Phosphagenics

news

MARCH 2017

HIGHLIGHTS OF THIS ISSUE

- 2016 in review: a year of progress and achievement for Phosphagenics.
- Company financials released: $6M+ in cash at end 2016 with $2M+ now received through R&D tax incentive in Q1 FY17. Disciplined Y–O-Y performance improvements.
- Phosphagenics and Terumo Corporation sign non-binding Term sheet for Phosphagenics' TPM®/Oxymorphone patch in Japan. An additional $400k received as Term sheet payment.
- Phosphagenics' transdermal TPM®/Oxymorphone patch—stability ongoing.
- Positive ProPhase arbitration outcome in Q4 FY16 released the BioElixia® brand for sale.
- Human Health R&D injectables program continues to progress with news flow planned for 2017.

Welcome to the latest instalment of the Phosphagenics newsletter and the first for 2017. It has only been two months since my last update and I gave quite a comprehensive update at that time. So rather than restate that information, my intent in this update is to address two main areas:

1. The significant progress Phosphagenics' has made in 2016, and the strong position this places us in as we start 2017; and
2. Additional commentary on the full year 2016 financials released earlier this week.

1. OUR PROGRESS

As I start 2017, and my third year with Phosphagenics, I am excited to tell shareholders that the Company's strategy is in good shape. This is the year I believe we can really start to see the rewards from all the hard work we have put in over the past two years. Looking back, I hope shareholders can see the systematic progress we have made to this point. 2015 was a year of assessment, reassessment, and consolidation. 2016 was a true foundation year, filling crucial gaps in our portfolio, resolving some long-standing legacy issues, setting the stage for us to rebuild confidence and attract new lucrative deals for the company. 2017 is now the year to capitalise on the successes and hard work of the past 12 to 24 months in a way that helps build our share value and generates key deals across our three businesses.

Despite a lot of hard work in 2015, 2016 was a year that started with some definite challenges with mixed results from the clinical trial assessing the TPM®/Oxycodone patch in post herpetic neuralgia (PHN) patients. The failure to meet the primary endpoint was, understandably, seen by the market as a negative. However, as we had anticipated, the strong functional performance of the TPM®/Oxycodone patch in the trial was recognised by potential partners – the mixed efficacy message being viewed as more likely a result of PHN being a "difficult indication" than any negative on the patch's performance. Ultimately the potential of both the TPM®/Oxycodone and TPM®/Oxymorphone patches encouraged the Japanese multi-national, Terumo Corporation, to enter an exclusive due diligence agreement with Phosphagenics in May 2016 involving a $200k payment. Following nine months of extensive due diligence, we announced in January 2017 the signing of a term sheet with Terumo covering the exclusive rights to develop, market and sell the TPM®/Oxymorphone patch in Japan. On signing this term sheet Phosphagenics' received $400,000 from Terumo in late February.

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The major R&D activity undertaken on the TPM®/ Oxymorphone patch through 2016 was the reformulation effort with tesa Labtec GmbH which successfully culminated in December with the announcement of multiple patch options with the desired commercially targeted attributes. The reformulation process not only took account of the requirements originally set for the global market, but also addressed those attributes identified by Terumo as specific for the Japanese market. The reformulated patches are now on real time and accelerated stability.

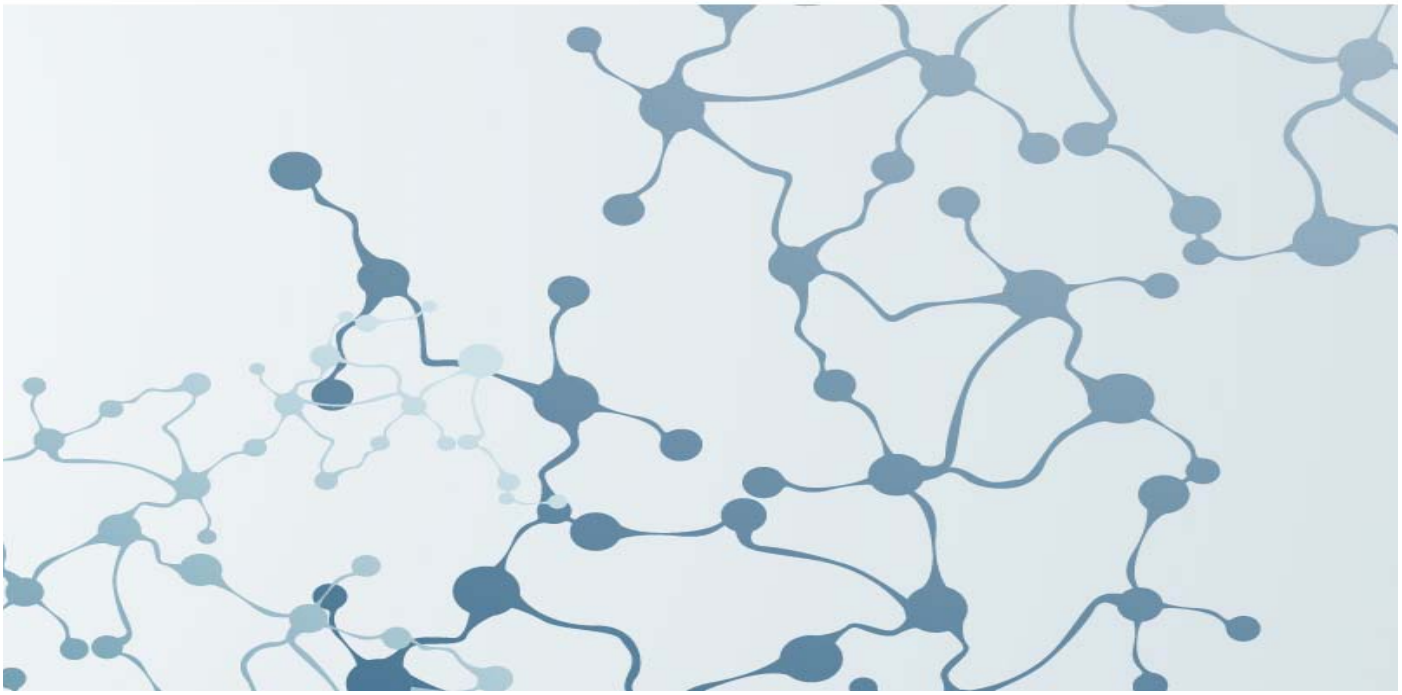
During 2016 the relationship with Terumo was further strengthened with three other R&D alliances – designed to build, evaluate and potentially develop TPM® enhanced versions of three existing molecules. The most advanced of these projects at this stage is a TPM® enhanced Propofol, while the other two projects are yet to be disclosed. I am pleased to say that the development of Propofol is moving rapidly forward with a new formulation and a development plan identified.

As of the date of this newsletter, Terumo have not yet formally provided a decision on their position on the TPM®/ Oxycodone patch. Although the period granted to Terumo to undertake exclusive due diligence and negotiation on both the TPM®/Oxymorphone and TPM®/Oxycodone patch expired in February and Terumo have satisfactorily completed their due diligence process, the question of whether they will decide to add both patches to the other ongoing TPM® projects (resulting in five TPM® related projects) or focus their resources across four TPM® projects remains open.

As the exclusivity period for the TPM®/Oxycodone patch has expired, Phosphagenics is now free to actively discuss this opportunity with other companies that have shown interest in the TPM®/Oxycodone patch over the past 12 months or so. We will advise shareholders in due course of suitable developments in this regard.

As previously mentioned, our internal R&D effort has increased its focus on the development and production of TPM® enhanced injectables. This is attractive for a number of reasons that were outlined in December's newsletter, principally that we have the potential to produce multiple valuable assets in a relatively short period of time for a relatively low cost. We have begun work on a number of formulations based on their commercial attractiveness and the clear unmet need for an improved formulation. The development effort is moving forward and we expect that these can provide great value for the company in 2017 and beyond as they target large and lucrative markets.

In many ways 2016 was both a successful and foundational year for both the "Animal Health & Nutrition" business and our "Production and Personal Care" business. The Animal Health & Nutrition business announced that it had successfully demonstrated that TPM® as a feed additive could improve feed efficiency across two livestock species (pigs and poultry). The announcement of the study results (particularly the results of the poultry study) has generated considerable interest amongst the industry. Dr Libinaki and I spent time in January meeting with several interested parties.



To add to this, the first placebo controlled study to investigate TPM® as a feed additive in dairy cattle is progressing well, having already reached its half way point, and is on-track to conclude the in-life portion in 2017. The dairy study will assess if TPM® can promote improved milk quality and fertility, in dairy cattle.

The Production and Personal Care business focussed its efforts in 2016 on strengthening the quality, protection and capacity of TPM® production, whilst also looking for clear savings in costs and new customers. The result has been truly impressive with a marked improvement in the production process, new opportunities to protect our production process, a 50 fold increase in TPM® manufacturing capacity and a marked decrease in the overall "cost-of-goods" – all resulting in an impressive improvement in financial margin and our ability to respond to an increase in demand associated with existing and new potential partnerships. Disappointingly, orders for TPM® and Vital ET® did not grow in 2016, mainly due to sales by our partner Integrated Animal Health Pty Ltd (IAH) not reaching their minimum targets as well as our global Vital ET® distributor, Ashland, having over stocked in the previous year. Ashland has reiterated its support for Vital ET® and we continue to work closely with them towards a product refresh and relaunch in 2017. Enthusiasm for the product remains strong and a product refresh will aim to reinvigorate existing partners as well as identify and develop new customer partnerships

As I mentioned earlier, I believe that the initiatives implemented over the past two years have put Phosphagenics in a strong position as we move into 2017, with the key highlights being:

- Cash position at the end of 2016 in excess of $6M with the further $2.3M now received from the R&D tax incentive;
- a disciplined continual year-on-year decrease in cash burn in 2016 and additional savings associated with the consolidation of our head office and manufacturing site - all designed to extend our cash runway;
- The strong partnership with Terumo is already projected to grow in 2017, bringing with it associated upfront and/or milestone payments, expertise and valuable additional data;
- Internal R&D work towards developing a number of TPM® enhanced injectable formulations is progressing with positive initial results and further news-flow planned in 2017;
- Multiple active discussions with potential partners for our TPM® technology and assets across each of the three businesses in progress – providing real potential for major deals in the short to medium term;
- The team continues to write and submit multiple scientific papers related to both new TPM® work and to the backlog of scientific data produced over the past 10+ years. We expect multiple publications in 2017;
- Quality, capacity, margin and opportunities for protection of our TPM® manufacturing have greatly improved – putting us in a better position to fulfil increasing demand;
- Strong trial results around the feed efficiency benefits of TPM® are forming the basis for ongoing partnership discussions. The pleasing progress of the dairy cattle trial adds to the potential for partnerships in the Animal Health & Nutrition field;
- The Themis TPM®/Diclofenac agreement continues to geographically expand, increasing demand for TPM® and associated revenues;
- The ProPhase Arbitration is complete and discussions around a sale of BioElixia® are well underway – successful signing of a full agreement is expected to provide an upfront payment and revenues from both the associated supply of TPM® and ongoing royalties; and
- The Mylan arbitration is established and progressing and carries the potential for substantial upside (the arbitration hearing is set for 4Qtr 2017). Phosphagenics has lodged multiple individual damages claims, each of which carry a substantial quantum. Phosphagenics remains convinced of the merit of vigorously pursuing this arbitration.

In summary, Phosphagenics has three strong business portfolios with:

- One commercialised gel, now licensed across 17 countries
- Two world first patch assets with clinical proof of principle
- Multiple R&D agreements with Terumo
- Positive R&D program ongoing with multiple injectables
- Successful results across multiple animal trials
- A profitable production business
- Interest from potential partners across all three businesses

2. OUR ACCOUNTS

Phosphagenics released its financial accounts for the year ended 31 December 2016 to the ASX yesterday. I don't intend to rehash the report here but would like to clarify a number of points that have generated questions, those being:

1. Our Performance and Cash Position
2. Spend Management
3. The "Emphasis of Matter" statement
4. Legal Activity and Costs

1. Our Performance and Cash Position:

I believe the results show a company with a disciplined approach to managing our existing cash, business and spending. During 2016 we again reduced our year-on-year spend and our overheads. At year end we had $6M cash with an additional $2.3M R&D Tax reimbursement due. This reimbursement has now been received. Our overall performance and ultimate year end cash position was however hampered in 2016 by lower than expected overall revenues (approx. $1.6M (2016) vs. $2.2M (2015)) from reduced demand from our key partners IAH and Ashland, and significant legal costs. Improving revenues and continuing to tightly manage our legal spend are priorities for 2017.

2. Spend Management:

Each year the financial report provides a number of values that seem to generate confusion and questions from shareholders. In particular "net loss after tax" and "expenses from continuing operations" which seem to generate the question "how can the company spend so much during the year – are they not managing spend". Neither of these amounts in the financial report directly reflect our utilisation of available cash for 2016. Both these values are a combination of cash and non-cash items such as impairment losses, amortization, depreciation, etc. Our aim is to responsibly manage our cash spend in a way that continues to improve a number of factors across the year. When assessing the performance of Phosphagenics and its management in controlling spend, it is important for shareholders to look across multiple metrics for improvements such as:

- reported net loss after tax: 14% lower (approx. $17.3M (2016) vs. $20.1 (2015)),
- expenses from continuing operations: 14% lower (approx. $20.6M (2016) vs. $24.0M (2015))
- expenses from continuing operations excluding non-cash expenses: 16% lower (approx. $10.9M (2016) vs. $13M (2015))
- employee and director expenses: 41% lower (approx. $3.4M (2016) vs. $5.9 (2015)), and
- net operating cash outflow (net spend): 26% lower (approx. $6.4M (2016) vs. $8.7 (2015))

3. The "Emphasis of Matter" Statement:

As a point of explanation, this year's financials came with an accompanying "emphasis of matter" statement from the Directors and Auditors. Emphasis of matter notes are not atypical in small biotechnology companies. They are used by the Directors and Auditors to point out areas of significant uncertainty in the accounts that, although disclosed appropriately in the Company's financial statements are in their opinion important enough to warrant an additional mention. In our case, the need over time to potentially supplement our existing cash position creates a point of uncertainty. Although the Directors have confidence that the Company will be successful in obtaining appropriate funding, as of today that funding has not been secured either in the form of revenue, a partnership deal, an equity raising or another funding source. For the reasons I have outlined above, we believe Phosphagenics is now well positioned to capitalise on some significant opportunities in 2017 and is a vastly different company to the company I joined in 2015. With this in mind, the Directors and Management have confidence that future funding can be obtained as these opportunities come to fruition.

4. Legal Activity and Costs

2016 saw substantial legal costs associated with the Mylan and ProPhase arbitrations: the latter completing successfully in November and freeing Phosphagenics to progress the sale of BioElixia®. Moving forward we remain convinced of the merit of continuing to pursue the Mylan arbitration as we believe there is a substantial potential upside regarding the multiple individual damages claims we have lodged. It is important to recognise however that pursuing these will require substantial future funding (estimated to be approximately $3M if it goes to arbitration). We have begun the process of investigating additional potential funding opportunities to cover the future costs of this action. We remain confident that suitable funding options are available and are actively investigating other options to raise funds.

Any potential awards related to this action have not been included in our budgets. We will obviously advise shareholders of suitable developments.

Finally, I would like to thank shareholders for their ongoing support in 2016 and look forward to delivering on the opportunities outlined above in the coming year.

CEO QUARTERLY UPDATE TELECONFERENCE

Interested parties are invited to participate in a teleconference.

Date: Friday, 3 March 2017

Time: 8:30 am AEST

Further dial-in details to follow in a separate announcement.

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