TECHNOLOGY TESTING UPDATE INCLUDING RECENT IN VIVO UNIVERSITY STUDY RESULTS

OBJ Limited wishes to provide a summary of results of an *in vivo* testing program using the Company's proprietary Enhanced Transdermal Polymer (ETP) drug patch technology. Results of the tests have shown enhanced dermal hydration during *in vivo* testing at the University of Western Australia.

In a multi-experiment *in vivo* study conducted between December 2008 and March 2009 at the Optical + Biomedical Engineering Laboratory (OBEL) at the University of Western Australia Dr Vincent Wallace and his team used Optical Coherence Tomography (OCT) laser technology and skin electrical analysis to monitor changes in epidermal thickness and electrical properties during the application of the cosmetic moisturising compound Urea under occluded and ETP enhanced delivery.

Summary

Enhanced Transdermal Polymer is the Company's powerless drug delivery technology designed for use in high volume drug patches in pharmaceutical, cosmetic and dermatology applications. In a multi-experiment *in vivo* study, Dr Vincent Wallace and his team generated 252 laser images and 240 skin electrical calculations to demonstrate an ETP induced increase in epidermal thickness when compared with passive. The study used a Urea gel in cosmetic concentrations being a commercially important compound used in many cosmetic and dermatology products.

Changes in epidermal thickness are believed to reflect changes in skin hydration, one of the major objectives of cosmetic and dermatology products. In studying changes in epidermal thickness under the influence of various ETP materials, the Company plans to demonstrate the ability of its technology to enhance the benefits of ingredients and products in a commercial environment and to provide a cost effective means for testing new molecules with the Company's technologies.

The use of *in vivo* (living subject) techniques rather than *in vitro* (in glass) methods previously used by the Company allowed the University to generate the data over much shorter time frames, providing an important new demonstration tool and greater insight into the interactions between the Company's drug delivery technologies and the skin.

Background

In September 2008, the Company reported that it had sought assistance from respected transdermal experts in Australia and Europe, to better understand the reasons behind the inter-laboratory differences in the levels of enhancement achieved when testing the Company's technologies at different Universities.

In December 2008, the Company further advised shareholders of the results of the consultants' reviews in which they suggested that damage to the epidermal membrane, differences in donor skin sample behaviour and normal inter-laboratory variability could have contributed to the variability. Consultants made a number of recommendations, which included the use of new test methods and models that reduced the potential impact of these influences.

The advice of the consultants is summarised by the statement:

"*The clear evidence of electro-osmosis being generated by both the ETP and DP mechanisms need to be taken advantage of rather than lost. It is important that OBJ moves away from further testing with epidermal membranes to dermatomed fresh skin, full thickness or, preferably, in vivo studies."*

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As a result of this and other recommendations the Company adjusted its research programs to reduce reliance on *in vitro* Franz cell type studies and to place more emphasis on testing methods that use *in vivo*, intact skin and living human subjects. By doing so, the Company's consultants suggested that the previous inter-laboratory variability may be reduced, be more reliable and achieve more commercially relevant results.

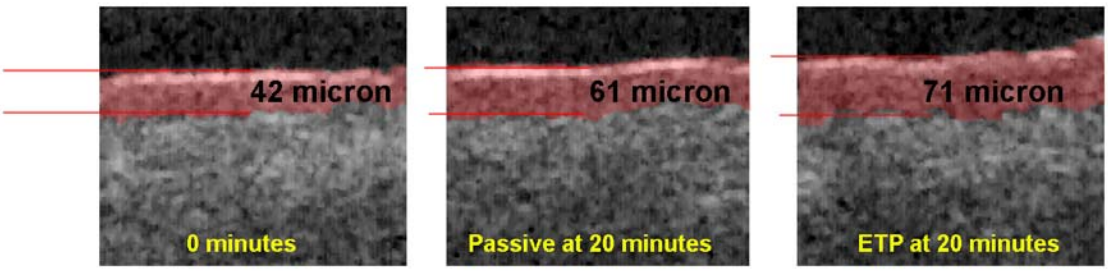
New Testing Techniques

In December 2008, the Company commenced work using a number of new models that provided information on how the skin's microstructures were potentially altered by the Company's technology and the penetration of certain drugs and compounds.

Three new techniques were adopted.

1. Optical Coherence Tomography (OCT) is a new imaging technique that uses laser light scattering to construct a detailed image of the sub-surface structures of living skin at a resolution similar to a standard microscope. A commercial OCT system was recently acquired by the University of Western Australia and installed in the Optical + Biomedical Imaging Laboratory (OBEL). The equipment is operated by experts in optical imaging and characterisation of skin and headed by Professor David Sampson.

OCT produces 3-dimensional images of the skin's microstructures to a depth of 2 to 3 mm. It constructs these images by measuring differences in laser light scattering by the various tissues and compartments of the skin. The image examples below were extracted from Experiment 1 and show the time dependant changes in epidermal hydration in response to the application of Urea gel. In the case below, passive Urea application has resulted in a plumping or swelling of the epidermis of 19 microns when compared with ETP which resulted in over 29 microns from 0 to 20 minutes. Cosmetic and dermatology companies should be interested in such data as it is reflects actual bioeffect in humans.



The ability of OCT to image changes in the components of the skin that are believed to determine the barrier effect and therefore the permeability of living skin makes it well suited to studying the effects of the ETP transdermal drug delivery technology.

In addition, as OCT displays morphological changes within the skin's microstructures and in response to the penetration of certain compounds, it is believed that it is suited to demonstrating certain biological effects in living skin. OCT is potentially well suited to the Company's cosmetic and dermatological application areas where potential partner companies are primarily interested in the combined biological effect of compounds and products in living skin.

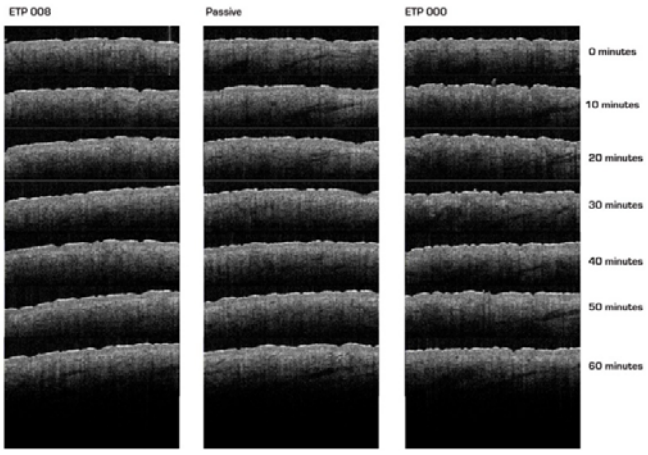
2. Skin Impedance is a technique that can be used in both *in vivo* and *in vitro* applications. It involves passing a low frequency AC signal between two electrodes on the surface of the skin and measuring the time dependent impedance to the propagation of the signal as it passes through the various skin structures. Skin impedance is widely used in the transdermal drug delivery industry to study the integrity or restoration of the skin's barrier function. Changes in skin impedance are believed to reflect changes in skin permeability to water-soluble (hydrophilic) molecules as the type of electrical charge used in skin impedance studies is believed to follow similar pathways through the skin to that of hydrophilic molecules.

3. Skin Capacitance is a technique used extensively by the dermatology and cosmetic industries to quantify and study changes in skin moisture content. The frequency dependent behaviour of human skin allows skin capacitance testing to be used to determine water content, where that water is accumulated and how it changes during the application of various drugs and cosmetic ingredients. The use of *in vivo* skin capacitance testing has the potential to provide the Company with commercially important information about the possible level of enhancements provided by the ETP technology when used in conjunction with active ingredients, formulations or products.

Study Methodology

The studies conducted by Dr Wallace and his team at the University of Western Australia, involved multiple experiments at OBEL. The primary objective of the study was to explore changes in epidermal thickness in response to the application of a cosmetic concentration of Urea in a gel format under passive conditions and under the influence of the Company's proprietary Enhanced Transdermal Polymer (ETP) technology.

ETP is a flexible material which contains programmed magnetic gradients in the form of arrays, each designed to provide differing levels of drug and skin permeability enhancement and drug interactivity. Each array or pattern is provided with a code to assist in evaluation and development. In the present study ETP pattern types with the code ETP000, ETP006, ETP008 and ETP011 were used.



Dr Vincent Wallace and his co-workers captured 252 OCT images involving 3 simultaneous images of 84 application sites following the application of a 5% Urea gel as an active ingredient, in addition to 240 skin electrical measurements.

All sites were occluded using a dense impermeable Parafilm to eliminate any potential occlusive effects of the ETP patch base material. Passive sites received a measured amount of Urea gel, plus Parafilm occlusive. Active sites received a measured amount of Urea gel, plus Parafilm occlusive plus a 25mm square section of ETP placed externally to the occlusive film. All sites were then secured using micropore breathable surgical tape.

In a number of the studies, EKG electrodes were applied to either side of the application area and simultaneous skin impedance and capacitance measurements were recorded using an AC-LCR Bridge meter (Model TH2811D Tonghui Electronics), as recommended by consultants and literature. Skin impedance and capacitance data was collected at 100Hz using parallel mode emulation and a 0.3 volt AC drive signal.

Experiment Protocols

Experiments involved the application of Urea gel and occlusion to 3 locations on the volar forearm of a healthy volunteer. The central site allocated as passive (occlusion alone), while the locations either side received two different ETP types applied externally to the occlusion. Urea gel was applied to the skin for periods ranging from 20 minutes to 60 minutes. In a number of studies, contact time was limited to 20 and 30 minutes with all sites being cleared immediately after and then allowed to air-dry until the end of the 60 minute study period. OCT images were taken in triplicate on both left and right arms prior to the experiment, at 20 minutes and 30 minutes intervals and then again at 60 minutes. In study 3, OCT images were captured every 10 minutes.

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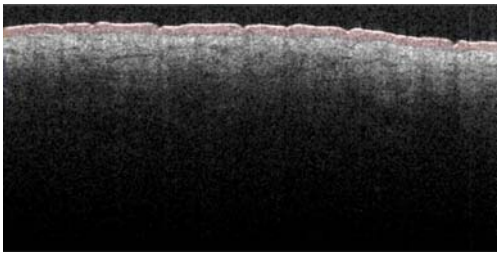
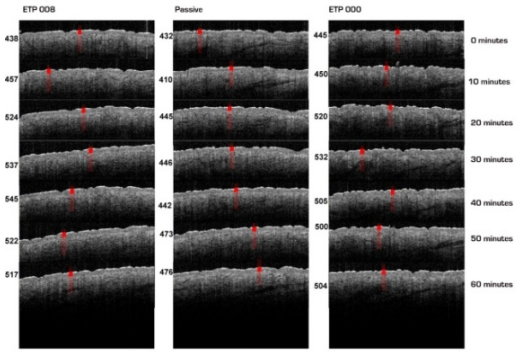
Experiments 2 and 3 used the OCT protocol as explained in detail in the results section. Simultaneous skin impedance and skin capacitance measurements were captured every 5 minutes during the application periods and every 10 minutes during the air-dry phases.



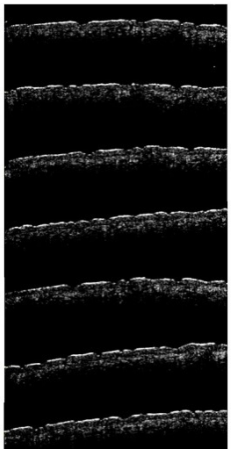
OCT data was analysed using three optical techniques.



- Total epidermal pixel count. This involved the manual selection of the region encompassed by the stratum corneum and dermal/epidermal boundary. This was then coloured using a primary fill and pixels calculated by histogram.

- Area selected pixel count. This involved the selection of a 200 by 150 pixel zone on each image free of surface and subsurface irregularities. The area of the stratum corneum and epidermis was then extracted using a pixel count technique.

- Filter selected area pixel count. This involved the use of various grey-scale threshold filtering techniques to isolate pixels of a preset luminosity prior to counting.



Skin Impedance and Capacitance data was plotted directly using standard spread-sheet software and required no further interpretation.

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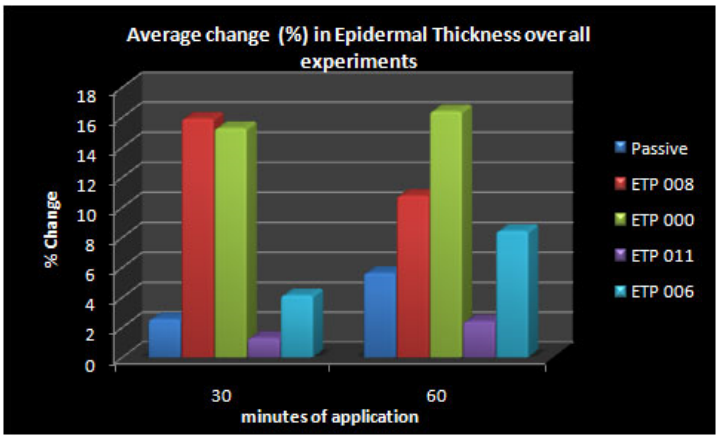
Results:

Average Over All Experiments

Based on time dependent changes in measured epidermal thickness, when averaged over all experiments, OCT suggests that after 30 minutes of contact with 5% Urea gel, epidermal thickness in passive locations increased by an average of 2.54% and rising to 5.62% over 60 minutes.



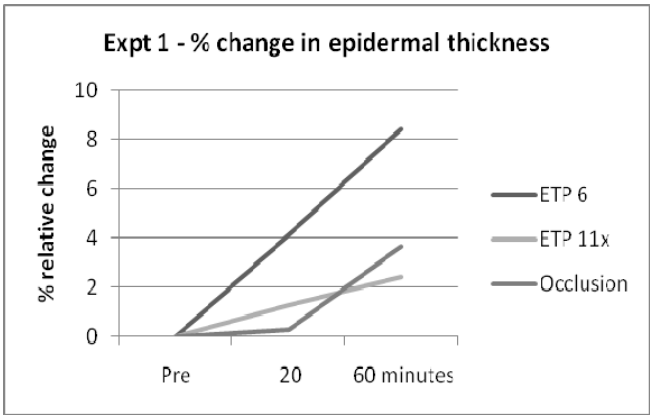
At sites enhanced by ETP pattern Type 008 in addition to occlusion, the average increase in epidermal thickness was 15.9% within the first 30 minutes and 10.76% over 60 minutes.

Sites enhanced by ETP Type 000 achieved an average increase of 15.27% within 30 minutes and 16.4% over 60 minutes, while ETP type 006 (4.13% and 8.42%) and ETP 011 (1.29% and 2.39%) were less effective at increasing epidermal thickness.

The results generated under the testing program by the University of Western Australia were summarised and interpreted by the Company.

Experiment 1

Experiment 1 sought to determine the time dependent nature of penetration in living skin and to determine the level of sensitivity of OCT to these changes. Urea gel was in contact with the skin for a period of 20 minutes and then removed and the area allowed to dehydrate for an additional 40 minutes.



OCT images were taken before Urea application to establish normal base-lines, then at 20 minutes (immediately following removal of the Urea) and then again at 60 minutes.

Both ETP types produced a relatively linear increase in epidermal thickness over the duration of the experiment and did not display the traditional lag time trend seen in passive occlusion. Lag time reflects the time taken for a drug to penetrate the outer stratum corneum region of the skin before it reaches the more biologically active regions. The lack of lag time in ETP enhanced sites is consistent with the Company's previous *in vitro* experiment results. The exact mechanisms are yet to be determined, however the Company's consulting experts have suggested a possible electro-osmotic effect. This requires greater research to be conducted.

While the number of data points were limited and provided no information regarding intermediate changes, results suggest that ETP 006 and ETP 011 achieved a high level of enhancement over passive occlusion at 20 minutes. Following 40 minutes of air-drying, ETP 006 maintained its effect while ETP 011 showed a lower rate of change. Passive Occlusion

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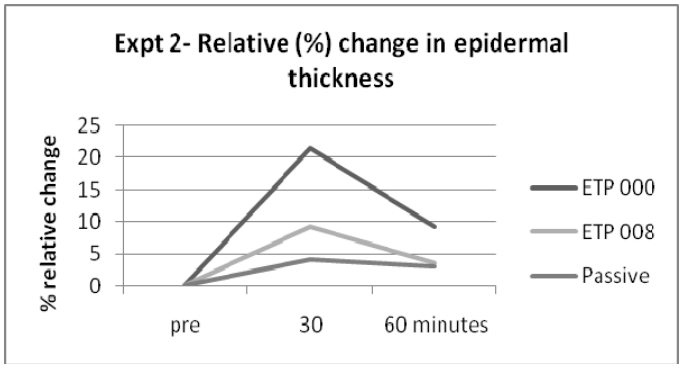
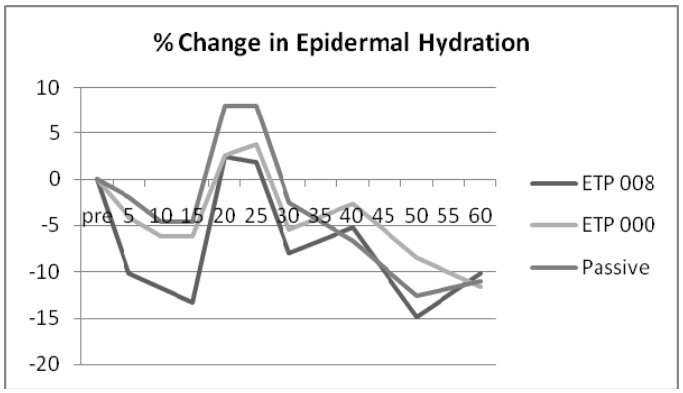
had minimal effect to 20 minutes then achieved a greater level of epidermal thickness change during the following period.

Experiment 2





Experiment 2 set out to explore the relationship between skin electrical properties and epidermal thickness changes. This required OCT images and skin electrical parameters to be gathered simultaneously. Two new ETP materials were tested, based on the experience of Experiment 1. A 30% longer Urea contact period (30 minutes versus 20 minutes) was also used during this experiment.

OCT results suggested that passive (occlusion) achieved an epidermal thickness increase of around 4.5% by 60 minutes, which was consistent with Experiment 1. The change in trend line may be attributable to the increase in contact time. ETP 000 and ETP 008, which are similar to ETP 006 from the previous experiment, achieved higher epidermal thickness changes within the first 30 minutes. The decline in epidermal thickness between 30 to 60 minutes may be due to the water binding properties of Urea once inside the epidermis. When used cosmetically, Urea is usually applied in conjunction with a moisture source acting to bind or hold that additional moisture within the skin. When used alone, it may be binding with natural free moisture temporarily reducing its bioavailability in the skin. This remains to be confirmed.

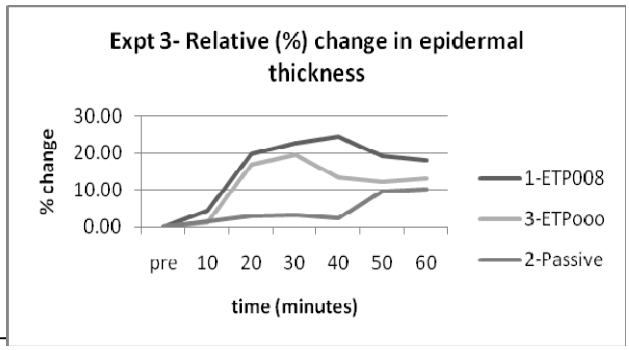
When the skin capacitance data was analysed, it suggested that considerable changes appeared to be taking place in skin morphology at a rate that was not captured by the 30 minute OCT images. Skin capacitance measurements at the 0 and 30 minute OCT images were similar, however substantial changes were apparently taking place between these capture points.

More research is required in order to better understand these changes although the speed of action and nature of the skin interactions with ETP magnetic gradients appear to be more complex than previously considered.

Experiment 3

Experiment 3 sought to provide data at shorter time intervals in order to better track the apparent rapid series of morphological changes that take place in the first 60 minutes of ETP and compound Urea contact.

In this experiment, OCT was captured every 10 minutes and



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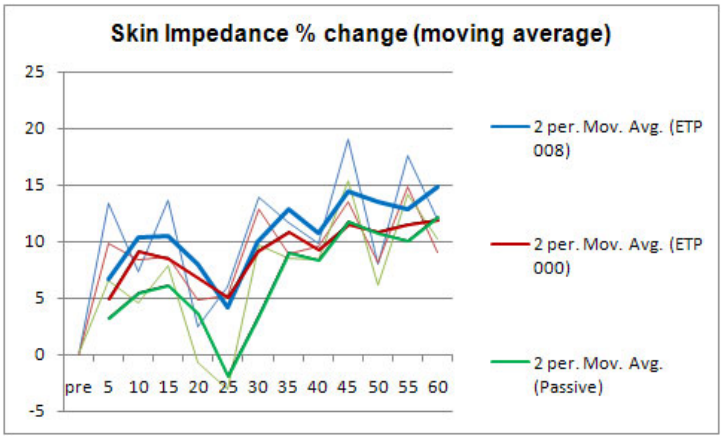
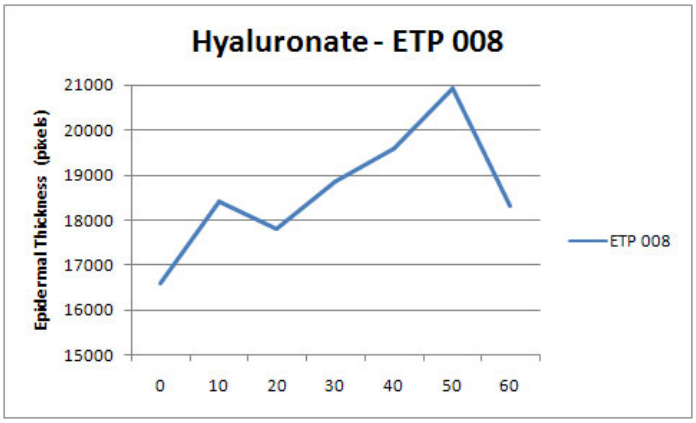
skin electrical properties every 5 minutes. To accomplish this and to provide OCT with a clean region for imaging, active and passive areas were setup to allow the occlusive and ETP components to be folded back to allow clear access for the OCT laser read head. At each time point Urea was removed to reduce laser flaring and reapplied immediately after. The period of contact for the Urea gel was increased for the entire duration of the experiment.

OCT imagery showed that passive was again in line with the previous experiments and followed similar trends. The gentle rise in passive epidermal thickness at 40 minutes is largely in line with lag time expectation in passive delivery. The rapid rise with ETP 008 and ETP 000 between 0 and 30 minutes is consistent with the previous experiments and their rising trend at 30 and 40 minutes suggests increasing drug bioavailability. The decline in epidermal thickness at 40 minutes to 50 minutes is consistent with the humectant effect of Urea as seen in previous experiments.



Skin Impedance, which is a measure of the quality of the hydrophilic pathway, revealed significant changes occurring between data points. The repetitive peak and troughs in the impendence data are possibly due to the need to remove and reapply Urea to each OCT image capture however the moving average shows the general trend.

The drop in skin impedance which occurred at the same time point as the rise in skin capacitance in Experiment 2 suggests that the inverse relationship between skin impedance and skin capacitance is also seen using this model. Further testing is planned.



Experiment 4

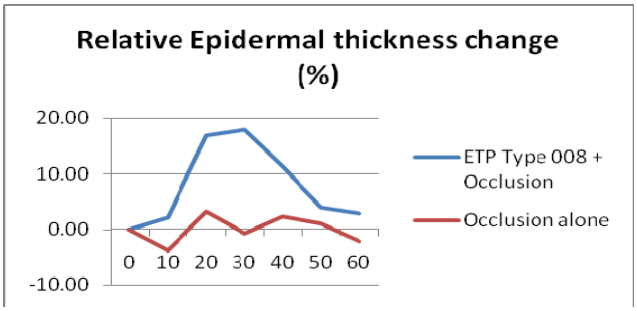
Experiment 4 set out to explore whether OCT could be used to demonstrate downstream bioeffect of high molecular weight Hyaluronic Acid, an essential biological component of the skin and the synovial fluid in joints. Hyaluronic Acid or HA is used widely in cosmetic and dermatological application. It is believed to permeate the skin poorly due to its large molecular size and complex construction.

HA is difficult to explore using *in vitro* techniques as *in vitro* assay requires the HA to be fully digested, making it difficult to demonstrate the intact delivery of the complete molecule.

Results suggest that after a period of increasing thickness possibly due to take-up of the water solvent, a substantial reduction in epidermal thickness occurred at around 50 minutes, possibly indicating that HA was binding with epidermal water. In a follow-up skin electrical study a similar pattern was observed using skin capacitance.

Experiment 5

Experiment 5 sets out to explore morphological changes in response to the use of a highly lipophilic oil based compound. There are a number of important commercial applications for such substances. The use of *in vivo* testing methods in such applications is a potentially valuable tool for the Company as such oils often contain over 100 individual molecules making *in vitro* testing both difficult and expensive.



In the UWA study, an unrefined oil fraction was investigated using passive occlusion techniques with ETP 008. The rapid rise in epidermal thickness using ETP 008 was similar to that seen in studies using other hydrophilic compounds. The rapid decline in epidermal thickness change between minutes 30 and 60 suggests bioavailability and a possible uptake by the skin's normal lipophilic bilayer.

Discussion:

The study by the University of Western Australia is part of the ongoing development and testing program recommended to the Company by international consulting experts which focuses on *in vivo* techniques rather than the *in vitro* methods previously used by the Company. The use of OCT and other *in vivo* techniques are believed to provide the Company with important new demonstration tools and greater insight into the interactions between its drug delivery technologies and the skin. They also allow studies into the effect of the Company's drug delivery technology in living systems and by doing so largely avoid the inter-laboratory differences in skin preparation, study and assay techniques that reportedly lead to variability between laboratories.

In vitro study methods are still being used and will continue to be used for diffusion studies into single active ingredients and for pharmaceutical applications. The benefits of demonstrating down-stream bioeffect in living systems are believed to provide more reliable and more commercially relevant data for cosmetic, dermatology and nutraceutical applications.

OBJ has now used *in vivo* study techniques at three different Universities. Murdoch University studied vaccine delivery in living sheep. Curtin University studied local anaesthetic delivery in a double blind human pilot study and now University of Western Australia has studied epidermal thickness changes in humans. The University of Queensland has to date conducted *in vitro* studies only, however the Company plans to utilise their extensive optical research facilities in future expanded *in vivo* programs. In each case where *in vivo* methods were used, results have been consistently positive and are believed to better represent the actual performance of the Company's drug delivery technologies than *in vitro* studies.

In the University of Western Australia study, ETP was shown to increase epidermal thickness during the application of a commercially important topical compound used by the cosmetic and dermatology sectors. The results suggest that ETP may enhance the biological effect of topical Urea in epidermal thickness with less delay and with greater overall effect than occluded delivery.

Research using these new models is continuing with a view to demonstrating the efficacy and benefits of ETP to potential commercial partners. OCT and other *in vivo* study techniques are unable to measure drug concentration, therefore the degree of enhanced delivery of particular molecules cannot be assured without further research using appropriate molecular techniques.

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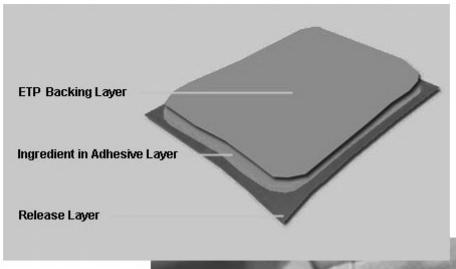
About:

Enhanced Transdermal Polymer (ETP)

ETP is a flexible polymer material with embedded magnetic arrays developed by the Company to provide a low-cost powerless active drug delivery capability. ETP can be manufactured as an industrial roll and is designed to replace the passive plastic backing layer in standard drug patch production. ETP is designed to add minimal costs to production but allow greater drug delivery, fast penetration and shorter times to onset in a wide range of applications in the pharmaceutical, dermatology and cosmetic sectors.

ETP functions by generating tightly controlled magnetic field gradients that are believed to interact with the skin's microstructures and the drug's formulation to enhance the time, rate and efficiency of transdermal delivery. Each magnetic field gradient is made up of an array of magnetic elements with the dimensions and orientation acting together to create 3-dimensional field structure.



It is currently believed by the Company that the magnetic gradients generated by ETP can be optimised to suit the delivery requirements of specific drugs and products.

Optical Coherence Tomography (OCT)

OCT is an *in vivo* imaging technique. It cannot display drug concentrations or blood levels, but is a powerful tool for imaging the critical downstream bioeffect that is of interest to the majority of cosmetic, dermatology and nutraceutical companies.

OCT when used in conjunction with established skin electrical models has the potential to provide reliable and consistent data on the behaviour of the skin during the transdermal delivery of beneficial substances. When used to explore morphological changes in the epidermis in response to ETP and passive delivery, OCT proved to be a valuable and reliable tool for the development of the Company's technologies.

About OBJ

OBJ Limited (ASX: OBJ) is an early-stage Australian drug delivery company focused on the development and commercialization of transdermal drug delivery technology for use in pharmaceutical, and cosmetic industries. OBJ's proprietary *Dermaportation* and *ETP* technologies use magnetic fields to control drug movement and skin permeability without disrupting the skin barrier. The delivery platforms may be employed in a range of cost-effective delivery solutions for hydrophilic small molecules and potential peptides in a *painless, controlled and cost-effective manner*.

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