

## **ASX ANNOUNCEMENT**

**28 September 2021**

### **IDT Receives Sterile Licence From The Therapeutic Goods Administration**

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**IDT Australia Limited (ASX: IDT)** provides the following market update.

The Company has received a manufacturing licence extension from the Therapeutic Goods Administration (TGA) for: *Medicine manufacture sterile injection / sterile solution of dosage forms of registered therapeutic goods and therapeutic goods for clinical trials* (Sterile Licence).

This Sterile Licence is an extension to the Company's existing licence to manufacture therapeutic goods which currently covers: *Manufacture of active pharmaceutical ingredients; manufacture testing and release for supply of solid unit dosage form tablets and capsules for registered therapeutic goods; and manufacture, testing and release for supply of liquids, powders and granules, inhalation, dry herb and oil products for therapeutic goods for clinical trials (and export of inhalation, dry herb and oil products).*<sup>1</sup>

The manufacture of sterile dosage form, Injections, solution, is restricted to aseptic primary filling in vials only.<sup>2</sup> The license will likely be further extended once IDT has certainty on product content, in alignment with the Company achieving other stages in manufacturing capabilities. Once product content is known, likely licence extensions IDT will be seeking in the future would include formulation, modifications to the facility and secondary packaging operations;

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<sup>1</sup> Non-Sterile

<sup>2</sup> At Building 51 located at 51-53 Wadhurst Drive and does not authorise the manufacture of preparations containing biological medicines (including live virus,) and penicillins, bulk formulation and 100% visual inspection.

and would be based on a successful inspection relating to the technical transfer of products into the facility.

The TGA's granting of IDT's Sterile Licence signifies the completion of the sterile readiness works pursuant to the Sterile Readiness Agreement finalised between the Australian Government Department of Health (Health) and IDT on 23 August 2021 (see ASX announcements 19 March 2021, 22 June 2021, 23 August 2021 and 15 September 2021). The Sterile Readiness Agreement provides for an exclusivity period with Health for the use of IDT's sterile manufacturing facility until the earlier of: executing a Supply Agreement for IDT to provide COVID-19 vaccine services to Health, or 4 months from completion of IDT's sterile readiness works.

The Company will provide updates as additional information comes to hand.

Ends..../

#### **IDT**

Authorised by the Board of Directors of IDT Australia Limited. For further information please contact:

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#### **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.