



## ASX Announcement

29 August 2019

### STRATEGIC UPDATE - MEDICINAL CANNABIS MANUFACTURING

- The requisite licensure is in place with the Therapeutic Goods Administration, The Department of Health - Office of Drug Control and the Victorian Department of Health and Human Services for IDT to manufacture medicinal cannabis products to Good Manufacturing Practice (GMP) standards.
- Being vertically integrated, IDT's Boronia manufacturing campus is well positioned to convert commercial quantities of medicinal cannabis biomass into a range of Active Pharmaceutical Ingredients (API's) and Finished Dosage Forms.
- Vertical integration affords IDT the unique ability to tailor make API and formulate finished dosage forms in order to address any botanical variation in the medicinal cannabis starting materials.
- Given the global push in the cannabis industry towards the requirement for GMP manufacturing, IDT can leverage off its long history of GMP API and finished dosage form manufacturing; including its extensive experience working with botanically derived compounds.
- IDT's manufacturing facilities are established with equipment installed, commissioned and validated. IDT's manufacturing suites and operations are designed to allow for the safe processing of the large volumes of solvent required for commercial scale medicinal cannabis API production.
- IDT has been actively expanding its GMP medicinal cannabis manufacture capabilities and will continue to leverage these key differentiators and expand the Company's footprint in GMP medicinal cannabis manufacturing on a global scale.

**IDT Australia Limited (ASX: IDT)** provides the following market update in relation to its medicinal cannabis manufacturing capabilities: On 20 May 2019 IDT announced that it had secured its own Medicinal Cannabis Manufacturing Licence from the Department of Health - Office of Drug Control. Along with the GMP licenses (active pharmaceutical ingredient and finished dosage form) in place with the Therapeutic Goods Administration and the Poisons licenses (Schedule 8 and Schedule 9) in place with the Victorian Department of Health and Human Services, the Company is working to leverage its fully licenced GMP manufacturing assets and materially expand its footprint in GMP medicinal cannabis manufacturing.

IDT has a long history in GMP manufacture of both API's and Finished Dosage Forms. GMP is a statutory requirement for the manufacture of both API and finished dosage form medicinal cannabis products in Australia. On the global stage, GMP manufacturing standards are also becoming increasingly more important as the cannabis industry expands from lesser regulated international markets like Canada to more regulated markets like Germany. IDT can leverage off its long history and technical expertise in GMP API and finished dosage form manufacturing, including its extensive experience working with botanically derived compounds, to become a global centre of excellence in GMP medicinal cannabis manufacturing.

IDT has a leading position in the medicinal cannabis space as the Boronia manufacturing campus is vertically integrated, meaning the site is capable of producing API's and finished dosage forms. IDT's vertically integrated GMP manufacturing capabilities combined with the fact that the Company has the potential to convert large quantities of biomass into crude resin or de-waxed oil, and on to downstream value added products such as a range of GMP finished dosage forms, puts IDT in a unique position in the Australian scene and ahead of many global participants.

#### IDT's GMP API Medicinal Cannabis Manufacturing Capabilities

In terms of Active Pharmaceutical Ingredient manufacturing, IDT has the capabilities to take biomass directly from a cultivator and:

1. Convert dry flower into crude resin (utilising a number of potential extraction methods including commercial solvent extraction);
2. Convert the crude resin into de-waxed oil;
3. Sterile filter de-waxed oil to comply with European GMP requirements;
4. Further purify medicinal cannabis oil into any of the cannabinoids such as Cannabidiol (CBD) or Tetrahydrocannabinol (THC); and
5. IDT also has the capabilities to potentially synthesize any of the cannabinoids to GMP specifications.

IDT already has the critical equipment installed, commissioned and validated, with little or no facility modifications required. Another key differentiator is IDT's long history and technical expertise in working with high containment products in a secure environment. IDT's manufacturing suites are designed to allow for the safe processing of large volumes of solvent, which is a feature of commercial scale medicinal cannabis resin extraction. IDT is currently working-up processes which have the potential to convert tonnage quantities of medicinal cannabis biomass.

#### IDT's GMP Finished Dosage Form Medicinal Cannabis Manufacturing Capabilities

Following on from the GMP manufacture of the medicinal cannabis API's detailed above, IDT is able to formulate and package these API's into a range of GMP finished dosage forms including:

1. Solid oral dosage forms (such as tinctures, liquid in bottle, capsules, gel caps, tablets);
2. Respiratory / nasal sprays;
3. Dermal (such as creams, ointments, dermal sprays, patches);
4. Liquid fill products (such as liquid in bottle, lyophilised products); and
5. IDT can also package medicinal cannabis biomass under GMP conditions.

IDT's ability to break the product right down to the sum of its parts (being GMP cannabinoids such as CBD and THC) and everything in between gives the Company the unique potential to offer a wide range of medicinal cannabis product formulations. It also puts the Company in a very strong position to deal with any botanical variation in the medicinal cannabis starting material.

In addition to IDT's API and finished dosage form manufacturing capabilities, the Company has well established in-house Ancillary Services including Quality, Regulatory, Analytical, Stability, Secure Storage and Shipping; all of which fall under the Company's GMP, Poisons and Medicinal Cannabis manufacturing licensure. IDT's GMP Analytical Laboratories offer a range of medicinal cannabis GMP testing and stability services to support its medicinal cannabis manufacturing facilities and capabilities.

"IDT is now fully licenced for medicinal cannabis operations, the site is vertically integrated in terms of GMP API and finished dosage form manufacture, and IDT has decades of history of working with botanically derived pharmaceutical products. We have been active in GMP medicinal cannabis manufacture for quite some time." said IDT's Chief Executive Officer Dr David Sparling. "IDT will continue to leverage these key differentiators; and believe that IDT is well placed to further expand its footprint as a centre of excellence in GMP medicinal cannabis manufacturing on the global stage."

ENDS

For further information please contact:

IDT Australia Limited

Dr David Sparling – Chief Executive Officer

0417 721 972

#### About IDT

IDT (ASX:IDT) is a public Australian pharmaceutical manufacturing company based in Boronia, Victoria, Australia. It has extensive experience in the development and production of high potency and high containment pharmaceutical products for local and international clients. IDT's facilities are cGMP compliant and are regularly audited by the US FDA and Australian TGA. With an experienced team of specialists within world-class facilities, IDT provides a full-scale service for new drug development and scale-up, commercial active drug manufacture as well as a variety of oral and injectable finished drug dose forms.