

Exclusive License Agreement for the Commercialisation of Dronabinol in the USA, Canada, Australia and New Zealand

Highlights:

- Impression licenses materials and intellectual property to support the production of generic Dronabinol (pure delta-9 Tetrahydrocannabinol ('THC')) capsules
- The licencing arrangement is intended to expedite the achievement of marketing authorisations of 2.5mg; 5.0mg and 10.0mg generic Dronabinol capsules for the USA, Canada, Australia and New Zealand
- Dronabinol is used to treat:
 - loss of appetite in people with HIV/AIDS,
 - nausea and vomiting caused by chemotherapy, and
 - other potential indications including pain management and sleep apnea
- Cannabis consulting firm, Pharmout is advising Impression on use of the materials
- Dronabinol was the first ever cannabinoid medicine permitted for patient use by the Drug Enforcement Agency in the United States; under the trade name Marinol[®], currently marketed by Abbvie Inc. (NYSE:ABBV) – all patents expired
- Impression anticipates distribution of Dronabinol under the Special Access Scheme and the Authorised Prescriber Scheme in Australia prior to pursuing wide-scale marketing authorisations in the exclusive countries.

In furtherance of its strategy to leverage the intellectual property of existing international cannabinoid market leaders and thus avoid the heavy expense associated with drug development and trials, Impression Healthcare Limited ('Impression' or 'the Company') is pleased to announce that it has executed an exclusive license agreement with Resolution Chemicals Limited ('ResoChem') to support the production, registration and commercialisation of generic Dronabinol (pure delta-9 Tetrahydrocannabinol ('THC')) capsules in the USA, Canada, Australia and New Zealand ('the countries').

Dronabinol was the first ever cannabinoid medicine permitted for patient use by the DEA in the United States and a synthetic Dronabinol has been marketed under the trade name Marinol[®] since in 1986. Any patents over Marinol have since expired. Abbvie Inc. (NYSE:ABBV), which is a recognised as a top-10 global pharmaceutical company by revenue, currently markets Marinol[®].

ResoChem has granted Impression the rights to all Intellectual Property ('IP') associated with the production of a complete non-synthetic Dronabinol product to assist with commercialisation in the exclusive countries.

Furthermore, Impression has the rights to use all associated materials, including;

- a complete drug master file (Abbreviated New Drug Application), which has been previously assessed and rated "approvable" by the Food and Drug Administration ('FDA') but not rescheduled by the Drug Enforcement Agency ('DEA') to allow importation at that time
- a detailed manufacturing process
- analytical methods and specifications for each manufacturing step
- Patents that detail a manufacturing process process similar to the manufacturing process approved by the FDA
- validation documentation.

The intention of the licensing arrangement is to leverage the existing work completed by ResoChem so to expedite the achievement of marketing authorisations of 2.5mg; 5.0mg and 10.0mg generic Dronabinol capsules for each of the countries.

As a part of the licensing agreement, cannabis consulting company, Pharmout, is advising Impression on use of the materials and any amendments required to determine the best route to market in each of the exclusive use countries for the treatment of long established indications; being:

- Loss of appetite in people with HIV/AIDS (acquired immune deficiency syndrome) who have lost weight.
- Nausea and vomiting caused by anti-cancer medicine (chemotherapy) in people whose nausea and vomiting have not improved with usual anti-nausea medicines.

Pharmout will initially assess the intellectual property associated with the materials and suggest amendments to the materials necessary to support either a synthetic or non-synthetic Dronabinol product relevant to the current laws of each country. Thereafter, Impression will manufacture and encapsulate the products, commission any further studies required to prove the regulatory acceptable quality and stability of the product in the countries and then submit applications for the achievement of marketing authorisations in each of the countries to the relevant authorities. It is anticipated that Pharmout's initial assessment prior to encapsulation will take up to 12 weeks.

The IP licensed by Impression opens an opportunity for significant international expansion into existing markets with patented and proven technology. It furthers the Company's strategy to become a major player in the growing market for cannabinoid medicines. And, expands Impression's growing cannabinoid product portfolio with existing, proven and patented technology.

The Company initially anticipates distribution of Dronabinol under the Special Access Scheme and the Authorised Prescriber Scheme in Australia prior to pursuing wide-scale marketing authorisations in the exclusive use countries.

Impression Healthcare CEO, Mr Joel Latham said;

"The licensing deal with Resochem sets Impression apart from its Australian competitors that are pursuing high-cost R&D projects for the development of products that may or may not achieve commercial success. It also consistent with our collaboration with AXIM Biotechnologies; announced in September (*link below).

Dronabinol has a long recognised history of safe use and, by pursuing this market, we have the opportunity to create a generic Dronabinol product to grow revenues within new markets for which attitudes for the use of cannabinoid medicines has changed rapidly. Our objective now is to develop and manufacture relevant products for each country as quickly as possible and we have a number of options in relation to manufacturers".

*Collaboration with AXIM Biotechnologies: <https://www.asx.com.au/asxpdf/20180919/pdf/43yfyrcrg879kk8.pdf>

ENDS



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ASX Announcement (ASX: IHL)

About Impression Healthcare Limited (ASX: IHL)

Impression Healthcare Limited is Australia's largest home dental impression company and is disrupting the dental devices market by providing consumers with an in-home method to consume laboratory-grade and personalised dental healthcare products at significantly lower prices than those offered by the traditional dental industry. Impression has significantly grown its distribution footprint and increased its revenues by 359% in the 2018 Financial Year. With its own dental laboratory in Victoria, Australia Impression offers best in class teeth protection and helps its customers combat bruxism, snoring, mild to moderate sleep apnoea and teeth discolouration with custom-fitted oral devices.

Impression is broadening its commitment to disruption in the healthcare sector by exploring opportunities in medicinal cannabis distribution and development, underpinned by a collaboration agreement with leading US Cannabinoid therapeutics Company, AXIM Biotechnologies Inc. AXIM is focused on research, development and production of oral health, pharmaceutical, nutraceutical and cosmetic products incorporating cannabinoids for a wide range of indications. Impression will leverage its oral health marketing activities to explore opportunities distribute a range of AXIM's over the counter and therapeutic products as public opinion of cannabinoid-based therapeutics steadily improves.

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