



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: IDT Australia

By **TIM BOREHAM**

**ASX Code:** IDT

**Share price:** 61.5 cents; **Shares on issue:** 239,860,170; **Market cap:** \$147.5 million

**Chief executive officer:** Dr David Sparling

**Board:** Alan Fisher (chair), Hugh Burrill, Mary Sontrop, Michael Kotsanis

**Financials (year to June 30 2021):** revenue\* \$16.9m (up 19.5%), net profit \$2.1m (up 210%), cash of \$6.92m (steady)\*\*

\* Includes \$900,000 of Jobkeeper payments

\*\* The company also has \$766,000 of debt and an undrawn \$2.5 million bank debt facility

**Major identifiable shareholders:** One Funds Management 11.7%, Sandon Capital 11.2%, Anthony John Huntley 3.1%, Dr Graeme Blackman 2.93%.

The adage that 'timing is everything' is relevant for many human pursuits, but is especially pertinent for IDT Australia as it rides a new wave of drug-making nationalism.

For years, IDT has been contract manufacturing finished drugs and approved pharmaceutical ingredients (APIs) at its mainstay facility in the eastern Melbourne suburb of Boronia.

But its approved sterile facility - suitable for injectable products - has been lying idle for years.

The odds are it won't be for much longer, with the company now in an official "state of readiness" to manufacture a home grown severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) or 'Covid-19' vaccine.

IDT's elevated preparedness is covered by an agreement with the Federal Department of Health, but the vaccine plan also intimately involves the Victorian Government and the Monash Institute of Pharmaceutical Sciences (MIPS).

While it's not guaranteed that IDT will make a single vial, the Victorian Government has already stumped up \$1 million for crucial equipment.

IDT chief executive Dr David Sparling says the deal reflects the reality that Covid-19 vaccines and boosters are likely to be required for years to come. More broadly, drug manufacturing capacity is returning to our shores after years of migration to low-cost India and then China.

"We have taken on the challenge because we genuinely believe in our business and we think Australia needs to have at least one facility to manufacture APIs and dose forms ourselves," he says.

"To lose those skills as a country would be a tragedy. When the borders close again for the next pandemic or problem, we will need the ability to make these things for ourselves."

While the vaccine work bubbles along, IDT is also furthering its plans to become a leading manufacturer of medical cannabis products.

## **The ABC of IDT**

IDT was conceived in 1965 thanks to a brainwave from Victorian College of Pharmacy dean Nigel Manning (to create an institute of industrial pharmacy).

As Gough clung to power in October 1975, the Institute of Drug Technology Limited (IDT) was established as an independent company. Initially an academic-flavored institution, the company developed a reputation for contract drug making and consulting work.

Under the renowned Dr Graeme Blackman, the company became private in 1982. After acquiring Nicholas Kiwi Central Laboratories, the company listed amid the bicentenary celebrations of 1988.

In 2014, IDT entered the US generics game, paying \$US18 million for a package of 23 drugs. The move was seen as a way to increase use of the largely fixed-price Boronia asset, but a US pricing war erupted in the generics sector.

In April 2018, IDT waved the white flag and sold most of its generics portfolio to ANI Pharmaceuticals for \$US2.73 million, plus an ongoing profit share on one drug.

Dr Sparling replaced Dr Paul MacLeman as interim chief executive in February 2018 and was then given the permanent gig a couple of months later.

## **Vaccine news a shot in the arm for share price**

IDT shares soared almost 25 percent when the company 'announced' the state of readiness on August 23.

We say 'announced' because the news had sorta been announced already. In a one paragraph release on March 19, IDT said it was assessing the possibility of such a deal.

The whole thing gained traction on June 20 when the Victorian Government said it would support Monash Institute of Pharmaceutical Sciences (MIPS) to develop Australia's first local messenger ribonucleic acid (mRNA) Covid-19 vaccine.

Through the newly formed mRNA Victoria, the government said it would invest \$5 million to support MIPS to make the doses of the vaccine for trials.

The August 23 announcement was a 'sterile readiness agreement' with the Federal Department of Health, by which IDT has agreed not to use the sterile facility for any purpose than government-mandated output. If a supply contract ultimately does not eventuate, IDT is free to do work for other parties.

The idea is that during the exclusivity period, the Feds nominate a vaccine - presumably the aforementioned one - and IDT and the relevant vaccine company then agree on commercial terms.

Meanwhile, the Victorian Government has committed \$50 million to mRNA Victoria to further the vaccine.

As part of this, the Canadian-built nano assembler has been installed at the Boronia facility. The device puts the mRNA into a lipid nanoparticle, which is then filled and finished into vials with IDT's equipment

In a phase I trial in collaboration between IDT, the Doherty Institute and MIPS, 150 doses will be produced. The trial is expected to start in October with preliminary results by July next year.

## **Any spare room bro?**

Dr Sparling said IDT's submission to the Federal Department of Health highlighted the readiness of the facility, one of only a handful of sterile ones in the country and probably the only one with spare capacity.

IDT was one of several drug manufacturers responding to the Health Department's 'approach to market' request about establishing mRNA manufacturing capacity.

"Sterile" by the way refers to strict requirements in terms of access and air quality, with virtually no tolerance for bio-burdens such as bugs and mould. Facilities that make tablets and creams aren't sterile, strictly speaking, but that's not to say there are rats scurrying around them.

Dr Sparling estimates a similar sterile greenfield facility would cost “north of a quarter of a billion dollars”.

IDT’s \$30 million sterile plant was built for Pfizer and was written off years ago after the project discontinued. Because it’s expensive to run, the facility was mothballed.

## **Finances and performance**

In the year to June 30, 2021 IDT posted its first net profit - \$2.1 million - since 2009. The company achieved revenue of \$16 million.

Dr Sparling says the improved bottom line had everything to do with improved use levels across the board.

IDT’s financials are somewhat opaque, in that the revenues are not broken down into product segments.

IDT used to be big in generics but it has pretty much vacated that market, owing to the poor margins resulting from ongoing pricing pressure.

We also don’t know how much the Federal Government has paid IDT for the privilege of the company being in a state of (exclusive) readiness.

“It’s not a trivial exercise getting a facility up and running again,” Dr Sparling says.

He says management’s priority is to tack up sustainable profits, bearing in mind the company lost \$1.9 million in the 2019-’20 year, \$6 million in 2018-’19 and almost \$17 million in 2017-’18.

Over the last 12 months, IDT shares have vacillated between 17 cents (December 21 2020) and 75 cents (August 27, 2021).

Four years ago, the company was valued at \$26 million, not much more than the value of its 12,000 square metre Boronia digs. The property plant and equipment are in the books at a heavily depreciated \$16.7 million and are likely to be worth much more.

## **Please explain**

After the vaccine announcement, IDT copped two ‘market aware’ queries from the ASX about its soaring share price (on August 19 and August 27).

The gist of the response was that the company initially did not consider the sterile readiness announcement itself to be material, because it did not amount to a commitment by the Feds to use the facility.

The earlier share price surge reflected “growing market awareness of IDT’s production facility and the imminent potential that IDT could manufacture the new [MIPS] Covid-19 mRNA vaccine or one or more other Covid-19 vaccines from those facilities”.

The later share movement reflected “press [media] comment ... on sovereign vaccine manufacturing alternatives in Australia” as well as vaccine manufacturing pharmaceutical companies reporting significant increases in profits and growing demand for new supplies of vaccines.

Aha! We get it ... we think. For a better explanation, refer to Biotech Daily (Aug 20 and Sep 8, 2021).

### **More than pot luck**

Meanwhile, IDT is pursuing its expansion into medical cannabis via a tie-up with the Nasdaq-listed grower Clever Leaves.

Announced in mid-June, the deal involves Clever Leaves shipping flower from its Portugal facility. IDT will package the flower and, pending positive stability testing will provide flower-in-a-bottle product to its distributors.

The bottles are currently made for other parties (white labelled), but IDT may sell under its own brand in future.

The company is aiming to provide low-potency product that can be sold across the counter at chemists when laws are relaxed, as planned.

Dr Sparling says the company is fortunate to have a certified API site that can carry out resin and isolate extraction. Export markets also beckon, because IDT’s audit status with the TGA means its facilities are also certified in Europe, Canada and New Zealand.

Because flower is less processed than resin, the quality specifications are tighter and that means the material can only be grown in greenhouses.

The Clever Leaves agreement is not exclusive.

“We are happy to use material from any sources, as long as it meets our quality requirements,” Dr Sparling says.

### **Dr Boreham’s diagnosis:**

IDT is one of those stocks that has been around since Adam was whelped, but never got its act together despite numerous reinventions.

Now, IDT looks like enjoying its time in the sun on the back of vaccines and the high-margin medical pot business.

“Sterile manufacturing is a more lucrative game than generic manufacturing and some of our commercial APIs,” Dr Sparling says.

“We are certainly trying to move into some of those higher-value parts of pharmaceutical manufacturing.”

Unlike CSL - which fills and finishes the Astrazeneca vaccine here - IDT does not have to slow the output of other products to make room for the vaccines.

Dr Sparling notes the base contract drug development and API businesses are benefiting from the willingness of clients to pay a bit more to have things done locally.

“People are looking to lower sovereign risk sites of manufacturer, a safer set of hands and quality products rather than just focusing on cost,” he says.

Bravo!

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he is fully vaccinated and immune from criticism about being a poor citizen.***