

ASX ANNOUNCEMENT

CORTEXA LANDS PATIENT READY GMP MDMA INTO AUSTRALIA TO SUPPORT PATIENT PRESCRIPTIONS AND CLINICAL TRIALS



8 NOVEMBER 2023

Melbourne, Australia - Vitura Health Limited (ASX: VIT) (Vitura and Company) is pleased to provide an update on its Cortexa Joint Venture with PharmAla Biotech (CSE: MDMA)(OTC:PMBHF).

Bulk and patient ready MDMA GMP Active Pharmaceutical Ingredient landed in Australia for patients and clinical trials

For what will be an Australian first, we have landed MDMA bulk GMP Active Pharmaceutical Ingredient (API) into Australia, which is being prepared to be batch manufactured into finished dosage forms to GMP standards. In doing so, Cortexa will ensure reliable local supply to meet growing clinical and research demands. Concurrently, the first GMP MDMA capsules have been imported from Cortexa's joint venture partner, PharmAla Biotech, and are ready for patient prescriptions and clinical trials.

The majority of this shipment is to satisfy demand under existing supply agreements including leading University clinical trials.

Psilocybin bulk GMP Active Pharmaceutical Ingredient in the process of being transported to Australia

Psilocybin bulk GMP API is also in the process of being transported to Australia. Cortexa Psilocybin is of GMP standard and synthetic in origin. Like MDMA, there has been significant interest in the clinical and research prescription of psilocybin and we look forward to continuing to update the market in relation to this molecule.

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First patients via the TGA's Authorised Prescriber Scheme expected in December 2023

The timeframe for patients to be treated under the TGA's Authorised Prescriber scheme via approved psychiatrists is expected to occur in December 2023. The first tranche of psychiatrists are expected to be approved in the coming weeks enabling the first patients being treated outside of clinical trials. This reflects the TGA process of safeguards to ensure the requisite experience and knowledge of Authorised Prescribers to maximise clinical outcomes and patient safety.

Onshore manufacturing remains a future option

As demand for GMP MDMA and psilocybin increases, Cortexa has access to PharmAla Biotech's intellectual property to enable onshore manufacturing of bulk API of both molecules here in Australia via GMP contract manufacturers. This valuable optionality allows for Cortexa to avoid costly and time-consuming importation activities and underpins future domestic supply for patients and clinical trial participants. We will continue to monitor the market for the right time to onshore manufacturing as demand scales.

Comments on Cortexa update

Commenting on Cortexa update, Vitura's CEO and Executive Director, Rodney Cocks said:

"In another milestone for both Vitura and Cortexa, we are extremely proud to have landed MDMA product in bulk and patient ready capsule form into Australia – for clinical and research prescription. By the end of November 2023, we also expect to have landed bulk psilocybin GMP product also for clinical and research prescription. This paves the way for the first expected clinical patients via the TGA's Authorised Prescriber Scheme access pathway in December 2023.

Moreover, as a Veteran myself, I am delighted that Cortexa now has MDMA GMP product in Australia that can be prescribed via the Authorised Prescriber pathway by authorised psychiatrists to those suffering PTSD who are some of the most vulnerable in our community, including Veterans and First Responders. We look forward to supporting those who have given so much to Australia.

We will continue to update our shareholders on the ongoing success of Cortexa, as a leading supplier of GMP MDMA and psilocybin for clinical and research prescriptions in the Australian market."

** ENDS **



About Vitura Health Limited (ASX:VIT)

www.vitura.com.au

Vitura Health Limited is diversified digital health business listed on the ASX (ASX:VIT) and, via its wholly owned subsidiaries, operates the following businesses:

• www.burleighheadscannabis.com

Burleigh Heads Cannabis - operates the market leading prescriber, patient, pharmacy and supplier online platform, CanView, which sells and distributes 260+ product SKUs within Australia from 39 international and domestic medicinal cannabis brands.

• <u>www.canview.com.au</u>

CanView is being developed to be a complete end-to-end healthcare ecosystem designed to provide doctors, pharmacists and patients with a simple and cost-effective way to facilitate the treatment of patients with increased efficiency and compliance. The CanView system is based on a medicines wholesaling platform which seamlessly brings together a number of disparate SAAS (software-as-a-service) providers including inventory control, invoicing, customer management, reporting and analytics, all linked together through customised integration from third party providers. Underpinning the suite of SAAS elements are a number of bespoke, internally-generated operating procedures and intellectual property assets, supported by the CanView customer support and infield customer engagement teams. Through the integration of the different elements which together make up CanView, the platform provides the best user experience in the industry.

Through the Company's relationships with third party integrators, CanView provides Australian doctors with the ability to integrate their patient management systems directly with the platform and to use their patient information to generate electronic prescriptions within the CanView platform, without the need to input the patient's details. Prescriptions are then sent directly to the CanView patient app where patients can manage their treatment and submit the prescription and subsequent repeats to one of the 3,600+ Australian pharmacies with accounts on CanView for dispensing.

While the Company's current operations focus on the sale and distribution of medicinal cannabis products, Vitura is fully licensed and equipped, via its two state-of-the-art distribution centres in Melbourne and the Gold Coast, to distribute all products under Schedules 2, 3, 4, 8 and 9. The establishment during the year of the Company's joint venture to distribute psychedelic products, including MDMA and Psilocybin, is a timely example of the many opportunities that the Company believes can be seamlessly integrated into its existing digital health platform business.

• <u>www.doctorsondemand.com.au</u>

The Company owns Doctors on Demand Pty Ltd, a nationwide $24/7 \times 365$ telehealth platform business that provide innovative primary health solutions to hundreds of thousands of B2C and B2B patients annually. Services include general medical consults, urgent care, medical certificates, pathology referrals, specialist referrals, men's health, women's health, medicated weight loss and smoking cessation.

• <u>www.cortexa.com.au</u>

The Company owns 50% of Cortexa Pty Ltd, an incorporated joint venture with Canadian-based PharmAla Biotech (CSE:MDMA). Cortexa aims to be the leading supplier of psychedelics, GMP MDMA and GMP psilocybin, for research and therapeutic use in Australia.



• www.cdaclinics.com.au

The Company owns CDA Clinics that undertakes nationwide telehealth consultations with patients seeking access to medicinal cannabis.

www.cannadoc.com.au

The Company owns 75.5% of Cannadoc Health Pty Ltd, a medicinal cannabis clinic business that undertakes nationwide telehealth consultations with patients seeking access to medicinal cannabis.

Authorised by

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Forward-looking statements

This announcement includes forward-looking statements which may be identified by words such as 'anticipates', 'believes', 'expects', 'intends', 'may', 'will', 'could', or 'should' and other similar words that involve risks and uncertainties. These forward-looking statements are based on the Company's expectations and beliefs concerning future events as at the date of this announcement. Forward-looking statements are necessarily subject to risks, uncertainties and other factors, many of which are outside the control of the Company, which could cause actual results to differ materially from such statements. The Company makes no undertaking to update or revise the forward-looking statements made in this announcement to reflect any change in circumstances or events after the date of this announcement.