Oral insulin capsules. Image: University of Sydney, Stefanie Zingsheim

# ADVANCING ORAL INSULIN WITH NANOTECHNOLOGY

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BIOLOGICS AND VACCINES

Insulin therapy is essential for managing type 1 diabetes, yet current treatments rely heavily on injection-based delivery. Researchers at the University of Sydney, led by **Dr Nick Hunt**, have developed a nanotechnology-based platform using silver sulphide ($Ag_2S$) quantum dots to enable oral insulin delivery—a completely novel manufacturing approach.

With TIA's support the team collaborated with the CSIRO Biomedical Manufacturing team in Clayton, Victoria. The CSIRO team successfully reproduced and then optimised the synthetic manufacturing process for the insulin-conjugated quantum dots, ensuring greater reproducibility and scalability.

TIA's support facilitated collaboration between the University of Sydney and CSIRO, demonstrating that the formulation could be externally produced at scale. CSIRO successfully manufactured a gram-scale batch that met key characterisation and efficacy benchmarks, providing a crucial blueprint for transitioning from non-good manufacturing practice (GMP) to GMP production. This batch was later used for GLP validation studies at Agilex Biolabs, and Ab Initio Pharma is now working on the GMP-grade formulation. Both facilities have joined the TIA Pipeline Accelerator scheme in 2025.

The project's success attracted significant investment, including $750,000 in MRFF TTRA funding, $50,000 in CSIRO Kickstart funding, and $3.2M from venture capital provided by Proto Axium for the newly established biotech spin out, Endo Axiom. With a focus on preventing autoimmune diseases and improving diabetes care, Endo Axiom is now advancing this platform toward Phase I clinical trials. By enabling critical early-stage development, TIA's support has accelerated the commercial pathway for this transformative technology, bringing the possibility of oral insulin closer to reality.

> "The TIA program enabled external manufacturing studies to show our formulation could be produced outside of our lab."
> **Dr Nick Hunt**

**Impact:** Collaboration, Publications, GRANT, Spin out

| TRL 1 | TRL 2 | **TRL 3** | **TRL 4** | **TRL 5** | TRL 6 | TRL 7 | TRL 8 | TRL 9 |
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