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MMJ PhytoTech on recent company successes, developments in the medical cannabis industry and key priorities moving forward

Interview with Andreas Gedeon (Managing Director, MMJ PhytoTech Ltd) and Dr Daphna Heffetz (CEO, PhytoTech Therapeutics Ltd)

In this Market Briefing interview, Andreas Gedeon, MMJ PhytoTech's Managing Director, and Dr Daphna Heffetz, CEO of MMJ's wholly owned subsidiary PhytoTech Therapeutics, discuss recent developments in clinical trials, the medical cannabis industry generally, and key priorities for the company moving forward:

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MMJ's operations to date have been focussed offshore. In light of legislation recently being passed in Australia, what is the company's strategy around entering the domestic market?

Andreas Gedeon

The staggered nature of international medical cannabis reform emphasises the importance of MMJ's experience in Canada, Israel and Europe. We've developed our facilities based on the distinct advantages those geographies provide - medical cannabis research in Israel is among the most advanced in the world, while Canada continues to support the growth of an already established and very favourable regulatory framework. Establishing European operations was another strategic decision, as we are currently distributing CBD pills in the EU as a dietary supplement but, in doing so, have developed a distribution network and close relationships with key industry contacts. Again, this means we're extremely well placed to capitalise on medical cannabis reform when it occurs. Having the ability to be flexible and react quickly to regulatory change is the key.

Whilst Australia is a different regulatory proposition, we are in a great position to leverage our offshore operations as we enter the market. The simple first step will be importing CBD capsules from Switzerland similar to those we are currently selling in Europe. We believe this can happen under existing legislation and, if our application is approved, this will mean that our CBD capsules will be available to Australian consumers within weeks of the approval. We are investigating potential partnerships with farmers, horticulturists, Australian growing facilities that stand to benefit from MMJ's Canadian operations and R&D capabilities in Israel. This approach avoids the long and costly process of establishing a facility ourselves so we can turn our focus to extracting and refining cannabinoids that can be applied to pharmaceutical style delivery systems. Not only is this end of

the value chain where the majority of value is captured, but it will likely account for a larger portion of the market than other jurisdictions as the Australian system is expected to be highly restrictive with physicians as the gatekeepers.

Beyond growing partners, we are also exploring relationships with pharmaceutical processors, compounding pharmacies with established distribution channels and patient advocacy groups in order to enter the Australian market with maximum momentum.

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You mentioned a focus on alternative delivery systems in Australia. Is smoking medical cannabis a thing of the past?

Andreas Gedeon

As global regulation of the medical cannabis market continues to evolve, so too must the product itself, to bring it in line with the standards and sophistication typical of other regulated pharmaceuticals. The industry's evolution is now moving away from unfavourable administration methods (e.g. smoking) and non-standardised, inefficient, expensive products that are currently the norm. The future of the industry is most certainly in pharmaceutical grade delivery systems that can be administered in hospitals, in standardised doses, without the harmful effects of smoking.

Daphna Heffetz

MMJ's products, as verified in Phase 1 clinical studies, have the potential to overcome the limitations of the alternative delivery products currently on the market. Our exclusively licenced oral capsules can be safely consumed and exhibit very high bioavailability when compared to other oral technologies currently available. The active cannabinoid used in these capsules is subject to extensive purification processes, which facilitate exceptionally high standardisation levels that allow specific dosages to be prescribed in line with the patient's condition. Capsules, however won't always be the answer. A water soluble product, for example, is more appropriate for children, the elderly and chronically ill, who have difficulty swallowing their medication let alone smoking it. Phytotech Therapeutics, our wholly owned subsidiary in Israel is central to MMJ's capability in this space. We are currently developing several alternative delivery technologies for medical cannabis to address varying patient needs. Whilst we envisage these products being the focus of our Australian offering, in other markets, with less restrictive regulatory systems, raw bud will be a much more significant part of the market so the ability to grow and sell dried buds is higher priority. This is the case in Canada where our Duncan and Lucky Lake Facilities are based.

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What do you see as the competitive advantages necessary to be a leader in the medical cannabis industry?

Andreas Gedeon

In my view, vertically integrated operations, first mover advantage and the ability to produce pharmaceutical-grade products that medical professionals can prescribe are the three competitive advantages that will define the winners once the industry reaches maturity.

MMJ's vertically integrated "farm to pharma" strategy means we can develop and retain key IP around bespoke plant strains and delivery technologies and bring these to market via in-house cultivation and refining facilities. This approach allows us to protect our IP and capture value along the chain which is increasingly significant towards the "pharma" end.

We now have established operations in Israel, Canada and Europe, and an extensive IP catalogue out of Israel, that is the result of years of hard work, capital investment and research. There are no shortcuts to establishing a vertically integrated global platform in this industry, so our existing operations around the world give us a unique ability to enter new markets quickly with a pharmaceutical offering.

As I mentioned earlier, we see non-harmful alternative delivery systems as the only logical option in the pharmaceutical end of the market, and ensuring we are producing high quality, refined pharmaceutical grade products will allow us to capture that segment of the market.

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GW Pharmaceuticals recently announced the successful completion of its Phase 3 study on the treatment of Dravet Syndrome (a severe, difficult to treat and rare form of epilepsy) using high-dosage CBD products. Their share price jumped 139% intraday and they are now capped at ~A$2 billion. What does this mean for MMJ and the broader medical cannabis industry?

Andreas Gedeon

The amazing growth experienced by GW Pharmaceuticals indicates how quickly the industry is growing and evolving. There is an increasing acceptance of the therapeutic applications of medical cannabis, and the growing cache of clinical evidence to support them. Applications range from insomnia and menstrual pain relief, all the way to the treatment of epileptic seizures, so I'm not surprised to see the market attribute a high value to these products as they come closer to market via successful clinical trials.

GW's clinical study was for a high-dosage CBD product called Epidiolex, which they plan to sell as a treatment for patients with Dravet Syndrome. There are currently no recognised treatments available in the US, which highlights the importance of the research medical cannabis companies are doing. MMJ's high-dosage CBD (100mg) capsules have passed Phase 1 clinical trials, and contain the same substance as Epidiolex, though our CBD capsules are currently being sold in Europe at a fraction of the predicted cost of Epidiolex.

Daphna Heffetz

The market clearly places a high very value on clinical trials, and rightly so. Completion of clinical trials will ultimately lead to access to larger markets, where the benefits of developed health care systems and reimbursement programs flow through.

We have successfully completed Phase 1 clinical trials for both the PNL THC:CBD as well as the CBD 10mg & 100mg GelPell capsules, which returned superior results to peer products and paves the way to conduct Phase 2 studies for various clinical indications. Our plan is to initiate two Phase 2 efficacy studies in tandem in the second half of 2016, and to commence Phase 3 studies in the second half of 2017. Once completed, the products tested should have all the necessary approvals to be prescribed by doctors.

While medical cannabis regulations will vary from market to market, this presents an opportunity for MMJ, as we can develop products for sale in the short term in markets with existing therapeutic medical cannabis programs, while also subjecting those same products to clinical testing for approval as prescription treatments in the longer term.

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What is your focus for the next 6-12 months?

Andreas Gedeon

We will continue pushing ahead with our clinical trials, with Phase 2 to focus on spasticity and pain in Multiple Sclerosis, with the possibility to expand the trials to include some additional clinical indications.

We also intend to begin the importation of existing Satipharm products into Australia, and we'll cooperate with other existing health, pharma and farm operators domestically to expedite our entry. The Australian market is at a tipping point in terms of regulation and acceptance, and we'll look to establish MMJ as a key influencer and industry expert in Australia given our Canadian and international experience.

We will also be bringing the Duncan facility online, and will progress plans to expand our capabilities in Canada in line with our strategy. Together with Lucky Lake, this has the potential to make United Greeneries one of the largest producers in Canada. Our Canadian operations will allow us to manufacture products for sale in Canada and export to Australia, while also allowing us to monitor the US market closely and should federal legislation change.

Finally, we will continue to research and develop new treatments and delivery systems, and add to our expanding IP catalogue through ongoing work with scientific institutions and other industries.

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Thank you Andreas and Daphna.