

ASX ANNOUNCEMENT

27 March 2023

IDT Achieves Key Milestone as TGA Expands its Licence to Manufacture Advanced Therapies

Highlights:

- TGA upgrades IDT's sterile manufacturing licence – allowing the Company to manufacture and release injectable medicines for clinical trials in Australia and overseas
- The updated licence allows IDT to expand its clinical trial product offering, which already includes Orals and Active Pharmaceutical Ingredients (APIs)
- IDT can now offer researchers significant capacity to ensure their trial materials needs are met, tailored with our product development services to deliver an end-to-end solution
- The updated licence is key to unlocking the Company's sales pipeline for sterile manufacturing (pipeline of potential sales stands at over \$6M and growing)
- IDT has capacity to make advanced therapies for clinical trials, which is in short supply in Australia, forcing much of our research to head overseas
- The Company is well placed to be the "go to" destination for clinical trials of parental formulations and to attract international groups to undertake clinical trials here

IDT Australia Limited (ASX: IDT) (the Company) is pleased to announce that the **Therapeutic Goods Administration** (TGA) has expanded the licensing conditions covering the Company's Aseptic Sterile Processing (ASP) facility.

The updated license enables IDT to manufacture and supply Good Manufacturing Practice (GMP) injectable drugs for use in clinical trials in Australia and overseas. GMP is a set of principles and procedures that ensures the drugs are of high quality, as defined by the TGA.

About IDT

IDT (ASX:IDT) is an Australian pharmaceutical manufacturing company based in Boronia, Victoria, Australia. The Company 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.

This is an important milestone for IDT as the upgraded license allows the Company to expand its offering to the clinical trial industry to include injectable medicines. IDT is already licensed to produce GMP Specialised Orals and Active Pharmaceutical Ingredients (APIs) to the sector.

The upgraded license further positions the Company to be a key partner for companies developing new therapies, particularly given the local and international shortage of ASP facilities that can manufacture advanced therapies.

IDT's sales pipeline for the ASP (advanced injectable therapies) business alone currently stands at over \$6 million and growing. ASP is a process that ensures every part of the manufacturing chain is free of microbial contaminants. This is critical for producing advanced therapies which have a modified release that binds specifically to targets, reducing side effects and delivering higher potency.

The Chief Executive Officer of IDT, Paul McDonald, said:

"The upgraded licence will enable us to play a crucial role in supporting Australia's sovereign manufacturing capabilities and the translation of research to address unmet medical needs.

"We have the opportunity to become the 'go to' partner for clinical trials and expect to attract international pharmaceutical companies and researchers to undertake trials on Australian soil, which will contribute enormously to the growth of the Australian biotech industry."

The ASP/Advanced Therapies business is one of the three divisions in IDT. The other two being Specialised Orals and API Manufacturing.

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Authorised by the Board of Directors of IDT Australia Limited.

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IDT Australia Limited
ABN 66 006 522 970
45 Wadhurst Drive
Boronia, Victoria 3155, Australia
T +61 3 9801 8888
W www.idtaus.com.au



For investor and media enquiries, please contact:

Brendon Lau

E: brendon@vantagepointpartners.com.au

M: +61 409 341 613

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