PHOSPHAGENICS LIMITED

news 03 14

Dear Shareholders

At the end of December 2013 the Company held $8.8 million in cash and cash equivalents. With the federal R&D tax rebates and the continuing recovery of misappropriated funds, Phosphagenics expects to receive over $7 million in 2014. In addition to these sources of revenue, Phosphagenics will derive cash flow from its normal business operations, which for the first time will include royalties from the sale of pharmaceutical products. Additionally, the Company expects to increase sales of TPM® products to the animal industry.

While 2013 was a difficult year, it ended on a positive note buoyed by the exceptional TPM®/Oxymorphone multiple dose Phase 1 study results announced in the last quarter. With an active program of clinical trials earmarked in 2014, we anticipate a year of scientific and commercial news flow.

The Company's pharmaceutical development program for 2014 includes the following studies:

- Phase 2 clinical trial on the TPM®/Oxymorphone patch, for a chronic pain indication
- Phase 2 clinical trial/s on the TPM®/Oxycodone patch, for a localised pain indication
- Phase 2 clinical trial on the TPM®/Tretinoin gel, for an acne indication (trial completion)
- Phase 2 clinical trial on the TPM®/Ketoconazole gel, for a dermatitis indication
- Non-clinical studies on the TPM®/Lidocaine patch, for a topical pain indication
- Non-clinical studies on the TPM®/Diclofenac patch, for a topical pain indication
- Non-clinical studies on multiple TPM®/NSAID gels under development.

Many of our assets are being positioned for short to medium-term licensing deals. Our lead commercial initiative is our opioid patch program, which comprises the TPM®/Oxymorphone patch and the TPM®/Oxycodone patch. These assets are aimed at different indications with different target product profiles.

The successful multiple dose trial announced in October 2013 indicates that the efficacy of the TPM®/Oxymorphone patch can reasonably be presumed. This confidence is based on the fact that each subject attained oxymorphone plasma levels in the therapeutic range (measured by reference to published plasma levels for the oral dosage form of Opana®) during the first rotation of the patch.

The proposed Phase 2 clinical trial, and other supplementary clinical trial(s), will be used to further characterise the dose response and delivery profile of the TPM®/Oxymorphone patch. All future studies will be designed to increase the commercial value of the patch and de-risk the product.

For our TPM®/Oxycodone patch, we intend to test the efficacy of the product on a number of different localised pain models. The single dose clinical results announced in July 2013 indicate that the delivery profile of the product is well suited for localised pain, whether peripheral or neuropathic. The Phase 2 clinical trial(s) are intended to demonstrate efficacy and assist in the selection of a target indication.

We are readying for Phase 2 clinical trials for both the TPM®/Oxymorphone and the TPM®/Oxycodone patch. We expect to commence a Phase 2 clinical study on one of these patches mid-year followed by a Phase 2 on the other. We have decided on this course of action simply because we do not have the internal infrastructure to undertake both studies simultaneously. While we have not chosen the patch that we will take into Phase 2 first, our focus remains squarely on oxymorphone because of its potential market size and because we have established that we can deliver it into the plasma in therapeutic concentrations. We will keep shareholders informed of our progress.

As we advance our commercial outreach for the TPM®/Oxymorphone patch and TPM®/Oxycodone patches, we are expanding different aspects of our infrastructure particularly our business development capability and regulatory expertise. Our New York office is being resourced with additional full-time employees with the intent that it will operate as our global commercial hub.

We are using expert consultants to guide our clinical development plan and commercialisation program for our oxymorphone and oxycodone patches. We are already in discussions with a number of pharmaceutical companies in the US that have the financial, clinical and regulatory resources to take our opioid patches through to market. We anticipate that these discussions will be ongoing throughout most of 2014.

We are also actively engaged in discussions with a number of pharmaceutical companies, in respect to our other pharmaceutical assets. Although, not part of our core opioid program, these assets nevertheless represent worthy short to mid-term revenue opportunities, many of them global. The assets include a diclofenac patch and gel, lidocaine patch, tretinoin gel, ketoconazole gel, additional NSAID gels, an antibiotic injectable and a clear propofol solution.

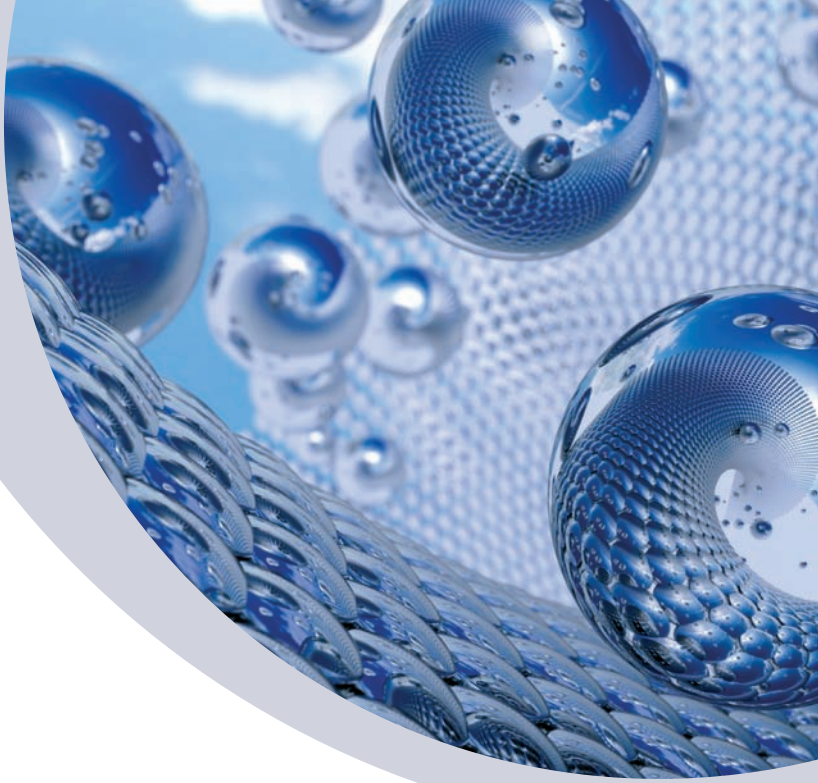
Early in 2014 we announced the commercial launch in India of diclofenac products – the Voveran® TPM diclofenac gel marketed by Novartis and the Instanac® TPM diclofenac gel marketed by Themis. These launches are of substantial commercial significance, not only because they corroborate the commercial power of our platform delivery system, but also because they raise the prospect of global licensing deals. You will find images of the packaging for these products are included below in the body of the newsletter.

With our increasing commercial focus in the US and the likelihood that we will conduct opioid Phase 2 clinical trials in the US, we aim to expand our corporate footprint in this critical market. The US accounts for approximately 70% of global opioid sales and this is where the licensee for the TPM®/Oxymorphone patch and the TPM®/Oxycodone patch will likely be based. Consequently we recently engaged the services of MZ Group, one of the world's largest independent investor relations advisory firms. We view this appointment as important in increasing our exposure to the investor community in the US. MZ Group has worked with a number of mid cap life science companies (mainly in the US), many of which experienced large increases in market capitalisation during 2013. MZ will assist us with developing and executing a comprehensive investor relations outreach program globally with a particular emphasis on North America.

Recently we announced the resignation of four directors and the appointment of three new directors. Our board renewal is part of our strategy to establish new leadership and relevant expertise. The new Board members are highly credentialed, exceptionally experienced and skilled operators in the life sciences industry. They will bring fresh insight to our company as we get nearer to our first major pharmaceutical deal. Our Board will focus on re-building the Company's credibility, moving the Company toward a significant licensing deal and growing the Company's cash flow by pushing more resources into revenue growth opportunities. The new Board will be completed in the near future by the appointment of at least one additional director.

We look forward – with renewed determination, excitement and focus – to a successful 2014.

Harry Rosen
Chief Executive Officer



New Board of Directors

The new members recently appointed to the Board are Mr Lawrence Gozlan, Dr Geert Cauwenbergh and Mr Nathan Drona. With their wealth of experience, they will help guide Phosphagenics through its transition from a research and development incubator to a fully resourced commercial enterprise. The process of changing the Phosphagenics Board took several months and involved the incoming Board members undertaking a thorough due diligence process. This changing of the guard signifies a new dawn for the Company.

We acknowledge our former directors and thank them for their dedicated and hard work for many years.

Mr Lawrence Gozlan

Mr Gozlan started his career in the industry as the biotech analyst for the Queensland Investment Corporation, which was at one stage the largest institutional investor in the biotechnology sector. He was well respected for his astute assessments and when he left QIC in 2006 he set up the boutique funds management group Scientia to primarily manage assets for Institutional investors and high net worth families and individuals. He continues his role as a fund manager today.

Mr Gozlan has held a number of board positions over recent years with a current position as a non-executive director of Prana Biotechnology Limited (ASX: PBT), a dual NASDAQ and ASX listed company that is conducting Phase 2 clinical trials for Alzheimer's disease and Huntington's disease. He was also appointed to the board of the industry's governing body AusBiotech, in March 2013.

He graduated with a Bachelor of Science honours degree, microbiology and immunology, from the University of Melbourne.

Dr Geert Cauwenbergh

Dr Cauwenbergh is a life sciences veteran, having started his career with Janssen Research Foundation in 1979-1982 in Belgium. He moved to the US in 1994 to take up the position of Vice President of Product Development for Johnson & Johnson. He later became global Vice President of R&D for J&J Consumer Group of Companies

In 2001 Dr Cauwenbergh left J&J and founded Barrier Therapeutics, a company that developed drugs to treat skin diseases. Stiefel Laboratories acquired Barrier Therapeutics in 2008. At the time of the acquisition the company's annual revenues had reached approximately US$45 million. He is currently President and CEO of OTC listed company RXi Pharmaceuticals (OTC: RXII). In this role he has guided RXII through its initial public offering and helped it successfully prepare and submit its first US FDA Investigational New Drug Application.

Dr Cauwenbergh has authored over 100 scientific publications. He received his Doctorate in Medical Sciences from the Catholic University of Leuven, Faculty of Medicine, where he also completed his Masters degree and an undergraduate degree.

Mr Nathan Drona

Mr Drona joins the Phosphagenics Board following a 15-year career in international investment banking, most recently as Managing Director of Challiss in New York and Sydney. He has a strong background in corporate finance and has executed more than 25 global banking and mergers and acquisitions engagements in biotech, medical devices and healthcare, leading to the award of the "Pharmaceutical Buy-Side M&A Advisor of the Year" by Frost & Sullivan in 2005.

Mr Drona is currently a non-executive Director of Alchemia Limited, which he joined in March 2013. Alchemia is one of Australia's most successful biotech companies with one drug in late stage clinical development and another that has been FDA-approved and generating sales. He has also been a board member of other public and private companies in Australia and North America.

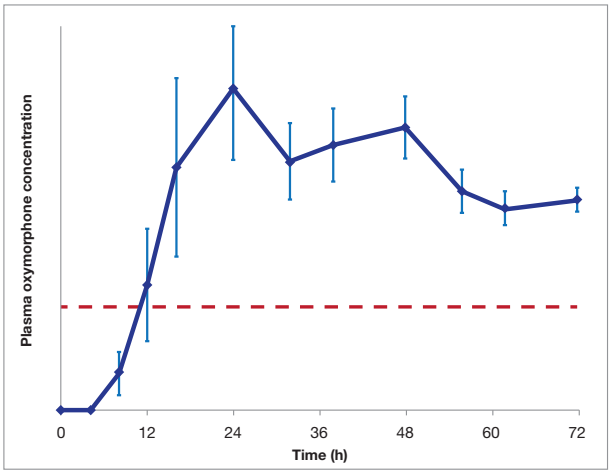
TPM®/Oxymorphone Patch – Clinical Trial Results

During the fourth quarter of 2013 we completed a multiple dose Phase 1 clinical trial for our TPM®/Oxymorphone patch achieving results that exceeded our most optimistic expectations.

The Company was able to show that the patch delivers oxymorphone through the skin and into the bloodstream at concentrations equivalent to the oral oxymorphone product, Opana®ER. These plasma concentrations, and by extension the patch product, are therefore therapeutic.

The delivery profile from a single application showed sustained delivery of the first 72-hour patch application period (represented in the figure below). The dotted red line represents a therapeutic plasma concentration previously established by oral Opana®ER. The delivery profile was reproducible in subsequent patch applications and average therapeutic plasma concentrations were maintained during patch changeover minimising or eliminating the incidence of breakthrough pain, both critical aspects of pain management.

Although many companies have tried, Phosphagenics is the first company to deliver oxymorphone transdermally at therapeutic plasma levels.



While this chart is based on average plasma concentrations, therapeutic levels were achieved in all 12 trial subjects and were maintained for the duration of the trial. Furthermore, some trial subjects achieved levels equivalent to the maximum dosage of the Opana® oral oxymorphone product (40mg). This is a significant achievement. It indicates the TPM®/Oxymorphone patch has the ability to cater for a wide range of chronic pain in a diverse group of pain suffers. This highlights the effectiveness of TPM® as a drug delivery system. These pK results have focused the Company's attention on efficiently executing the next steps in the product's development program to rapidly generate data for submission of an IND to the FDA.

TPM®/Oxymorphone Patch – Forecast Peak Sales

During 2013 we completed a comprehensive strategic plan for our TPM®/Oxymorphone patch incorporating qualitative and quantitative studies. The strategic plan, which includes input from globally recognised key opinion leaders in pain management, also incorporates a financial model including revenue projections. As part of the financial model we conducted a survey of 100 health care practitioners with practices in pain medicine to determine demand for the patch. The results of the quantitative analysis showed that 82% of practitioners surveyed expressed a very high likelihood of prescribing the TPM®/Oxymorphone patch.

The financial analysis also included the development of preference share projections for our TPM®/Oxymorphone patch, which was discounted according to standard market research methodologies to arrive at peak market share projections. These market share projections were combined with analysis of a) the target market for chronic pain treatment, b) competitive pipeline products expected to launch through 2020, and c) the current and potential future state of pricing and reimbursement for strong opioids. The final value of TPM®/Oxymorphone will depend on many factors, including the final product label and how the product performs in clinical trials. Nevertheless, we estimate that commercialisation of the patch could lead to significant sales in the US, with peak sales exceeding $1 billion per annum in an upside scenario.

TPM®/Oxymorphone Patch – The Program Moving Forward

The Company has been aggressively strengthening its internal capabilities with the appointment of a Regulatory Affairs Manager in Australia and a Vice President of Business Development and Commercial Operations in the US. Other appointments are likely to follow. We are developing an optimal approach to open an IND to conduct clinical trials in the US. We need to ensure that all future trials will address the many questions that the FDA may ask before approving our products.

We have been in constant contact with our advisers to finalise the plans for the clinical programs. Protocols for Phase 2 trials and other studies required for an IND application such as toxicology, skin irritation and sensitisation are being prepared.

In the meantime we are active in our outreach program to larger pharmaceutical companies that may have an interest in partnering our TPM®/Oxymorphone patch. The response has been positive with Phosphagenics entering discussions with several companies.

TPM®/Oxycodone Patch

In our September Newsletter we unveiled our opioid strategy. Oxymorphone would be targeted for systemic delivery while oxycodone would target peripheral pain and would be delivered topical with little systemic exposure.

Our strategic plan for oxmorphone is more advanced than it is for oxycodone. Opioids have been used for the reduction of pain for over 5,000 years through systemic circulation into the central nervous system. Only a small number of physicians use opioids for peripheral pain indication by applying them topically. Consequently there is dearth of information available to formulate a strategic plan for our oxycodone patch. If the topical application of opioids succeeds, we will be establishing a new market for these class of products.

The market for peripheral pain is around $6 billion annually. Current clinical strategies to deal with these indications by topical administration are poor. The only opioids used for topical administration are produced by compounding pharmacists. We have demonstrated that we can deliver oxycodone topically with little spillage systemically. We have established the concept of topical delivery in an animal study.

The oxycodone strategy falls outside our normal strategy. We know that we have an elegant patch that delivers oxycodone topically. However, we do not know whether it will be clinically efficacious when delivered in this manner. This is a departure from our strategy. However we have taken this approach because of the large market size of the peripheral pain market; because we are dealing with a disease state that is poorly treated with current clinical strategies and lastly because of the large commercial outcome that an opioid with little side effects and little potential of abuse would have in the market. When taking all these factors into account, the potential rewards outweigh the risks. The risk is no greater than the usual risk of developing a new drug.

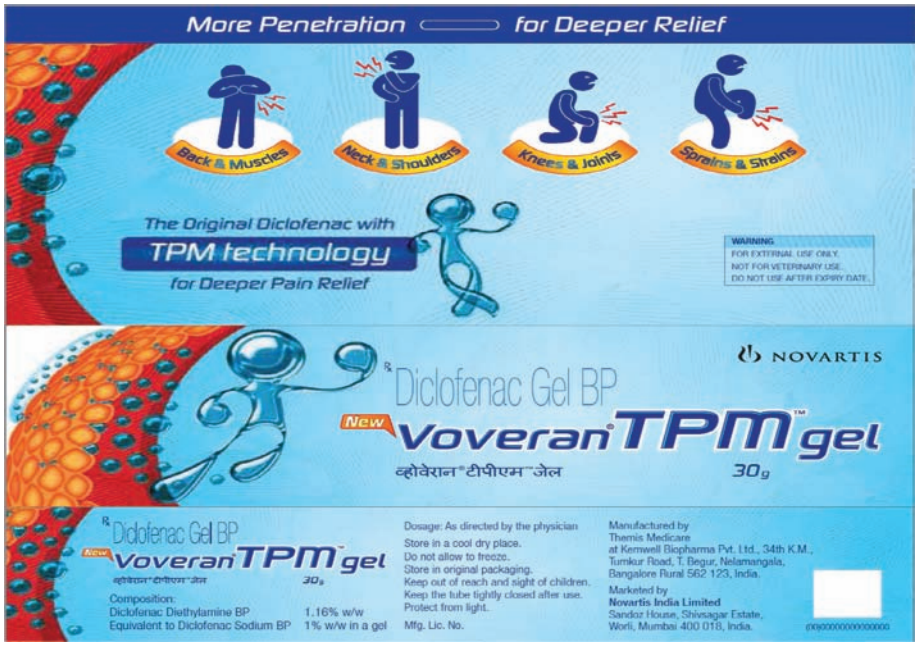
TPM®/Diclofenac Product Launch

Novartis India Limited has recently launched a topical gel formulated with TPM® transdermal drug delivery system licensed under an agreement with Themis Medicare Ltd. Themis will also launch its Instanac TPM® Diclofenac Gel shortly. Both the Novartis and Themis products highlight the benefit of TPM® which is promoted as a point of differentiation from other products. The packaging of Themis and Novartis products is displayed below.

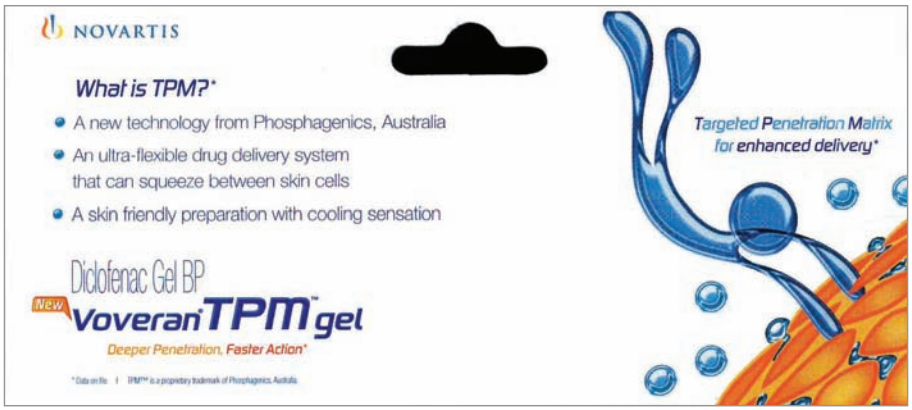
A successful launch of the TPM®/Diclofenac products in India may stimulate interest in TPM®/ Diclofenac products in other global regions.

Diclofenac is a non-steroidal anti-Inflammatory drug (NSAID) indicated for the treatment of pain and inflammation. The global sale of diclofenac products is around US$1.6 billion annually. It is sold in various forms including tablets, patches and gels.

Voveran® TPM® packaging (Front)



Voveran® TPM® packaging (Back)



Product purchased from a Pharmacy in India

Patent Update

At the time of announcing our TPM®/ Oxymorphone multiple dose results we also announced that, we had been granted a US patent for our TPM® matrix patch.

This patent covers a broad range of polymers, matrices and biological actives. The patent is due to expire in 2030, with possible extensions once the technology is used in a registered pharmaceutical product. The significance of the patent is that it protects the TPM® matrix patch technology not just for the current opioid programs but also for a substantial number of additional applications. The patent should be eligible for inclusion in the FDA's Orange Book, which provides notification of patent exclusivity in relation to FDA-approved pharmaceutical products.

While the patent applies to the US, the US patent examination process is so widely respected by examining offices in other jurisdictions, granting the patent in the US may lead to favourable outcomes in other regions where it has been submitted for examination.

Update on Other Products/ Projects

Tretinoin Trials

In our September newsletter we indicated that recruitment for our acne topical TPM® tretinoin treatment trial was slower than anticipated. We have since expanded our recruitment efforts to New Zealand and, although we obtained suitable candidates, the recruitment process is still continuing.

This has been extremely disappointing and will result in a delay. The trial should now be completed at the end of the second quarter. Recruiting patients in Australia for clinical studies is unpredictable.

A new formulation with the ability to deliver greater absorption of tretinoin, reduce irritation and dryness and limit systemic circulation should substantially increase the topical prescription retinoid market.

Animal Health

In December 2013 we completed a study examining the prophylactic effect of a feed that includes a combination of TPM® and beta-carotene has on dairy cows. The feed had been administered as a supplement under normal dairy farming conditions at a large dairy farm (over 700 cows) in northern Victoria. The inclusion of the TPM®/Beta-carotene feed supplement enabled the farmer to reduce the use of antibiotics by 50% in cows whose Somatic Cell Count were over one million cells/ml when compared to the same period in the previous year.

While this was not a controlled scientific trial, the dairy industry has reacted well to this result with interest by a number of large farms starting to translate into orders. Our partner, Mastitis Management Australia (MMA), is targeting large and influential farmers as well as agricultural nutritionists to become early adopters of the product. The Australian and New Zealand dairy herd of over six million cows is around 2% of the global market.

Based on internal projections made by MMA management, animal feed and the sale of TPM® formulated product could become a strong revenue contributor for Phosphagenics.

During the last quarter we reached agreement with a company related to our partners, Veterinary Research Australia (VRA), that will investigate a product to assist racehorses with pain and inflammation.

With our partners MMA, Equine Nutrition Australia and VRA, with which we have royalty-based arrangements, we continue to pursue opportunities to use TPM® in a growing range of products to improve animal health. For Phosphagenics, the animal health sector represents a substantial opportunity to ramp up sales volumes for TPM®.

GNC
LIVE WELL.

BioElixia® and Personal Care

In May 2013 Phosphagenics' partner General Nutrition Corporation (GNC) launched its Total Lean™ Toning Cream product in all of its corporate owned stores in the US. The product, which is marketed as a skin firming and toning cream, is manufactured by Phosphagenics and supplied to GNC in the US. It is the first topical product ever marketed under a GNC label and the TPM®- based formulation was selected for use in the product based on the strength of its performance in human efficacy studies. Total Lean™ is the leading brand, by revenue, in GNC's diet category.

In July 2013 the Company launched four new products as a line extension to its BioElixia® BodyShaper brand of skincare products (targeted solutions for the body):

- BioElixia® BodyShaper Stretch Mark Diminishing Crème
- BioElixia® BodyShaper Firming Toning Body Lotion
- BioElixia® BodyShaper Radiance Body Cleanser
- BioElixia® BodyShaper Exfoliating Body Polish

Like the previously launched Cellulite Contour Crème, the Stretch Mark Diminishing Crème performed exceptionally well in a photogrammetric study demonstrating an objectively quantified reduction in the appearance of stretch marks. A significant budget was committed to the Australian launch of this product in July 2013. The discovery and announcement of the misappropriations by the Company's former CEO impacted adversely on the product's launch. Our South Korean partner, Korean Drug Company, will launch the anti-cellulite product during the first quarter of 2014. The Company supplies a bulk material that it sells to the Korean Drug Company, which then packages the product and sells it under its own brand.

In addition to these product launches, the Company continues to generate revenue through its distribution arrangement with Ashland Inc of the Vital ET® ingredient to the cosmetics industry and royalty arrangements.

Expansion of the Company's USA Office

Phosphagenics will lift its profile and presence in the US. The US, and particularly the northeast part of the country, is the centre of the global pharmaceutical and biotech industry. The US is the key market for all of the pharmaceutical products we are developing. The key personnel in the Company's US office are:

Mr Jason Rosen

Mr Rosen joined Phosphagenics in October 2011 and serves as its General Counsel. He is based in our growing New York office, and as well as fulfilling the role of the Company's chief legal officer, he assumes a business development and commercial operations role.

He obtained a BComm and LLB (First Class Honours) from the University of Melbourne in 2004 having received a Law School Scholarship. In 2011 he completed an LLM (health law/pharmaceutical law focus) from New York University Law School having gained an Arthur T Vanderbilt Scholarship.

After being admitted as a lawyer, Mr Rosen practiced in the litigation department and corporate and commercial department of international law firm Allens Arthur Robinson. He then completed an appointment as judicial clerk to the Honourable Justice Finkelstein at the Federal Court of Australia, where he was involved in Corporations law, trade practices law, intellectual property law, consumer protection law and administrative law proceedings. Before joining Phosphagenics, he worked for several years as a Senior Solicitor in the litigation branch of the Victorian Government Solicitor's Office, the primary source of legal advice to the State of Victoria, Australia.

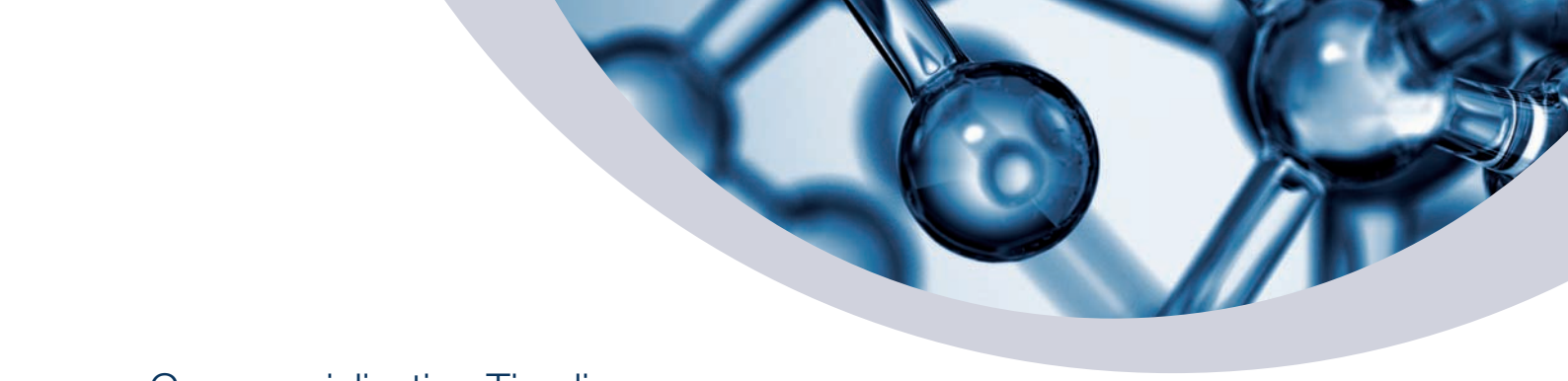
Mr Rosen founded the Association for the Prevention of Medical Errors, a non-profit organisation that seeks to improve patient safety through law reform. In this role he has worked with the World Health Organisation's Patients for Patient Safety program, submitted a law reform report to the Victorian State Parliament and presented at various conferences on patient safety. He was Assistant Editor at the Melbourne Journal of International Law. He is currently a member of the Food and Drug Law Institute as well as the General Counsels Committee of the Biotechnology Industry Association in the US.

Dr Alex Stojanovic

Dr Stojanovic joined Phosphagenics in February 2014 as Vice President of Business Development and Commercial Operations. He has ten years of broad commercial experience, during which he has advised, worked for, or partnered with more than 30 pharmaceutical, biotech and medical device companies across business development, commercialisation, marketing, pricing and market access, and corporate strategy. Most recently, he was the Pharma & Biotech Practice Lead for Kromite LLC (USA), a strategy consulting firm specialising in R&D portfolio management and decision analysis.

Between 2011 and 2013 Dr Stojanovic served as Senior Director of Global New Compound Marketing at Grunenthal GmbH, a pharmaceutical company specializing in pain therapeutics. At Grunenthal he managed the commercial planning for two novel opioids (cebranopadol & lexanopadol) in Phase 2/3 clinical development for the treatment of severe chronic pain and peripheral neuropathic pain. In addition to managing a team responsible for commercial strategy, market access and forecasting, strategic communications, and stakeholder engagement, Dr Stojanovic served on the Joint Commercial Committee with Forest Laboratories, Grunenthal's development partner. He also briefly managed the lifecycle strategy for Versatis®, a 5% lidocaine patch and participated in a variety of commercial activities related to Grunenthal's many other opioid and non-opioid programs.

Dr Stojanovic spent six years at ZS Associates, a management-consulting firm that is globally recognised as a leader in providing sales and marketing strategic services to the life sciences industry. He completed a Post-Doctoral Fellowship in Drug Discovery at North-western University (USA), where he conducted research on neurodegenerative disease. He completed his PhD in Pharmacology & Toxicology at Dartmouth College (USA) and BS degrees in Chemistry and Cell & Structural Biology from the University of Illinois (USA). Among his many academic accomplishments, he was granted two doctoral fellowships and co-authored a peer-reviewed article with Nobel Laureate, Har Gobind Khorana.



Commercialisation Timeline

Product Category/Project	Partner/Territory	Status
Pain – Oxymorphone patch		Phase 2 scheduled for mid 2014
Pain – Oxycodone patch		Phase 2 scheduled for mid 2014
Pain – Lidocaine patch		Product development continuing
Pain – Diclofenac patch	Nippon Zoki (Collaborative research only)	Product launch in the US expected 2015
Injectable – antibiotic injectable	Mylan (Global)	Product launch expected 2015
Injectable – propofol injectable		Product development completed
Dermatology – Tretinoin gel		Phase 2 commenced July 2013, currently in progress
Dermatology – Ketoconazole gel		Phase 2 scheduled to commence H2, 2014
Animal health – mastitis treatment		Work with USDA ongoing

Commercialised Products

Product Category/Project	Partner/Territory	Status
Pain – Diclofenac gel	Novartis Themis (India)	Product launch in India occurred in Q1, 2014
Animal health – horse supplements	Equine Ergogenics Australia	Commercialised (Australia/NZ)
Animal health – horse feeds	Equine Nutrition Australia	Commercialised (Australia/NZ)
Animal health – mastitis prophylactic	Mastitis Management Australia (Australia/NZ)	Commercialised (Australia/NZ)
Consumer skincare – BioElixia® range of skincare products	Henri Bendel; Fred Segal; Dermstore; Amazon etc	Commercialised (USA; Asia; Australia)
Consumer skincare – GNC Total Lean™ Toning Cream	GNC (USA)	Commercialised (USA)
Consumer skincare – Peau Vierge skincare range	Le Métier de Beauté (USA)	Commercialised (USA)
Consumer skincare – Vital ET® active ingredient	Ashland (Global)	Commercialised (Global)
Consumer skincare – KDC BodyShaper cellulite cream	Korean Drug Company (South Korea)	Product launch in Korea expected Q2, 2014

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