, patch wearability and performance, and the potential for irritation and sensitisation were all tested. Unfortunately, despite considerable work being done, the stability and wearability of the new patch were still not adequate to justify moving into further clinical studies. In an attempt to solve this and keep to schedule, we engaged three external formulation experts to look into the data, review it and provide possible solutions. Despite their experience and their review, the recommendation was that further “hands-on” reformulation work was needed. We realise how very disappointing this is and it is very disappointing and frustrating to us as well. We remain keen to solve this and ensure that we can get value from this asset. Unfortunately it is impossible at present to accurately predict how long it will take to fix but we do know that it will push the development out beyond 12 months. We are at present investigating how we can expedite this process.

As I mentioned earlier, I believe TPM<sup>®</sup>/Diclofenac gel presents a great opportunity for us. We already have a commercialised formulation sold by Novartis in India and we are now looking to make a westernised TPM<sup>®</sup>/Diclofenac gel product. The landscape for western approval and the dynamics in the western markets demand further work, including potentially further clinical work. Having said that, although future work is required, the technical, regulatory and commercial risk profile for a product such as this is very favourable and much lower than starting from scratch. Work on this has already started.

In the area of TPM<sup>®</sup> based injectables we already have a development deal with Mylan. Although I am not at liberty to give many details, I can say that this is progressing and the commercial attractiveness of the opportunity remains strong.

Finally, as part of the change in strategic direction the R&D team is undertaking a full re-review of all the data we have to better characterise and identify the type of drugs best suited for formulation with TPM<sup>®</sup>. In parallel we have started the review of optimal commercial targets. By cross matching the output from each review, we believe we will be in a very strong position to identify our next targets. Targets with the best probability of success and strong commercial drivers.

**Slide 12:**

So in conclusion, where are we with Phosphagenics today?

Despite the very disappointing share price, we remain a company with strong fundamentals.

- As of the end of 2014, we had approximately \$20 million in cash providing us with a two year runway.
- Multiple sources of further non-dilutive revenue which generated over \$2.1 million last year and I am pressing each of the businesses to grow these further this year.
- We have already restructured to become “business focused” rather than “research focused” and we have already started to up-skill and tighten spending. This will allow us to free up cash to develop more of our technology and further extend our runway.
- Our lead product TPM<sup>®</sup> /Oxycodone is in Phase 2 with results later this year, oxymorphone will be progressed using external experts, and we have initiated work on opportunities in the gel and injectable space.
- A publication strategy is in place with one paper already accepted and multiple others are planned and being written. Our strong patent portfolio will be supported and, where possible, enhanced.
- We have an up-skilled leadership. The new Board members, and myself, are all seasoned pharmaceutical and biotech industry executives and we intend to further up-skill with key hires and external expert input; and
- The technology continues to generate strong interest with prospective partners, and we have a number of simultaneous partnering discussions ongoing, right at this moment.

In conclusion - again thank you for your patience - I realise this was long but I hope it provided you with a better understanding of what we are doing and how I see the Company moving forward in the future. I will need your support and understanding as we move forward. I am keen for you and I to be able to draw a “line in the sand” from today and push forward Phosphagenics as a new company. My commitment is to do all I can to regain the value that has disappeared from shareholders over the past few years and then build from there.

## Ends

## Enquiries

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### **About Phosphagenics**

Phosphagenics Limited is a drug delivery company that is commercialising various products within the pharmaceutical, cosmetics and animal health sectors, using its proprietary drug delivery system called TPM<sup>®</sup> (Targeted Penetration Matrix). TPM<sup>®</sup> is a patient friendly and cost effective system, based on Vitamin E, that enhances the topical or transdermal delivery of active molecules. The lead products advancing through clinical trials are oxymorphone and oxycodone patches for the relief of chronic pain.

Phosphagenics' shares are listed on the Australian Securities Exchange (POH) and its ADR – Level 1 program in the US is with The Bank of New York Mellon (PPGNY).

### **Inherent Risks of Investment in Biotechnology Companies**

There are a number of inherent risks associated with the development of pharmaceutical products to a marketable stage. The lengthy clinical trial process is designed to assess the safety and efficacy of a drug prior to commercialisation and a significant proportion of drugs fail one or both of these criteria. Other risks include uncertainty of patent protection and proprietary rights, whether patent applications and issued patents will offer adequate protection to enable product development, the obtaining of necessary drug regulatory authority approvals and difficulties caused by the rapid advancements in technology.

### **Forward-looking Statements**

Certain statements in this announcement may contain forward-looking statements regarding Company business and the therapeutic and commercial potential of its technologies and products in development. Any statement describing Company goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the process of discovering, developing and commercialising drugs that can be proven to be safe and effective for use as human therapeutics, and in the endeavour of building a business around such products and services.

[www.phosphagenics.com](http://www.phosphagenics.com)